Verdict in Cancer Immunotherapy IP Case

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Ben Rand: Hello and thank you for listening to the Harris Beach podcast. I'm your host for today's episode, Ben Rand. Today we're going to explore a recent patent infringement action between Juno Therapeutics, now part of Bristol-Myers Squibb and Kite Pharma, now part of Gilead Sciences. In connection with this dispute, a trial jury rendered a damages verdict including a $535,000,000 up front payment in a 27.6 percent ongoing royalty. After post-trial motions the Court entered judgment against Kite and in favor of Juno for approximately $1.1 billion. It's a hugely important case in the area of Pharmaceutical IP and today I'm joined by Laura Smalley to discuss the legal impact. Laura is a partner in the Harris Beach Intellectual Property group. She is an authority in this area, having been a regular contributor to the American Intellectual Property Law Association Biotech Buzz Newsletter as well as a presenter on Regulatory and IP issues for immunotherapy including CAR-T and antibody technology. Laura, thanks for joining us to discuss this really important case. I'd like to start with a general question, just to frame the conversation. What is the importance of this case and what got you interested in it?

Laura Smalley: Thanks Ben for the introduction. I think this case is important and I was interested in it because it's another successful use of the reasonable royalty theory of damages in the pharma and medical realm. Basically, this case shows how a reasonable royalty can be used to support a large damages award, where perhaps lost profits would be difficult to prove, or technically, inappropriate. In addition, a recent issue in the last couple of years has been lack of written description and enablement for biotech inventions. This case is another example of that. I assume eventually the Federal Circuit will hear the case and it will be interesting to see how written description and enablement, which has often been used to torpedo antibody patents, will be applied to CAR-T technology and just another patent in general.

Ben Rand: Interesting. So what is the technology involved in the *Juno v Kite* decision?

Laura Smalley: *Juno* alleged infringement of its patent on clay acid encoding Chimeric Antigen Receptors, which is U.S. Patent No. 7446190. The invention was developed by inventors at Sloan Kettering and licensed to Juno by a Sloan Kettering entity. The patent relates to CAR-T cell therapy. This therapy is a form of immunotherapy that uses specially altered T-cells, a part of the immune system to fight cancer. A sample of a patient's T-cells are collected from the blood and modified to produce special structures called Chimeric

Antigen Receptors on their surface. When these CAR-T cells are reintroduced into the patient, the new receptors enable them to latch onto a specific antigen on the patient's tumor cells and kill them. *Juno* alleged that [inaudible], which according to *Kite*, is the first CAR-T therapy for adults living with certain types of Non-Hodgkin's Lymphoma infringed its Patent.

Ben Rand: Can you describe a little bit about what the competitive position was of the parties?

Laura Smalley: Basically, the parties were direct competitors, but there was a twist in this difficult situation. Basically, *Kite* had introduced this cancer therapy on the market after receiving marketing approval from the FDA on October 18, 2018. As of trial *Juno* had not yet brought its therapy to market and apparently CAR-T therapy, which was still in the pipeline, did not actually use the patented technology. *Juno* basically had switched technologies a bit. And one of the key points at trial, with regard to willfulness and damages, was that *Kite* infringed the Patent so it could be first to market to get the financial advantages from being a first mover. Being a first mover, which is the first person to introduce a certain therapy, confers substantial benefit due to the ability to set pricing and creates a sticky market share because physicians and treatment centers tend to be loyal to the first treatment they used.

Ben Rand: That is so, what were some of the issues involved at the trial?

Laura Smalley: I thought this case had several interesting issues. Basically, infringement really hinged on a validity issue. There was a Certificate of Correction issued on the Patent and the question at trial was, was the Certificate of Correction valid? During the prosecution of the Patent, the applicants had noted an error in the e-sequence ID number and requested removal of the first four [inaudible]. Because an incorrect sequence listing was submitted, the change was not actually made during prosecution of the Patent. After five years the applicants saw the Certificate of Correction correct this error. So the jury in essence was asked to decide whether the Certificate of Correction was valid, which it did not overturn the Certificate of Correction, so in essence it was found valid. And because *Kite* had in essence conceded that it infringed the Patent if the Certificate of Correction was valid, the jury's determination resolved the infringement issue in favor of *Juno*. This case was also interesting in that validity over the prior Art was not really at issue at trial, which is uncommon for important drug cases. Basically, at 2015 *Kite* had petitioned for Inter Partes Review of a Patent to review its validity over the prior Art, but the Patent trial [inaudible] upheld all of the claims in the Patent in a final written Decision issued in December 2016. So basically, due to the procedural posture of the case, the validity of the Patent over the best prior Art had been determined before the litigation was instituted. And as I noted before, *Kite* challenged the Patent on the grounds of lack of enablement and lack of written description, which the jury found not proven. The jury was asked to decide also whether infringement was willful and the amount of damages. A little bit

of background, the T-cell receptors encoded by the claimed invention including the intercellular domains of a cd3 zeta chain and a signaling region from a [inaudible] protein, such as cd28 with a binding element that specifically interacts with a selected target. The jury heard evidence and apparently accepted that evidence that *Kite* knew that it's collaborator copied the backbone, in essence the cd28 [inaudible] region and the zeta chain of [inaudible], the infringing product from one of the Sloan Kettering researchers. Thereafter *Kite* had tried to invalidate the Patent unsuccessfully, tried to license the Patent unsuccessfully, and when it could not license the Patent, simply went ahead and commercialized this infringing product. So, in essence the story that *Juno* put in front of the jury that *Kite* stole the backbone of the invention and then just put out the product instead of licensing it, I think helped sell the jury on the damages theory advanced by the plaintiff.

Ben Rand: That makes sense that they would think that. What type of damages were awarded?

Laura Smalley: Basically, the jury awarded an upfront payment of $585,000,000 and a running royalty of 27.6 percent. So the Court determined the amount of running royalty through the time of trial, which was approximately $193,000,000 plus pre-judgment interest. Then, based on the jury's finding of willfulness, the Court awarded enhanced damages of approximately $389,000,000, making the final verdict approximately $1.1 billion. There will also be post-judgment interest and a running royalty of 27.6 percent on the net revenues of the infringing product.

Ben Rand: And what was the basis for the damages?

Laura Smalley: As I indicated before, the damages sought were a reasonable royalty based on the terms of a comparable license, which was adjusted based on the party's bargaining position at the time of first infringement. Basically, *Juno* and Sloan Kettering had a License Agreement with a 7.25 percent royalty rate, an upfront payment of almost $7,000,000 and some other milestone payments. There was also a Side Agreement with a stock success appreciation fee of $150,000,000. So based on that license, Dr. Sullivan, *Juno's* damages expert, opined that based on the direct competitiveness of the situation between *Juno* and *Kite*, the upfront fee should be $585,000,000 and the running royalty should be 27.6 percent. There were also other licenses relied upon, agreements with St. Jude and Novartis that had a similar structure but lower upfront payments and lower royalty rates.

Ben Rand: Is relying on the reasonable royalty theory of damages beneficial?

Laura Smalley: In some instances, yes. To recover lost profit, you have to establish the [inaudible] infringing activity the patentee would have captured the infringer's sales. Patent owners generally have to satisfy a four part test to obtain lost profit, which includes showing demand for the patented product, the absence

of successful non-infringing alternatives, manufacturing and marketing capacity to exploit demand and the amount of profit it would have made. On the other hand, a reasonable royalty which is evaluated under a different set of factors known as the Georgia Pacific factor, doesn't require that a multi-part test be satisfied and can be more flexible in terms of proof. And as we've seen in this case and other recent cases, even though it is typically thought that a reasonable royalty may be lower than lost profit, it can actually support a fairly large damages award. And a lot of flaws in an expert's opinion such as whether licenses are comparable, are viewed as issues of fact for the jury, rather than a legal reason to throw out the expert's opinion.

Ben Rand: Okay. What are the next steps in litigation, is there room there for *Kite* to appeal?

Laura Smalley: Yes. *Kite* filed a Notice of Appeal at the end of April and presumably the case will end up at the Federal Circuit. The timing for resolution, assuming everything follows the normal pace, is approximately 15 months from docketing to the decision, based on the last specifics from the Federal Circuit. So I would expect that we would see a resolution to this case in the third or fourth quarter of next year.

Ben Rand: So more broadly Laura, what do you think the effect of the litigation may be on cancer treatments in general and do you think the case has some precedential value, is it something that pharmaceutical companies need to keep an eye on?

Laura Smalley: As to the first part of your question, it doesn't look like the litigation will affect the availability of the infringing treatment. *Juno* agreed it would not seek an injunction if it received the upfront payment sought and it doesn't appear that an injunction was requested or granted. As far as profitability, it doesn't appear that *Kite* argued that the ongoing royalty left it with no profit so I assume that it will continue to manufacture the treatment. With respect to the second issue, each factual situation on damages is different, but I think this case is a good continuing precedent, assuming it's affirmed by the Federal Circuit of use of a reasonable royalty in pharma and medical device cases and the ability of a reasonable royalty to support a fairly large award.

Ben Rand: Well thank you Laura for your time today, and thank you everybody for joining us. For more information including how to get in touch with Laura, please visit www.HarrisBeach.com.

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