Podcast Transcript

Promoting the Progress of Science, Part Two: Avoiding Inherent Anticipation

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Kattman: Congratulations, your team has made a critical discovery based on its analysis of your company's clinical data. You want to file a patent application so that your company can secure patent rights for that discovery. Simple, right? Wrong. Patenting clinical stage inventions requires planning and strategizing to give the patent applications its best chance of success. I'm Amy Kattman and you're listening to BakerHosts. On today's episode we welcome back Stephanie Lodise, a partner in BakerHostetler's Intellectual Property Group. Stephanie has a Ph.D. in organic chemistry and co-leads the firm's Biotechnology, Chemical and Pharmaceutical Practice team. This is part two of our series, "Promoting the Progress of Science," and Stephanie is here to discuss what companies should think about when drafting clinical stage invention patent applications that satisfy the U.S. novelty requirement of patentability. Stephanie, welcome back to the show.

Lodise: Thank you, Amy.

Kattman: To begin, could you define what is a clinical stage invention?

Lodise: I think of clinical stage inventions as inventions that are conceived or reduced to practice during the course of human clinical trials and this can take lots of different forms. It could be a new formulation that was first tried in humans. It could be a new dosing regimen, or it could be a discovery that an old drug, one that's already been approved for use in humans, is now useful for treating a different disease than it was originally marketed for.

Kattman: So is patenting a clinical stage invention just like patenting any other invention?

Lodise: In terms of the laws that apply, yes, clinical stage inventions are subject to the same laws that any other invention would be subject to. But clinical stage inventions will typically face challenges since there's usually much more expansive prior art that can be applied to the clinical stage invention and a lot more is known so overcoming the hurdles to patent ability are a little more challenging.

Kattman: Now we mentioned the word novel, what does it mean for a clinical stage invention to be novel?

Lodise: Novel, according to the patent laws, means new but it's more than that. It means that there's nothing in the prior art in a single reference that describes this invention. Meaning that there's no prior art that anticipates the invention. That means there's no single prior art reference that discloses each and every limitation of what you're claiming, in the way that you're claiming it. The disclosure can have either an express or an inherent disclosure of an invention. Interestingly novelty is a question of fact. Certainly, something in the statute, it is a legal term but it's something that's determined based on the facts of each case. It can be determined on summary judgment if necessary.

Kattman: You mentioned inherent anticipation. What does that mean?

Lodise: Inherent means that the prior art reference doesn't say anything about a particularly claimed feature but that the feature is present if you practice the prior art. It's sort of like there's a reference and it can describe elements A, B, and C, you're now claiming element D, but the reference doesn't describe element D expressly, so we ask, is element D inherent? So the question is, is element D maybe present when you practice that prior art reference. According to the law, inherent anticipation means that the feature is the inevitable result of practicing the prior art. There's a lot of case law on what this means, for example, clinical stage invention for the prevention of stroke in high-risk patients by administering Ramipril. There's prior art disclosing treating hypertensive patients with Ramipril. The prior art was silent though about whether Ramipril can prevent stroke in high-risk patients. The question we ask is, is stroke prevention inherent in administering Ramipril to hypertensive patients? This inquiry is, is the prior arts patient population, those hypertensive patients, is that population co-extensive with a patient population at high risk of stroke? Another example is there is a clinical invention directed to a method of increasing the oral bioavailability of Metaxalone by administering the drug with food. In the prior art, there was a disclosure of administering Metaxalone with food. The increase of bioavailability would have been the natural results of taking Metaxalone with food.

Kattman: That makes sense. What if the treatment method was previously performed, but no one noticed the particular therapeutic advantage the team had just discovered?

Lodise: What's significant for clinical stage inventions in the U.S., if they're going to be non-patentable as inherently anticipated, those of ordinary skill in the art need not have appreciated the inherently disclosed element. In the United States, newly discovered properties of known methods and compositions are not novel if the composition or method was previously known.

Kattman: Does novel mean that a particular treatment method was never actually performed on a person before?

Lodise: No, so certainly we want that single prior art reference in order to be anticipating to destroy novelty for your invention, it has to describe all the elements of the invention. But a clinical invention can be anticipated by a prior art reference where it wasn't actually reduced to practice, it wasn't actually performed. All that's required in a single prior art reference is that that reference disclose all the elements of which you're claiming and that this disclosure is enabling. That's another legal term of art that we can talk about another time. It's really where the prior art reference isn't an invitation to investigate, that wouldn't be anticipating. It means that, say you have a clinical trial protocol, it's published before there are results of that trial, but if the protocol could be followed by those of skill in the art, that would be a novelty-destroying reference. So prophetic examples can be anticipating.

Kattman: Is inherent anticipation the same standard around the world?

Lodise: Interestingly, it's not, so certainly when we think of whether something as new, you would think that new would be the same no matter where in the world you were sitting. But the laws of novelty are similar around the world, but not exactly the same and certainly they differ in respect to whether inherent anticipation exists. Inventions that would not be considered novel in the U.S., might be considered novel outside the U.S. for example, major jurisdiction being Europe. In Europe, if the prior art disclosure is missing a claim element, that reference can only destroy the novelty of your invention. If that missing claim element is derivable directly and unambiguously from the prior art reference. What they're looking for in Europe is whether your invention was available to the public in the broadest sense. So secret or hidden uses cannot negate novelty in Europe, but they can in the United States.

Kattman: Now why is it so difficult for a new discovery to be novel?

Lodise: What's difficult for clinical stage inventions I find in my practice is that there's usually so much prior art that we've met when facing. It's usually the case that there was already a publication already on the molecule, so the molecule is known. Perhaps there is already a formulation developed and described in the prior art. There's lots of hurdles as to what is actually new in the invention and the extra difficulty in the United States is that you can get a patent if you've just discovered an inherent property that no one else discovered before. Even though that might be a fantastic discovery that really truly benefits patients, if you're just doing the same method or using the same composition that was previously described in the art, that would not be patentable. It would be something you

could get FDA-approved so that you would be able to market it for that purpose, but you might not be able to get a patent.

Kattman: Could you share with us some of the strategies for increasing a clinical stage inventions chances for satisfying the novelty requirement?

Lodise: I think there's a few. The one that I think of most often is when we're thinking about the large expansive prior art being out there. Not creating more prior art and certainly not creating your own prior art. Being careful what you publish, when you publish, and what you say. Research papers, giving a talk, protocols described on clinicaltrials.gov. They shouldn't be published unless the publication has been vetted by patent counsel. In many cases a patent application should be filed prior to that publication or prior to that seminar so that we can get that new research covered in a patent application. Then when you are publishing, just think about what's necessary to say. Do you have to give every nuance of the clinical trial protocol on clinicaltrials.gov or would just a high-level description of the drug that's going to be administered suffice? The other thing that I think is important is to critically analyze, what is the invention? I think that's something that becomes harder for clinical stage inventions because you think in these broader terms like 'I found a new method of treating stroke.' Well true, but when you're looking at the prior art, that might have already been described in a single prior art reference with an inherent treatment of that stroke. We're looking for, we're treating a particular subpopulation, or we found that treating at a particular time, or treating with a particular dosage. Critically thinking about what the invention is and accepting that very likely it's going to be much narrower than what traditional patent claims would describe. That's very important and being able to correctly frame and crystallize what the invention is can be very helpful in both securing patent protection and being able to enforce that patent once it's obtained.

Kattman: One final question for you Stephanie. Once a novelty of clinical stage invention is established, is getting a notice of allowance pretty straightforward?

Lodise: No, not at all. Novelty is certainly a big hurdle for getting clinical stage inventions patented, but it's not the only hurdle and it's not even the biggest one. Clinical stage inventions also need to be non-obvious, but that's a topic for a whole other day so maybe we can talk about that next time.

Kattman: Would love to. Thank you so much Stephanie. If you enjoyed this podcast, please be sure to check out part three of our series, "Promoting the Progress of Science," focused on avoiding inherent obviousness. The novelty barrier of patent ability can be high, but the obvious barrier can be even higher. Stephanie will discuss the concept of inherent obviousness and strategies for avoiding it. As always, thanks for listening to BakerHosts.

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