**Podcast Transcript**

# Promoting the Progress of Science Part 4: Written Description and Enablement

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Kattman: After thoughtful consideration, you're sure your company's clinical stage invention is both novel and nonobvious. The inventors then must surely have possession of the invention and be able to describe it so others can make and use it without undue experimentation. Of course they do. But how do we get what's in the inventor's minds into a written form that is full, clear, concise and exact? Stephanie Lodise discusses the dual concepts of written description and enablement.

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 four of our series Promoting the Progress of Science and Stephanie is here to discuss the concept of satisfying the enablement and written description requirements for clinical stage inventions. Stephanie, welcome back to the show.

Lodise: Hi Amy. So glad to be here.

Kattman: To begin, can you tell us what is a clinical stage invention?

Lodise: I think of clinical stage inventions as those inventions that are developed later in the R and D process. They're beyond the discovery phase, they're beyond the animal testing. Usually these are discovered during clinical trials in tests in humans.

Kattman: Is patenting a clinical stage invention different from patenting a discovery stage or a pre-clinical stage invention?

Lodise: Well no, the laws are the same. Typically there's much more prior art to overcome because these inventions do come later in the R and D phases. Often the prior art is the applicant's own which can be challenging. We're usually encountering something that was surprising, surprising even to the very experienced scientists that are running the clinical trials, and describing and claiming that surprising discovery can be challenging.

Kattman: Switching gears a little bit, what is 35 U.S.C. § 112 and why is it relevant to the institution of a post-grant review?

Lodise: So 35 U.S.C. § 112 is one of the patent laws that we follow in getting patents patented. It states, and I'm paraphrasing, the specification shall contain a written description of the invention and of the manner and process of making and using it in such full, clear, concise and exact terms so as to enable any person skilled in the art to make and use the same. § 112 also refers to the best mode requirement but we'll table that topic for now.

How § 112 relates to post-grant reviews. Post-grant reviews, we call them PGRs, these were initiated with the passage of the America Invents Act just a few years ago, and a PGR is a trial proceeding conducted at the board at the United States Patent and Trademark Office and it reviews the patentability of one or more claims in a patent. This is an administrative proceeding, it's not a federal court proceeding. § 112 is a ground for a PGR institution. Now why might that be significant now? Well, PGRs are new. Previously, third parties can only bring inter partes review petitions to the board, and those are, we call them IPRs. IPRs can only be instituted on novelty or obviousness grounds and only on the basis of patents and printed publications. Patents granted under the America Invents Act are now subject to much broader scrutiny, and it's likely now that § 112 is an issue that can be raised in a PGR we're gonna see a lot more decisions coming out from the board on these issues.

Kattman: Thank you. What does it mean for a clinical stage invention to be enabled?

Lodise: The law requires that a patent specification must describe the invention and the manner and process of making and using it, and it must do that using full, clear, concise and exact terms to enable someone skilled in the art to make and use it. So, that's a lot of work. But that is enablement. In practice we ask, could one of skill in the art make and use the full scope of the invention, without undue experimentation? This, how-to prong touches on the utility requirement of the patent laws and those are in 35 U.S.C. § 101. All inventions must have a practical utility. So, to make and use the invention, that question, is it enabled? We look at what is being claimed. And enablement is a question of law, it's based on factual findings. What are the claims? Are we claiming a formulation? If so, we must enable the full scope of the claim formulations, that is, the claims, the claim formulations cannot be useless. If we're claiming a treatment regimen, we must enable the full scope of the claimed regimens, the methods cannot be useless.

The question of, is someone enabled to make the full scope of a treatment method? That language is a bit awkward, but we can rephrase and it's better to think of it as enabling one to perform the full scope of the claimed regimens.

This all, it still sounds very complicated, I know. How do we analyze it? What the court's given us are from *In re Wands* and we call them the *Wands* factors. And there are eight of them, and I'll list them out. There, we look at the nature of the invention, the relative skill of those in the art, the predictability or unpredictability of the art, the state of the art, the breadth of the claims, the amount of direction or guidance presented, the presence or absence of working examples, and the quantity of experimentation necessary.

Kattman: So, eight *Wands* factors is a lot to consider, Stephanie. How are the *Wands* factors analyzed?

Lodise: So, we look at the *Wands* factors because at the basis of patent law, patent is a *quid pro quo*. You, patent owner, teach others how to make and use your invention and the government grants you a monopoly on that invention for a limited amount of time. So, the *Wands* factors analyze, have you, the patent owner, satisfied this give and take, this *quid pro quo*? So, some of these factors, the *Wands* factors, are fairly straightforward. What's the nature in the invention, what's the relative skill of those in the art, is there predictability? Largely these questions will require experts to weigh in, those of the field of art. Generally don't see a lot of fighting on these three factors, but they are important, because they set the table for the analysis of the other five factors.

The state of the art asks, what did those of skill in the art know about the field at the time of the invention? In some fields this can be straightforward and other fields, like the life sciences, this can be challenging to go back in time and to understand what was known or not known and what was the prevailing view at the time. There's not always a consensus on that point. We look at the breadth of the claims. Are they narrow, are they broad, are they claiming a lot? Are they claiming just a little? The broader the claims, the more work the applicant needs to put in to establish enablement of that breadth.

We look at the amount of direction provided by the applicant in the specification. Did the inventor give the public what it needs to know, in order to practice the invention after the patent expires? This can tie in with the presence or absence of working examples, and those working examples can give the skilled person a lot of information. Examples aren't required, but they can be critical for clinical stage inventions. In particular, a working example can be necessary to satisfy that utility prong we spoke about a little bit ago to really ascertain whether it's useful. Is it useful or are you just guessing whether you've created something?

The big *Wands* factor is the quantity of experimentation needed to make or use the invention based on the content of the disclosure. Some amount of trial and error is permissible. Even a considerable amount of experimentation is permissible, so long as it's routine, and so long as the specification provides guidance as to the direction of the experiments that you should take. To satisfy

that *quid pro quo*, the specification must provide more than just a starting point for research. The skilled person should not have to engage in iterative trial and error experiments in order to practice the invention.

Kattman: You mentioned the full scope of the claims needs to be analyzed. What does that mean?

Lodise: The full scope means the entire breadth of the claim at issue. Claims are typically drafted to recite each of its elements as a range of possible choices. For example, a formulation claim might recite that it includes a disintegrant. That could be one of several specific kinds starch, methylcellulose, carmellose sodium, and those various kinds of disintegrants might be present, not in a specific amount, but in a range of possible amounts, say 5 to 20%. The specification must generally enable every possible formulation that could be made for mixing and matching those elements. So, in certain fields like formulations, once you have the ingredients, making a final formulation can be a relative straightforward endeavor for a formulator. But remember, the enablement inquiry necessarily touches on the utility requirements. So sure, one could make all those formulations that are within the scope of the claim but would each one be useful? So we go back to that initial inquiry of, what are these formulations useful for? All the formulations within the scope of the claim must have some use, and the specification should guide the formulator in making a formulation that will be useful for something. The specification must guide that formulator in knowing how do changes in the formulation impact the utility of that formulation?

Kattman: Can you provide an example of an enablement analysis?

Lodise: Sure, because these concepts are very difficult to understand in a vacuum. And even when there's a particular claim at issue there are so many factors that can come into play. But let's work with a super oversimplification. Let's assume we have a claim to a cake batter. I love cake.

Kattman: Me too.

Lodise: Let's say our new, nonobvious cake batter comprises one to five pounds of eggs, one to five pounds of flour, one to five pounds of sugar, and one to five pounds of butter. Okay. Cake batter invention. Let's look, ask the *Wands* factors. What's the nature of the invention? Well it's cake batter. It's in the culinary arts, it's baking, that's how we're analyzing that factor. Relative skill in the art. This might be a little questionable, because are we talking about a professional baker or a home baker? A novice, or someone with lots of years of experience?

The next factor, predictability or unpredictability of the art. I don't know about in your kitchen, sometimes my kitchen baking can be a little unpredictable. But generally I think if you're a skilled baker you know what things can change to get certain kinds of results. There is some kind of predictability, but maybe not a 100%. The next *Wands* factor, the state of the art, well if we look at the culinary arts today, they're very advanced. There's lots of baking happening, lots of gadgets, lots of tools, people can get degrees in it. So state of the art I'd say

would be high. So, just like we spoke about earlier there are some *Wands* factors that are pretty straightforward and speaking about those they're not so bad.

But now we get to the breadth of the claims. And now we're starting to get something into a little complicated. So I spoke about a cake batter that has four ingredients, eggs, flour, sugar and butter. Doesn't seem like a lot. But each of those ingredients can be from one to five pounds. So this isn't just one cake batter that I'm saying you can make. If we go in, say, half-pound increments, it's nine different amounts for each of the four ingredients. That means our cake batter has 6,561 variations. That's pretty broad. That's a lot of cake. So looking at all those different variations we would look to the specification and say well, what sort of guidance has the applicant given us? What is the application specification tell us to do with those ingredients in order to make a cake batter? What kind of eggs are we supposed to use? Are they quail or chicken? What kind of flour? Is it all-purpose, is it cake flour, is it coconut flour? Do we use brown sugar or white sugar? Melted butter, cold butter? And what do the ratios of all these things, if I use five pounds of flour, how much sugar do I use so that it comes out as a cake batter, and if I baked it, it makes a cake? These are all questions that we would ask and it starts to seem like ooh, that sounds very, very complicated but, we know that we're not just looking at the claims, we're looking at the claims in view of the specification and hopefully in that specification there'll be some examples that'll give us some direction as to the kinds of eggs, the kinds of sugar, and maybe even couple that with the skills of a professional baker. They might know reading the specification how do you mix all these things together so that you get an actual cake and not bread or glue.

And then after looking at all that, we ask the big question what's the quantity of experimentation needed so they can use this invention? Does the skilled person need to make all 6,561 variations of cake batter to know what works? To be enabled we don't require that a baker be able to predict whether any particular ratios or specific types of ingredients will produce a cake batter, and the specification doesn't have to provide an example of every possible working ratio. But the specification must provide guidance so that the baker doesn't have to keep trying different ratios or just guessing at which ones might work. So we'd look at well, how many cake batters can be duds and not be useful to make a cake before we can say there's no enablement. And that will vary, depending on the art. So maybe it's such that well, if one doesn't work, the whole scope isn't enabled. Or maybe it's okay for 50 not to work at over 6,000 and it's still enabled. But that would be how we'd analyze that enablement question.

Kattman: Wow. There is a lot that needs to be considered. Can you ever be sure that the full scope of the claims is enabled?

Lodise: So, it's challenging because it is so fact-dependent. What I like to do when I'm drafting patent applications is I like to push the inventors to look at the claims objectively. If there's something they want to claim but they don't have an example for it, well look to the specification. Are we providing a guide to that something? Do the inventors want to claim that something because they know it will be useful? Or do they want to claim it because well, why not? Would

someone be left to guess and resort to trial and error in order to arrive at something useful based on what's claimed?

With clinical stage inventions, another complication is that, remember we're here because something surprising and unexpected has generally happened. And how broad can the claims be and how sparse can the specification be before you're moving away from something that was surprising and unexpected, and now trying to classify it and argue that well, someone of skill in the art would have eventually found it and filling in the gaps of maybe your broad claims and saying they're enabled because well, someone would have been able to figure it out. That's a tension between what is surprising and unexpected with what someone of skill in the art would be able to find out on their own.

Kattman: Stephanie, what's the written description requirement?

Lodise: So we talked a lot about enablement, *Wands* factors. The 35 U.S.C. § 112 actually has two pieces to it, that's the enablement one. The written description requirement, this ensures that the inventor actually invented what they claimed, that they had "possession" of the claim subject matter when the application was filed. And this is a question of fact. This is an objective inquiry of the specification from the perspective of the person of ordinary skill in the art. The phrase that we use, possession of the invention, that sounds odd. The claims say what's been invented, right? How could someone not have possessed what those words say? But remember, when we talked about the claims how they're usually drafted to include ranges for each element, and the specification might have some examples, but there need not be an example for every single embodiment. The written description requirement recognizes the gap between what's been exemplified in the specification and the full scope of the claims.

So going back to our cake batter example, did the inventor know at the filing date what ratios make a cake and which ones won't? And, could someone skilled in the art reading the specification be able to tell that the inventor knew that. So we're gonna keep going back to this 101 inquiry and that informs the written description inquiry. Is the invention useful? Did the inventor know it was useful at the time of the filing?

Kattman: As a final question, what should we remember about patenting clinical stage inventions?

Lodise: I think what's helpful to remember is that none of the patent laws live separately. Everything is connected. So all these levers are going to be pushed up and down as you're thinking about the invention. What you think is novel will affect what is nonobvious. It will affect how you describe it, whether you have possession of the invention. So to always think about the inventions holistically, and not focusing on one aspect of the law like for example novelty. I think that's where you run into trouble.

Kattman: Thank you, Stephanie. If you have any questions for Stephanie, her contact information is in the show notes. As always, thanks for listening to BakerHosts.

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