Knobbe IP+

PODCAST

The Biggest Patent Cases of 2026 So Far: The Federal Circuit Tackles Patentability

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[Cold Open]
Jeremiah Helm (00:01)
Now, there's a tension between these two sections, the 112 disclosure and the obviousness. As a patent owner, you want to thread a needle here, which is you want to say that it would have been really hard to get from what was previously known to what you invented. But on the other hand, there would have been sufficient understanding for a skilled artisan to recognize that you invented the claimed thing. And also a skilled artisan would have sufficient ability to do what is claimed. And so we're gonna see in a series of cases how that tension manifests. And sometimes it comes out in favor of the patent owner and but it is, I think, a very powerful tool for an accused infringer.

Voiceover (00:47)
Welcome to the Knobbe Martens IP+ podcast where we bring you engaging conversations with the people at the forefront of IP. Now let's go to the host of today's episode.

Jeremiah Helm (01:00)
Welcome to this episode of Knobbe IP+. I'm Jeremiah Helm. I am a litigation partner with Knobbe Martens and I am Co-Chair of the Appellate practice here. And with me is…

Carol Pitzel Cruz (01:13)
Hi, this is Carol Pitzel Cruz. I'm a litigation partner as well, and I am Co-Chair of the Hatch-Waxman or ANDA practice.

Jeremiah Helm (01:21)
We're the host of today's episode where we are continuing our discussion of the biggest patent cases of 2026 so far. Last time we explored the Supreme Court's ruling in *Hikma v. Amarin*. Today, we're going to be talking about some of the Federal Circuit's jurisprudence with respect to the requirements of Section 112 and the challenges faced by litigants when defending or asserting invalidity of a patent.

Carol Pitzel Cruz (01:44)
So let's move to a trend that we have been seeing in the district courts in various litigations we've been involved in. And I'd say, you know, this, this trend has been kind of increasing over maybe the past five, ten years. And I definitely see it in almost every case that we're dealing with today.

More and more we're seeing defendants asserting enablement and written description defenses, especially in combination with an obviousness defense when they're challenging the invalidity of patents asserted against them. So, Jeremiah, can you provide our listeners with an explanation of these defenses at a high level?

Jeremiah Helm (02:24)
I'd be happy to, Carol. The written description and enablement defenses are what I would call 112 defenses, and that refers to the statutory section that they fall under. These are two distinct requirements in the statute, and both of them focus on what the inventor has disclosed in their patent specification. For written description, the specification has to disclose what the inventor ultimately claims. And so the standard, general standard for that, is that the specification must convey to one of ordinary skill in the art that the inventors possessed the claim invention at the time of filing. They're different articulations, but that's the general idea is that, did they have that thing that they invented? It doesn't mean physically having, but it means at least have the idea of it that they put down in their patent specification.

Enablement is slightly different. And enablement deals with whether the inventor has given enough information to convey to a person of ordinary skill in the art how to make and use the invention without undue experimentation. And oftentimes, that undue experimentation is where there's some fight on the enablement, on the enablement front.

Obviousness is different. Obviousness has to do with whether the invention that's being claimed is some addition to the things that were previously known. And we call those prior art, of course. So if there's an obvious variation of the prior art that's being claimed, that's not patentable.

Now, there's a tension between these two sections, the 112 disclosure and the obviousness. As a patent owner, you want to thread a needle here, which is you want to say that it would have been really hard to get from what was previously known to what you invented. But on the other hand, there would have been sufficient understanding for a skilled artisan to recognize that you invented the claimed thing. And also a skilled artisan would have sufficient ability to do what is claimed. And so we're gonna see in a series of cases how that tension manifests. And sometimes it comes out in favor of the patent owner and but it is, I think, a very powerful tool for an accused infringer.

So Carol, let's go to the first case, *Wyeth v. AstraZeneca*.

Carol Pitzel Cruz (04:40)
Okay, so in this *Wyeth v. AstraZeneca* case, this one deals with enablement, the enablement standard that Jeremiah just discussed. And so here we had a method of treating, and just broadly, it was a method of treating cancer involving administering daily to a patient a pharmaceutical composition, which had and a term that's going to be important is a unit dosage of a certain type of inhibitor. And essentially the claim was claiming the entire genus of these specific types of inhibitors.

And so here what the court did was looked at the specification to see was there anything in the specification that described what unit dosage meant. And in fact, the specification defined the unit dosage as, I won't read the entire description, but the relevant parts was that it was a predetermined quantity of the active material drug calculated to produce the desired therapeutic effect. So here the desired therapeutic effect was this method of treating cancer.

So the case proceeded through to a jury trial. The jury decided that the claims were not invalid. They were enabled and the parties then proceeded to file a judgment as a matter of law, which was granted by the district court saying that the patents were invalid for lack of an enablement.

Jeremiah Helm (06:09)
So in this case, the jury made findings about enablement. And the party, the accused infringer, was unhappy with those findings because the patent was held upheld as valid. And so they moved the judge to order as a matter of law that their patent lacked enablement. One of the key issues here was whether the jury applied the correct understanding of the claim. And the judge here said that applying the correct understanding, no jury could come to the conclusion that they did, and as a result, the patent was not enabled. That led to the appeal that we're dealing with here at the Federal Circuit.

Carol Pitzel Cruz (06:46)
And in that appeal at the Federal Circuit, there were two issues that were dealt with, the claim construction and then the enablement issue. So, the Federal Circuit looked at that JMOL decision and essentially agreed with the district court. They found that the patented specification itself described that there needed to be this therapeutic effect and you needed to calculate the dosage that would provide the therapeutic effect in a patient. Those were all words within the claim, and the unit dosage information was described in the specification. So the Federal Circuit affirmed that portion of the district court rulings.

Then moving on to enablement, the claims here, as I mentioned earlier, were for a genus of compounds. And really what was limiting them were that they administer, were administered as a unit dosage in an amount calculated to produce a therapeutic effect, that treatment of cancer, in a patient. So as Jeremiah mentioned earlier with respect to this standard, the specification has to enable one of ordinary skill in the art, enough guidance to determine that daily dose that was going to provide the therapeutic effect in a patient. So when the Federal Circuit went to look at the specification, what information did they find there?

So first, they only had a few limited examples of in vitro testing, and that's testing in a laboratory setting. It's not testing in a patient. There was no testing described in the specification that showed what dose would be effective in a patient. Second, there were some statements about total daily dosage amount, but the dosage ranges that were disclosed in the patent were very broad. And unfortunately for the patentee here, there was testimony from their scientists that demonstrated that dosages within that claimed range were beyond the maximum tolerable dose you would provide to a patient. So, in other words, they were beyond what you would ever give to a patient. So they wouldn't be that therapeutic amount that you would provide for the claimed invention.

The other part of the specification that was not helpful to the patentee was that they described the determining of the dosage amount as being unpredictable and also very complex, very individualized. So those statements really made it difficult for the Federal Circuit to say, you know what, one of ordinary skill in the art looking at this patent can look at this information and translate that in vitro data, that lab data, to “What dose would you give a patient?” So ultimately the Federal Circuit looked at that and said the specification just doesn't provide enough information, and it would be undue experimentation for one of ordinary skill in the art to be able to determine that unit dosage amount. And so they found that the claims were invalid for lack of enablement

Jeremiah Helm (09:46)
Carol, I think one of the things that you one of the points you raised here is really key, which is the unpredictability, the admission of unpredictability in the specification, and also the admissions from their own inventors and their own witnesses are what drove this, this decision. Now, I think that there's a trend here in a lot of these patents, and this is what we talked about at the outset with this tension between obviousness and 112 types of defenses, in this case enablement. And we see it here, which is where there's close prior art, you really have to rely on unpredictability or the work to get from what seems to be relatively similar previous disclosures to the claims. To avoid obviousness, you have to make a strong argument that there's something special about that extra step. For example, administering it to a patient, which was the relevant type of limitation in these claims.

So, even though the particular molecule may have been known or the type of molecule may have been known, taking that extra step and administering it to a patient and administering it to a patient in a correct dose and administering it to a patient in a correct dose to avoid toxicity, each of those are steps along the way that you would take and make arguments about as a patent owner to avoid obviousness. Here we see that those arguments can come back around and bite you when you're dealing with 112, specifically enablement.

So, Carol, what do you think about moving forward, the types of arguments we're going to see from accused infringers in these types of chemical cases, which are typically unpredictable arts?

Carol Pitzel Cruz (11:25)
I mean, in most of these chemical cases, you are as a defendant alleging an invalidity defense of obviousness. So you're going to want to have the invalidity defense of obviousness plus enablement and also written description, as we'll see. So that we you force the patent owner into that tension that – they have to walk the line between this is an advance and no one knew about it, but did they provide enough information in the specification to enable one of skill in the art or to show that the they've met the written description requirement?

And I think also during patent prosecution, you know, if you have to narrow the claims, you really need to take a hard look at the specification and determine, you know, if we narrow it to this, do we have enough? We add this limitation, even if it's maybe not a narrowing, but you're adding a limitation, is there enough in that specification to pass the enablement and written description requirements? Because it may not be the original claim you thought you were going after when you filed the application.

Jeremiah Helm (12:27)
Yeah, that's a great point. I, I believe, if I remember correctly, this case, the *Wyeth* case, I think this was a $100 million verdict that was overturned.

Carol Pitzel Cruz (12:34)
That it was, yes. It had some serious consequences. And I think in the interest of time we should probably move on to our next case. Jeremiah, do you want talk about the *Teva Eli Lilly* case?

Jeremiah Helm (12:48)
Yeah, I'm happy to talk about that. So *Teva Lilly* is a case that is kind of the other side of the coin. Because in this case, there's an important predicate fact, which is the parties had previously fought over the patents at issue. These are similar in the sense that this is a method patent, a method of treatment. And there were a series of other patents, related to the underlying compound or the underlying antibody. It's an antibody case. And Lilly had brought IPRs seeking to invalidate the patents, including the method patent at issue in this particular appeal. However, they were unsuccessful in the method patent, successful on all the other patents. And during the course of their arguments about obviousness, Lilly made some statements to the Patent Office. They talked about how well known the, this different steps needed to go from the prior art to the claimed invention were. They talked about how it was routine. And that type of admission or that type of statement is great for obviousness. But what we see here in this case is that it came back to negatively impact them on the issue of enablement—so, and—enablement and written description.

So, *Teva Lilly* deals with both written description and enablement. And the question that came up to the Federal Circuit was whether the claims to the method of treating a headache using a particular antibody or class of antibodies were sufficiently described, also sufficiently enabled. And to me, this case—there's not a huge amount of room between this case and the prior case we just discussed—but with the important fact difference of the accused infringer was the one who made all of these admissions about what was known. And based upon all of these extensive admissions about what was known, what would have been routine, what would have been understood, the Federal Circuit found there was sufficient evidence to support the jury verdict in favor of the patent owner. And so, I think that this is an important kind of bookend to what we just discussed, where if you're an accused infringer, you also have to be wary and cognizant of the types of statements you make when seeking obviousness. And so, you really do have to make a very important choice early on in your case when you're setting up your defenses and your invalidity arguments, how extreme you want to be to succeed in your obviousness case and how you want to prioritize your obviousness case versus your 112 invalidity.

Carol Pitzel Cruz (15:25)
Thanks, Jeremiah. That was a great summary of the *Teva Lilly* case. Let's talk about another case that's in the 112 arena here. So that's the *Duke v. Sandoz* case. Can you provide us a brief summary of that case as well?

Jeremiah Helm (15:38)
Sure, I'm happy to, Carol. And I, I will admit that this is a bit of a cheat because this case came out at the very end of 2025. Even though this purports to be about 2026 cases, I pushed it in under the under the wire because I think that it does establish an important trend at the Federal Circuit, which is a real renewed focus on 112. And there are, there's a sort of cyclical focus as patent owners try to push the bounds of their disclosure in both written description and in enablement, for the Federal Circuit to rein in periodically. And I think we're in the midst of one of those reigning in sessions.

So *Duke v. Sandoz* is a written description case, and if you recall, written description is what we how we assess whether the inventor possessed it. And this case is all about blaze marks. That is the classic formulation of the written description test, whether there are sufficient blaze marks in the patent to get to the claim. Now, in *Duke v. Sandoz*, the thing is you had a disclosure of a chemical compound that's very, very typical of a patent. You have a core structure, you have different features hanging off of the core structure, you have different variations on these features

in the core structure. And there's a very long disclosure of all the various differences that you can have at different positions and different functionality, on and on. This is not unusual.

But what the court did in this case is they said, you cannot just rely on the fact that a specific modification was mentioned. You actually have to reason, have a reason to go there. So, you can't just have an almost infinite set of disclosures in your patent, infinite in this combinatorial sense, where you pick one from column A, one from column B, and one from column C, and you end up with your invention. You have to have a reason to make each of those decisions at each of those steps. Why would you choose this particular thing from column A? Why would you choose this particular moiety from column B, and so forth and so on?

So, I think this is very important because oftentimes, again, this comes back to the obviousness written description tension. Oftentimes, the arguments that a patent owner makes against obviousness have to do with "Sure, those types of modifications were known, but there was no reason to choose them." And *Duke v. Sandoz* takes a step that I thought was very interesting, which is it almost applies that same type of rationalization of you have to have a reason to take the step and make that selection to the patent itself when assessing written description.

So, I thought that this was an important case. But also more generally, it was a great marker, a blaze mark, if you will, in the Federal Circuit's tightening of the disclosure requirements. Carol, how do you like the Federal Circuit's discussion in *Duke v. Sandoz* of written description?

Carol Pitzel Cruz (18:38)
I think it was helpful because it, it gave you some real specific numbers and examples too. So, at the district court there were experts involved on both sides and they looked at the claim and you know, Allergan or Duke's expert said that the claim at issue was disclosing, I believe, roughly 4,000 different compounds that could be claimed. And Sandoz's expert was roughly 1,600. So you're talking about a claim with a substantial number of potential compounds back to your description of, of the basic structure and there were all these different things you could plug in. And so when you have that many different options, you have to—what the Federal Circuit was saying—is you really have to describe how to get there. You know, what choices should you be making to have this method of treatment claim and be able to really show that the inventors possessed that specific claim. Because the original disclosure is actually much broader and I believe that one of the experts agreed that it could potentially disclose billions of compounds. So even though you're narrowing it to this narrower subset, it's still a large amount of compounds. How do you get there? Why? And that disclosure just wasn't there.

And I think it's an important case in terms of the defendants to be able to look at these patents, look to see what the disclosure is. Same thing for the patentee. When you're narrowing those claims or writing new claims, you have a continuation, a new set of claims, you have to really focus on what you disclosed and make sure that you're meeting that requirement.

Jeremiah Helm (20:22)
I agree completely. That's definitely how this case is going to be used moving forward, and I do expect to see a renewed focus on 112 for district court litigants as a result of these cases that we've discussed.

Okay. So, you know, I wanted to just bring up one other case since we've been doing a lot of 112. There are other sections of 112 that are relevant to patent litigations, and one of them is the indefiniteness requirement, or the definiteness requirement, that's embodied in the second paragraph of Section 112. It's only a dozen years old, but we still are dealing with patents that are pre-AIA.

So the case I want to talk about was *Envirotech v. Safe Foods*. I like this case just because the technology is a little bit different. It involves dipping chickens into a bath to kill microbes but not lose weight. So I think one of the things that happens during food processing is you process the food and then you lose some weight. I think, my understanding at least—although it may be wrong, please do not hold me to this, Carol—is that somehow this helps the chickens absorb a little bit of water and not lose too much juice during processing. And I know that you're somebody who really enjoys talking about processing chickens. So, I pick this case for you. [Laughs]

Carol Pitzel Cruz (21:36)
[Laughs] Thanks, Jeremiah.

Jeremiah Helm (21:37)
[Laughs] You're welcome. So, in this case, what I like about this case is that it involves claim construction for a term “about”. This is a term of approximation, and this happens. This comes up a lot in patents, is that patent claims will use terms like “approximately” or “about” or something like that to describe what they're claiming. And the definiteness requirement in the patent statute says you have to be clear about what the boundaries are for your patent claim. You can't make it too uncertain. And there's a little wiggle room, but you can't be too uncertain in what you claim. Otherwise it deprives the public of the ability to understand what falls inside or outside your patent claim.

And in this case, the bath that the poultry went into had a pH of “about” a certain range. Now, this is consistent with the themes that we saw earlier involving close prior art. During prosecution, there was some art that was pretty close to what was being claimed. And to avoid that prior art, the patentee modified the claimed pH range, but left that “about” limitation in there. When the Federal Circuit looked at this case, the district court invalidated the patent. And by the way, indefiniteness is a great way to invalidate a patent because it comes relatively early on, and it tends to be a claim construction issue, which is a matter of law. There may be some underlying facts, and some district court judges will not deal with it until those facts have been developed, but it can still be a relatively early way for you to get at invalidity as a patent litigant.

The Federal Circuit heard this appeal and concluded that the claims were indefinite because of that term of approximation “about”. And the problem was that there was no definition in the specification, the statements during prosecution were not clear enough, and ultimately, what was in the prior art could also be viewed as “about” the claim pH range. So, I like this case because it does say be careful as a patentee. Be careful what you are claiming. And if you want to use these terms of approximation, which are perfectly valid to use, make sure you've defined them adequately. If you’re not defining your specification, make sure you define them during prosecution. So, I like this case as a warning to both patentees and a signpost to accused infringers that they should consider whether the terms of approximation used might be subject to an attack.

Carol Pitzel Cruz (24:06)
I just wanted to mention one last takeaway for these cases we were looking at. Now we talked about getting your case through the jury verdict and then having to deal with the JMOL and making sure you consider what statements you're making along the way. The same is true of serial litigation. We've seen a lot more of that trend, which we're not discussing today, but where one drug is litigated for many years with different waves of patent litigation. And so, the same applies there that you need to really determine early on what positions you're going to take because statements you make in one context can really end up hurting you or helping the other side later on down the road.

Jeremiah Helm (24:45)
That's a great point, Carol. That wraps up today's episode. Thank you so much, Carol, for doing this with me. It's been a lot of fun. We've gotten to think about a lot of interesting trends in patent litigation. And a big thanks to you, the audience, for joining us today. Be sure to visit Knobbe.com, K-N-O-B-B-E.com, to listen to or view written transcripts of this and other episodes of Knobbe IP+. Until next time, we appreciate your listening.

Carol Pitzel Cruz (25:13)
Thanks everyone.

Voiceover (25:22)
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