Knobbe IP+
PODCAST

The Biggest Patent Cases of 2026 So Far: ANDA Litigation at the Supreme Court

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[Cold Open]
Jeremiah Helm (00:01)
Carol, is there something that we should take away from Hikma in your view?

Carol Pitzel Cruz (00:04)
I think based on this case, if you are the patentee and you're drafting your complaint, you really want to focus on all three aspects of that induced infringement showing. You know, you have to have the direct infringement by a third party, you have to have intent to induce that infringement. But from this case, it's really stressing that you have to show those active steps to encourage that direct infringement and you really need to make sure you have as much information in that complaint as possible to avoid a motion to dismiss.

Voiceover (00:43)
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 (00:54)
Hello and welcome to this episode of Knobbe IP+. I'm Jeremiah Helm. I am a litigation partner here at Knobbe Martens and Co-Chair of the Appellate Practice Group. And with me is…

Carol Pitzel Cruz (01:09)
Hi, I'm Carol Pitzel Cruz. I am a litigation partner in our Seattle office, and I am Co-Chair of our Hatch-Waxman practice.

Jeremiah Helm (01:17)
We're hosts of today's episode, where we'll be discussing some of the biggest patent cases of 2026 – with the caveat that because we're doing this in July, it's only so far. Lots of amazing stuff to get into here, Carol. And let's start with the Supreme Court.

Now, it's not every year that we get a Supreme Court case dealing with patents, and this year we were lucky enough to have *Hikma v. Amarin*, which was a case that dealt with induced infringement. I want to make a couple of prefatory statements about this case. Number one, it's an

ANDA case. And Carol, you are a co-chair of our ANDA practice. Can you talk a little bit about what it means to be an ANDA case?

Carol Pitzel Cruz (02:05)
Sure. There's a statutory framework called the Hatch-Waxman Act that governs all of ANDA litigation. It's also referred to as Hatch-Waxman litigation. And essentially, it allows a generic drug manufacturer to file an abbreviated new drug application, referred to as an ANDA application, at the FDA, and as the name describes, it is an abbreviated application. So, they're allowed to rely on some of the safety and efficacy findings from the brand name work that was done and filed and approved with the FDA. As part of that process, the brand name company will list the patents it asserts cover their product in what we call the Orange Book. The generic companies then look at those patents and, as part of their ANDA filings, they have to certify as to all of the patents that are listed and they can say they don't infringe, they'll wait till the patents expire, or they can challenge the patents. And if they challenge the patents, they can say that they don't infringe, they're invalid, or both.

Jeremiah Helm (03:16)
So, one of the things that I think is really fascinating about ANDA litigation in general is that it reflects this very precise balancing of different policy incentives, both inherent in the Patent Act and also in the FDA statutes, to bring generic drugs to market to compete with branded drugs while not undermining the incentive for the branded drug makers to innovate in the first place. Now, part of that delicate balance comes up in this case because *Hikma* received approval to market its drug based upon the very evocative process of skinny label labeling. Now, skinny labeling is kind of the lawyer's name for a particular statutory section. Carol, could you talk just a little bit about what skinny labeling might entail?

Carol Pitzel Cruz (04:10)
Sure. First of all, what is the label? So, the label is that piece of paper that you get with your prescription that you should read, but may not, but it describes various aspects of the drug. One of those aspects is what is the drug approved for? And we call that the indication. So, there may be more than one indication that a drug is approved for.

You know, one example we see today are all the GLP-1 drugs. So, they were originally approved for diabetes treatment, and now they're also approved for weight loss. And so that's an example of two different indications that have been approved on a label. So, a generic company, if they'd like to pursue selling one of those drugs – or a drug – with one of the indications, they can do what is called a skinny label or a Section VIII label. And what they will do is seek approval only for one of the indications, or maybe if there's multiple indications, only two of the indications. Generally, what you see is that there will be a patented indication and a non-patented indication. And so, they'll be carving out or excluding the patented indication. Or maybe there's just one indication that they want to challenge that they believe they don't infringe or is invalid.

Jeremiah Helm (05:32)
So, in this case, Hikma received approval for fewer than all of the indications using a skinny label, and then went to market and tried to market their drug. And that brings up the second prefatory

point I want to make, which is that Hikma was not itself infringing. The patents here, the relevant patent in this case, had to do with the method of treatment. So, Hikma was not going out and treating patients. That was something that a physician would do or a patient would do by administering the drug.

So induced infringement is a concept in patent law, it's under the statute, where even though you are not yourself infringing, you're still responsible for the infringement. I just want to touch a little bit on this because this provides you the framework for understanding what happened in this Supreme Court case. The distinction between direct infringement, which is, “I myself am infringing,” and induced infringement, which is, “I cause somebody else to infringe,” is very important.

Direct infringement is a strict liability tort. And so, when you directly infringe, it doesn't matter what your intent is. Inducement is different. Your intent matters, and the actions you take in furtherance of that intent matter a lot. The typical expression of that standard, both at the Federal Circuit but also at the Supreme Court, is that you need to have someone with the intent to cause infringement, and the entity must take an affirmative act or an affirmative step to cause the infringement.

Now, Hikma was at the pleading stage, which means it was at the very outset of the litigation. And because it was at the very outset of the litigation, the relevant standard on a motion to dismiss, which is what Hikma brought, is whether there's a plausible allegation of induced infringement. Carol, do you want to talk a little bit about what happened at the district court with this? Because I know we've discussed this and there's a little bit of a ping pong situation. So, you want to talk a little bit about what happened?

Carol Pitzel Cruz (07:28)
Sure. So, this case was originally – there was a motion to dismiss brought by Hikma, and they were alleging that the claims of induced infringement were insufficient, that basically Amarin had not pled enough information to say that the relief they were asking for was plausible on its face. So, they brought that before the magistrate. The magistrate denied the motion, and then that motion went to the district court judge, and the district court granted the motion to dismiss. Then it went to the Federal Circuit on appeal, where the Federal Circuit reversed that and found that the motion to dismiss should not have been granted. And then that was appealed to the Supreme Court, which is what we're talking about here today.

Jeremiah Helm (08:15)
That's right. And so, at the Federal Circuit, the Federal Circuit—when it reversed the district court's dismissal of the case for essentially Amarin not pleading sufficient information—the Federal Circuit came to the conclusion that what was pled was sufficient to support the induced infringements. So, the things that were, the things that were in the pleadings were that things like Hikma's website described the therapeutic category in general terms instead of the specific indication that it was approved for.

The website indicated that the drug was AB-rated, which means it was equivalent to the branded drug. And there was a press release that discussed the branded drug's overall sale numbers, not just the sale numbers for Hikma's approved skinny label indication. And the press release

described the product as a generic version of the branded drug, VASCEPA®, without mentioning only the approved use. And what the Federal Circuit did was they drew a line between those and said at each step it was plausible, which is the relevant standard, that you might have somebody look at this information and interpret it in a specific way and get to the final result of inducing infringement. Therefore, they found that that was an active step and that was the basis of reversal.

When it went to the Supreme Court, the Supreme Court disagreed. And the reason for that disagreement was that none of the evidence alleged in the pleadings was sufficiently tied to the act of infringement. And I think this is an important point and a reason, the reason why this case is of interest, is because the Supreme Court rejected the Federal Circuit's general approach where a plausibility standard for the ultimate actor, the physician, is different from an instruction or encouragement by the person inducing infringement. So, even if you look at every individual step and decide that's plausible to get to the end result, that still doesn't, that's still not enough to establish that there was an active step that was an instruction or an encouragement to infringe.

Now, I want to talk just very briefly about some of the things that the Supreme Court said. So, one thing was whether there were obvious alternate explanations for what was done. So, for example, we – I – alluded to earlier the step of releasing a press release about how much money they might make, the total market for the drug. And what the Supreme Court said was when you look and you release a press release, that's not the type of encouragement that you would otherwise expect. It's not directed to the right party. It's not – has nothing to do with administering the drug. What it has to do with is your business. So that type of evidence is not going to be sufficient at the pleading stage, even at the pleading stage, to give rise to a claim of inducement. It's not the type of affirmative step in furtherance of infringement.

Likewise, I think this is one of the more interesting parts here, is that when the law requires you to do something, for example, to copy the label, as in the case of ANDA litigation, you can't look at that and say, “Well, that's in, that's a step” or “That's evidence to induce infringement” because that's what the law requires. It's not an affirmative step. It's a step that's required by the law.

Carol, one of the things I think is really interesting about this case is that there's a lot of laws involving, that involve pharmaceuticals. One of the ones that came up in the government's briefing, but that the Supreme Court didn't get into in the decision because I don't think it was properly raised, is the fact that there are state substitution laws that require pharmacies to dispense generic equivalents of a drug when they receive a prescription. Can you just talk a little bit about what those types of substitution laws do, what effect they have?

Carol Pitzel Cruz (12:33)
Sure. So, once it's determined that your generic is what we call AB-rated, that means under most state laws that the pharmacist can automatically substitute the generic drug for your brand name drug. Now your doctor can alter the prescription and say, “I only want brand name only,” and that's fine. But what it does allow for is that whatever indication this drug is being prescribed for, the pharmacist can just go ahead and substitute the generic. So here, even if the patient receiving the drug was receiving it for the patented indication, it could still be—the generic could still be prescribed because of the automatic substitution. But the generic is not the one actively inducing

that prescription and the treatment of the patient for that indication. That's not what they sought approval for. That's just a result of the state laws.

Jeremiah Helm (13:35)
Yeah, so I think one of the interesting parts of this is that even though the Supreme Court didn't reach that issue, I do read their opinion as likely to give rise to the types of arguments that Carol just articulated, which is the generic may not be able to be held responsible for inducement because of these state substitution laws.

By the way, for inducement, one of the things I really like to think about for inducement is culpability. And I think that this case has a broader application in patent law.

We've been talking about it in the ANDA context, and there's a lot of legal framework in the ANDA context that makes this specific holding of interest to practitioners in the ANDA context. But it applies more broadly. And one of the things that the Supreme Court was clear about was there is no specific rule. There's no specific inducement rule. It is a general statute and we apply general principles. And so, you have to look at this case as potentially influencing all inducement. One of the arguments that came up was whether the inducement has to be an express inducement as opposed to just an active inducement. That was one of Hikma's arguments on appeal.

And the Supreme Court actually dealt with that and said, “No, you don't have to be express.” And that makes good sense because there are lots of situations where the inducement, the trying to get somebody to do bad things, is not express. And so, you can think of in movies or crime procedurals, where there are a couple of guys in sharp suits who come down and tell the shopkeeper, “Hey, we just wanted to let you know that every single shop that did not buy our fire insurance subsequently burned down.” Now there's no express statement there, but the threat is definitely implied. And there's bad action. And you can imagine the same type of thing in advertising from Hikma or from a generic company that says, “By the way, we just wanted to let you know our drug could be used for all of these patented indications as well. If you prescribe it, it's going to be used. We're not telling you to prescribe it, but ‘wink wink.’”

Now, so there's going to be a lot of litigation in the ANDA context, figuring out exactly where that line is. But in the general context as well, we're going see a lot more, I think, efforts at the pleading stage to get these inducement claims dismissed. Because there are a lot of patents that are written in a way where the person who you want to sue is not the one who's directly infringing.

Carol, is there something that we should take away from *Hikma* in your view?

Carol Pitzel Cruz (16:12)
I think based on this case, if you are the patentee and you're drafting your complaint, you really want to focus on all three aspects of that induced infringement showing. You know, you have to have the direct infringement by a third party. You have to have intent to induce that infringement. But from this case, it's really stressing that you have to show those active steps to encourage that direct infringement.

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Jeremiah Helm (16:49)
Unsurprisingly, Carol, I completely agree. It's that's a great, a great summary of this case.

Well, Carol, I think that brings us to the end of today's episode. It's been a really interesting discussion of the Supreme Court's *Hikma* case. I'd like to thank you, listeners, for joining us as we begin our exploration of the biggest patent cases of 2026 so far. Be sure to join us for our next episode where we're going to continue this discussion and look at some of the trends that we've seen this year in the development of the Federal Circuit's 112 jurisprudence.

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Voiceover (17:38)
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