Podcast Transcript

Wait, what? IDS Trouble and the PTA Penalty Trap

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Lee: Welcome to Wait, what? The podcast that explores the unexpected twists and turns of patent law, where even the most seasoned attorneys find themselves asking, wait, what? In each episode, we shine a light on the surprising, confusing, and sometimes downright frustrating moments that come with navigating the U.S. patent system. Whether you are a new associate, a seasoned practitioner, or just curious about how innovation gets protected, this show is for you. I'm Leeann Lee, and you're listening to BakerHosts.

Today's episode kicks off with a topic that is deceptively simple, but packed with pitfalls, the timing of information disclosure statements, or IDS filings, and how they can impact patent term adjustment. It is a classic case of the rules say yes, but the consequences say no. To guide us through this maze, we are joined by two battle-tested patent attorneys who've seen it all, Laura Gordon and Stephanie Lodise. They'll break down the rules, the risks, and the real-life cases that show why timing truly is everything. So, grab your coffee, your sticky notes, and maybe a copy of the MPEP, because it is time to dive into Wait, what?

Gordon: Welcome to Wait, what? The podcast where patent law meets real-life head scratchers. I'm Laura Gordon, a neuroscientist-turned-patent attorney. I went from studying how brains process information to helping inventors protect the information that they discover. These days, I'm a partner in the Life Sciences and Advanced Materials group at BakerHostetler, and I spend my time decoding the mysteries of the MPEP. And I often rely on the insights of my brilliant partner in arms, Stephanie Lodise. Hi, Stephanie.

Lodise: Hi, listeners. I'm Stephanie Lodise, also a scientist-turned-patent attorney with a PhD in organic chemistry. I traded my lab coat for legal briefs. And now I help innovators protect their breakthroughs. Together, Laura and I have decades of patent prosecution experience, and we've seen our fair share of wait, what moments in patent practice.

Gordon: Thanks, Stephanie. Okay, let's get started. Today's episode is about one of those moments, the filing of information disclosure statements, or IDS for short. These are submissions to the Patent Office to disclose known or relevant references, including patents and publications that might affect the patentability of the invention that we're prosecuting.

Lodise: IDSs seem straightforward until they're not, especially in complex cases with potentially hundreds, even thousands of possibly relevant publications and patents that can pop up at anytime from anywhere during prosecution. The issue we're teeing up today is one of the trickiest issues for IDS filings and frankly, one of the top issues susceptible to getting bungled by patent practitioners. So, buckle up, because we're diving into the timing traps that can cost you precious patent term adjustment.

Gordon: Okay, let's start with the basics. Why are we even bothering to submit references to the Patent Office? This isn't a requirement in most other countries around the world.

Lodise: No, Laura, it is not. But Rule 56 in the U.S., this is the duty to disclose information material to patentability, known to individuals associated with the filing or prosecution of a patent application.

Gordon: Wow, that seems pretty broad. Who are those individuals?

Lodise: Those individuals are inventors, patent attorneys, patent agents, or every other person who is substantively involved in the preparation or prosecution of the application. So yeah, everybody.

Gordon: Okay, yeah, that does seem like a lot of people. So, tell me, how do you comply with this rule?

Lodise: Rule 56(d) tells us how to comply, and the way we can do that is we can file an IDS statement.

Gordon: Okay, so when these references come in, you can just file these whenever in an IDS?

Lodise: No. No, you can't. You can only file an IDS at certain times in prosecution. Sometimes you have to pay a fee, and other times you don't.

Gordon: Okay. So, to help our listeners, here is when you can file without paying a fee, in other words, for free, which is something we always want. Under 37 CFR 1.97, so that is the code of federal regulations for any of the non-patent nerds in the audience, the U.S. Patent and Trademark Office says you can file for free within three months of the application's filing date or before mailing of the first office action, quote, on the merits, unquote, including after filing a request for continued examination.

Lodise: Great. Laura, just a note about the office action on the merits, a restriction requirement does not count as a first action on the merits.

Gordon: Okay, so that is helpful. And you can also file at other times, not for free, if you pay a fee. The fee varies. But it is about $280 after any of the events that I just mentioned but before a final office action or a notice of allowance or after any of these events but before you pay the issue fee.

Lodise: In essence, you can file an IDS while patent prosecution is open. If prosecution of the application is closed, for example, there is a final office action or notice of allowance is issued, the Patent Office then will not accept any IDS, even if you pay a fee.

Gordon: Okay. In that situation, how do I get my references cited?

Lodise: The applicant has to reopen prosecution in those cases. This could be done with a request for continued examination. That requires a fee, it can vary, but about $1,500 or more to reopen prosecution, then you can file your IDS.

Gordon: Okay. That is a lot of money, and these are a lot of rules. But even though they're detailed, these rules are pretty easy to look up. You can put them on a sticky note on your desk and follow them without too much angst, I think.

Lodise: Yeah, sounds reasonable. But then there is 37 CFR 1.704, which governs patent term adjustment, or PTA.

Gordon: Another word. What is PTA?

Lodise: So, PTA is a whole bunch of more complicated rules. So, Congress had recognized that patent prosecution can take a long time. Congress decided that applicants should be given back some of this time if there is Patent Office delay. Congress also decided that it should be offset by any of the applicant's delay. It is all very complicated, but the net result is that applicants can extend their patent term beyond the 20 years from filing if there's been a patent office delay in prosecution. And for some inventions, extending your patent term as long as possible can be extremely valuable.

Gordon: Okay. I can see how that would be valuable, but what does this have to do with the filing of an IDS?

Lodise: Filing an IDS can, under certain circumstances, be considered applicant delay.

Gordon: Okay, I get it. So just because the IDS is free or just because you pay the Patent Office fees for the IDS doesn't mean that PTA isn't affected.

Lodise: Wait, what?

Gordon: Yes, filing an IDS at the wrong time can be considered a failure to engage in reasonable efforts to conclude prosecution. That is a fancy way of saying you just lost PTA.

Lodise: Laura, you're disclosing information that you're required to disclose. You followed the rules, but you might get penalized on your patent term adjustment. No good deed goes unpunished, it seems.

Gordon: Yeah. Basically, if you're filing an IDS and if you care about PTA, not everyone does, but if you do, make sure that you check the rules for when an IDS is considered applicant delay.

Lodise: Okay. That is all super complicated. Maybe let's make it a little more concrete by talking through some examples.

So, say you get a restriction requirement. I mentioned before that is not an action on the merits. You get that restriction requirement, you submit a reply. You get your references together, and then you file an IDS. Because a first office action on the merits hasn't issued, you don't have to pay a fee. Totally allowed under Rule 97. And a sticky note that you put on your desk says that you're in the clear. But what about under Rule 1.704? That is applicant delay and possible loss of patent term adjustment.

Gordon: Exactly. That is really scary. This was the issue in the 2015 case, *Gilead Sciences v. Lee*. There, essentially, the Federal Circuit said, even if it is allowed under the IDS rules, it is still delay under the PTA rules. So, in essence, you're penalized for being too thorough.

Lodise: So, Laura, what should have been done in that instance?

Gordon: In this case, before you file the response to the restriction requirement or with your reply to the restriction requirement, that is when you should pull in the IDS, not after.

Lodise: Okay, how about another example? Because it gets better. Say you filed an RCE and you haven't gotten a first office action after that RCE, but you filed an IDS.

That is allowed under the IDS rules, but it still might be applicant delay under the PTA rules.

Gordon: Wow. Okay. So, that is what happened after *Supernus Pharmaceuticals v. Iancu*. There, the court basically said that the Patent Office can dock PTA for a filing after the RCE if the applicant could have filed the references sooner.

Lodise: So, Laura, is there any way to avoid a PTA penalty?

Gordon: Yeah, sure. There are situations that the Patent Office says don't fall under the could have known earlier category. So, you can find these in 37 CFR 1.704(d).

Basically, the rule says that applicant's IDS won't be considered a delay if it is based on, for example, a communication from a patent office or a foreign patent office and a counterpart application and that communication was received less than 30 days before the IDS filing. Then you're safe. No applicant delay, but the 30-day window is tight. We all get busy. It is hard to meet that. But miss it and you're back in the delay category.

Lodise: Laura, is there anything else that can be done?

Gordon: Yeah. Before you file an IDS, stop, think. Have you filed an RCE, received a restriction requirement, or responded to a non-final office action? If any of those apply, then think again about your timing for the filing.

Lodise: Or you wait to file the IDS until after the Patent Office issues another office action. Holding the IDS until later in prosecution might mean the applicant needs to pay an IDS timing fee, but the PTA you save might be far greater than the cost of that fee.

Gordon: The takeaway, timing is everything. And just because the Patent Office says you can file an IDS, doesn't mean that there aren't PTA implications.

Lodise: So, Laura, overall, today we talked about IDS filings and that they're a classic example of the rules say yes, but the consequences say no. It is a balancing act between disclosure and delay.

Gordon: Exactly. And that is why we're here to help you avoid those wait, what moments, because in patent law, the devil is in the details and sometimes in the timing.

Lodise: So, thanks for joining us. If you have a favorite wait, what moment from your own patent practice, send it our way. We might just feature it in a future episode.

Gordon: Until next time, keep your IDS timely, your PTA intact, and your prosecution drama-free.

Lee: Thank you, Stephanie and Laura. If you have any questions for Stephanie or Laura, their contact information is in the show notes. As always, thanks for listening to BakerHosts.

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