

HP: The final issue for today will be the doctrine of the promise of the patent. This is an issue which affects inventors who promise results when they apply for a patent, and there's been a new direction on the case for the past couple years, which will have locations on determining the liability of indicators who produce a variety of products. So, Geoff, what is the promise of the patent?

GM: So section two of Patent Act states that you must have a new and useful invention to obtain a patent, and so useful—the utility threshold has often been held to be quite low. Basically, as long as you demonstrated some utility by the Canadian filing date, then your patent will meet that threshold, and the demonstrator utility didn't even need to be in the patent itself

The caveat that actually goes back for a number of years is that while you don't have to make any promises of utility in your patent, if you do make promises you're going to be held to those promises. If you have a patent application, you don't have to actually state what the utility is as long as you had demonstrated the utility. But if you went as far to make a promise of an elevated utility, for example, in the case of a small molecule drug, if you have promised it would work for a certain indication but it turns out that you either hadn't demonstrated it would work for that indication by the Canadian filing date, or there was no sound basis for prediction of utility in that way, then your patent could fail on that basis.

HP: So this whole issue of the promise of the patent—in what context would this become a contentious issue?

GM: This becomes issue when, say you have a party, the patentee decides to sue somebody else for patent infringement as an example. The defendant, the party alleged to infringe, as a counterclaim or as a defense they say the patent is invalid. You can attack the validity of the patent on various grounds, one of which is utility or lack of sound prediction. So what you would say as the defendant is you'd read through the specification of the patent, the description, you'd look for anything that would seem to be a promise of utility.

If there is a promise of utility, you would allege that the promise has not been met. Maybe through the discovery process or through some other means, you've determined that the product, as of the Canadian filing date, the patentee did not actually know the product would work for a certain indication. So you'd say as of the Canadian filing date, that promise in the patent was not met.

HP: When you're applying for this patent, I guess there's a patent office when you submit your application. Is that the context we're talking about, when we're making promises in that application?

GM: Yes, exactly. You prepare and final the patent application with the Canadian patent office. There's a bit of back and forth with the patent office, they tell you to amend the language a bit. The patent office may challenge you on the wording or the scope of your patent claims.

Once you're ultimately granted a patent, then there's a grant date and it's enforced from 20 years from the filing date and you can enforce it. But if you then try to enforce it and the validity is challenged, the court looks at the description of the patent and if in that description, so what was originally filed, if there's words or phrases in there that suggest that the inventor or the patentee is promising that it works for certain things, that's the promise you're going to be held to.

HP: How has the Plavix case changed this?

GM: Right, so we were seeing this promise of the patent doctrine rise and rise in prominence in Canadian patent decisions over the past number of years. In recent years specifically in the pharmaceutical area, you saw it rise in prominence. And so, there were a lot of concerns that this promise of the patent was somehow creating some sort of different threshold that patentees, especially those that file in Europe or file in U.S, don't see in those jurisdictions, some elevated threshold for utility that was invalidating Canadian patents and those patents were being upheld in other jurisdictions.

So in 2013, in the case of the Federal Court of Appeal on the drug Plavix or Clopidogrel, the Court of Appeal pulled the reins back a bit and advocated for a bit more restrained approach to the restrained approach of the idea of the process of the patent. In that case, the court basically said you needed an express promise, not just a statement of an advantage or something like that. You have to look more closely at what was actually said, there has to be an express promise.

HP: What does an express promise look like?

GM: It will be a case by case basis. Obviously if the inventor uses the words I promise, it will work for that, but I don't know if it needs to be that explicit. A mere statement of advantage or hopes that it will work for something are not going to be held to be a promise that will invalidate a patent. The court will really look at expressed promises that are then unfulfilled and look at those as self inflicted wounds. But the court should also not be looking to invalidate a patent for an otherwise useful invention.

HP: Can you give an example of when inventors have been held to their promises?

GM: I can think of at least two cases, and those as an example are, there are two Eli Lilly decisions, one on the drug Zyprexa. The patent was, the claims were directed to use of Olanzapine for schizophrenia and then it was found that there was insufficient data to support that use of the drug for that indication. In a Strattera decision, which is another Eli Lilly decision on the drug atomoxetine, the court construed there were certain promises for use of ADHD of that drug, and looked at the studies that were actually done, and found the studies to be actually flawed, therefore they did not support a sound prediction of utility as of the Canadian filing date.

HP: What is the judiciary's rationale for holding inventors to their promises?

GM: If you look to the quid pro quo of the whole patent regime, the whole idea is that the patentee gives full disclosure of their invention. In exchange for that disclosure, they get their 20-year statutory monopoly. Where the patentee puts in their specification that the product will, they promise it will work for this or that, and that promise as it turns out was actually not a sound basis for obtaining their patent, they haven't fulfilled their end of the bargain.

HP: And so what are some takeaways lawyers should consider, if you're an IP lawyer and you're advising a client and their patent application process. What is something lawyers should tell them?

GM: So if you're advising your client with respect to preparing and filing the application, in particular if it's a client that's filed in other countries as well, you should make sure the client is aware of the way that Canada approaches promises and the specification. Make sure that you would typically want to avoid promises; you can state advantages, you can state things you would hope it would result in, but you would typically want to avoid promises unless those promises are substantiated as of the Canadian filing date.

HP: Are there any advantages for promising anything in the patent application?

GM: The only time you would want to promise something in a patent, I think, is if it were a selection patent. A selection patent is basically where you were seeking protection for a sub, a certain drug, for example, that was part of a previously disclosed genus of drugs. If you could establish that the later compound that you're seeking protection for has unexpected results, to substantiate or to sustain that selection patent, you're going to need to expressly state what those surprising or unexpected results are.

HP: And given the restraint approach by a judge in this area, is this a positive change in the area?

GM: I think it is. We want predictability, and so this gives a bit more predictability. The brand companies, certainly, are probably relieved somewhat that the courts are being prudent in the way they apply this promise doctrine, if you can call it that. Others, like generics, they want their predictability and to be properly advised by their counsel, so I think it is any time you get court decisions that more clearly delineate what is and what is not a promise, it's a good thing in my view.

I guess the only other issue which kind of shows how significant this issue has become for some parties is the NAFTA challenge by Eli Lilly. Eli Lilly as a result of—likely linked to having lost a couple of key patents in Canada related to this so called promise doctrine, they brought a NAFTA challenge to challenge this approach by the courts, as different from what you would see from the international state. And then contrary to international treaty. So it will be interesting to see how that plays out.

HP: It's been a really interesting conversation learning about these current and upcoming issues. Geoff, thanks so much for your time, and thanks for joining me on the season finale.

GM: Thank you, it's been a pleasure.