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Skilled in the Art: A Reply to Senators' 'Thicket' Concerns

By Scott Graham

A bipartisan group of six senators wrote to the USPTO last week to air concerns about patent thickets. A thicket is a large number of patents that cover a single product or variations in a product. In the drug industry, minor "tweaks to delivery mechanisms, dosages, and formulations" can lead to dozens or hundreds of patents on a single drug, the senators noted. "The Patent Act envisions a single patent per invention, not a large portfolio based on one creation," they contend.

The senators asked **PTO Director Kathi Vidal** for her thoughts on higher examination standards or limited time frames for continuation patent applications; a procedure for a "second look" at continuations before issuance, and other proposals.

We caught up this week with **Hughes Hubbard & Reed partner Patrice Jean** for the other side of this argument. Jean is the chair of Hughes Hubbard's Life Sciences Group, and has more than a decade of experience counseling established and startup pharmaceutical, chemical and biotechnology companies in all areas of patent law.

Skilled in the Art: Let's start off by telling me how you would define a patent thicket. What exactly is meant by that? Patrice Jean: This whole idea of a thicket is when you think of great vines growing all together and maybe preventing you from sticking your hand in and reaching a rose. A patent thicket exists when there's a group of patents—or maybe patent portfolio or patent estate—that cover a process, a drug, a product, or some type of technology in a certain industry.

So patent thickets can occur in other industries as well, but the focus in this letter was on the pharmaceutical space? That's exactly right. So if you think about smartphones, I think that that's one area where people understand that lots of different technology can embody or cover a particular device. Like you might have a patent for the camera or for the touch screen or how thin it is. And there are many things that that can cover a particular device or a drug.

I know Humira was famous for having more than 100 patents. Is there a number that you would consider to be a thicket? Would 10 or 20 or 30 patents? The answer to that question I think is no. People think that it's any number of patents that they would refer to as too many. But I can tell you as a patent professional, it's hard for me to come up with with a concept of what's too many. If you think about someone's house or kitchen, there may be many, many, many different patented devices in someone's kitchen. Likewise, if you're trying to treat a particular disease, there may be many, many different drugs or devices that would treat a particular ailment out there.

If a tablet, maybe it's extended release, maybe it's the packaging that you have on a particular tablet, maybe it's the formulation, maybe it's the active ingredients. But in many cases, you can have several different patents that are covering a particular invention of a certain thing.

Courtesy Photo

Patrice Jean, partner with Hughes Hubbard & Reed.

So you're saying a thicket is not necessarily a bad thing, depending on the circumstances. Depending on the circumstances. Your example was Humira. In the biotechnology industry, if you think about how complicated some of these drugs and devices are and what actually went into making them, it can be understandable that you would have dozens of patents that potentially cover what the outcome is.

That being said, there is some concern about having coverage of a particular thing for periods of time that were not necessarily intended by the patent laws of the United States. That's one of the things that was called out in the letter. You might have a particular drug that's covered by patents—first it was the active ingredient, and then maybe it's the method of making it or the

formulation or whatever. And by the time you come to the end of the patent portfolio, maybe it's decades of coverage that a particular drug has received.

More than the 20 years? Yeah, more than 20 years from the date of filing, plus any term extensions that you might receive. The reason why some of those term extensions exist is because when you're developing a drug there are clinical trials that are involved that sometimes take years. Because when we put drugs and treatments on the market, you want them to be safe.

There's a reason why pharmaceutical companies, sometimes when they file their initial patents, they don't know exactly what is going to be the drug that's ultimately going to be on the market. And the continuation process is a way of allowing these companies or independent inventors to narrow and figure out how to make sure that whatever ends up on the market is ultimately something that's covered by the patent. So that they can benefit, quite frankly, from all the hard work and research that they've done in the area.

The senators' letter seems to conflate patent thickets with continuation patents, but they're not necessarily the same thing, right? They're not the same thing. And the thing that concerned me and I think others is they just made this statement in their letter that continuation patents make up something like a quarter of the patents out there. I was like, where did they get that number from? Is it all pharmaceutical patents that are in the 25%? I don't think that is right.

I did read on a patent lawyer blog that an advantage of applying for a continuation is it "can be used to create uncertainty around the final scope of patent protection and provide a deterrent to competitors." Is that a fair use of the patent system? I disagree with that. I think that most inventors and companies, when they enter into the patenting process, they're looking to make sure that they have protection for the invention that they're eventually going to see go to market. It is true, for continuation patents, you change the claims. But the specification has to be the same for all of the continuation progeny. In continuations-in-part, you're allowed to add some new material, but it still must be close to, sort of linked to what you put in your original specification.

What do you think of the solutions proposed by the senators? One of them was to get rid of continuations altogether, or explain why you couldn't get rid of them. [The problem there] is predictability. Companies want to know that, if they enter into the patent process, that they can work with USPTO so that they will have protection for a certain period of time. That type of agreement and protection is moreso important in some industries than others, such as the pharmaceutical industry. It's very hard to keep secret formulations and various other things in the pharmaceutical industry, because all of that detail has to be provided to the FDA to get a drug approved.

One of the proposals was to require the PTO to take "a second look, by a team of patent quality specialists, before issuing a continuation patent on a first office action." That kind of sounded like having an AIA trial before the patent issues instead of after. What do you think of that concept? It sounded a little like that to me too. And let's be real. In a lot of litigation that happens, you know, many years or decades after a patent is filed, no one really knows what the issues are going to be or the defenses that are going to be raised. So I'm not sure exactly how that will help.

That's probably one of the least sort of invasive things that they suggested. If that would make people feel better, then that might be a workable solution. But what you don't want to have happen is have this body look at every patent that is issued, or right before it's issued, and then say "No!" Because companies invest a lot of money in the patenting process. And I think most of them would like to know that at the end of the process, that they'll end up with something that is patentable, that will have the benefit of being presumed valid, and that they can use to enforce their rights.

The way you described it, it sounds as if, between applying for a patent and holding those clinical trials and then having the patent term, that that can add up to a long time for that invention to be under protection. Yes. When you think about it, how long is the patented drug or device covered by a patent while it's actually on the market? Almost all of these patents that get challenged by generics and others, it's generally because it was a successful, usually a blockbuster treatment. Otherwise we wouldn't be in court.

It is through Paragraph IV or the Biosimilars Act that companies that believe that certain products shouldn't have patent protection any more can challenge them. And there's a benefit to those companies for doing that, getting on the market earlier than others. So we have systems in place that I think have been successful, quite frankly, at helping to ferret out patents that might have issues.

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