

Bob Barrett: This is the podcast from '*Clinical Chemistry*', I am Bob Barrett. Whoever invents or discovers any new and useful process, machine, manufacture or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore subject to the conditions and requirements of this title.

That's what the US Patent X states and ever since the courts have construed this statement is covering in the words of the US Supreme Court, "anything under the sun made by man." Although this language is very encompassing, not everything is patentable. Inventions must be both novel and non-obvious.

In addition, laws of nature, natural phenomena, and abstract ideas are not patentable, but novel applications of laws of nature, natural phenomena, and abstract ideas can be patentable. The courts have been struggling with just how much application is required to turn an unpatentable natural phenomena or law of nature into a patentable invention, and the recent US Supreme Court decision involving the Prometheus case has factored into future patents of this sort.

In the August 2012 issue of *Clinical Chemistry*, Jill Powlick, Legal Counsel and a Patent Attorney at Idaho Technology, wrote an opinion piece on the fine lines drawn in the decision reached in the Prometheus case and other similar patent decisions involving natural phenomena and how these decisions will affect future research. Ms. Powlick is our guest in this Podcast, and Jill, let's get basic first just what is a patent and how long does it last?

Jill Powlick: Okay, a patent is a form of intellectual property that protects inventions, but it's an unusual form of intellectual property because it gives you the right to exclude others. Most people think a patent gives you the right to practice your invention, but other people can have patents on different aspects of your invention. So it just gives you the right to exclude others. So anybody who wants to practice your invention needs a license from you to get it.

You asked how long a patent lasts. There was a change of patent term in 1995. Any patent application that was served with the US Patent Office prior to 1995 is good from 17 years from the date it issues, and there has been a few of those that had issued in the past few years, so there still are some out there with that earlier term which would get them 17 years from the date they issue.

In 1995, they changed the patent rules and they are now more consistent with what the rest of the world does; and what the rest of the world does, is you get 20 years from

your earliest filing date. So if you filed a patent application in 2000, it would expire in 2020. There are a few exceptions to that which would take a long time to go into that can make your patent term a little bit longer just by a year or two, maybe three, I have seen a few that have been longer than that, but not significantly. Once a patent expires, it is expired. You cannot buy more patent life.

Bob Barrett: You can't renew that.

Jill Powlick: You cannot renew a patent; once it's gone, it's gone.

Bob Barrett: I'd heard like with songs or compositions, you have a copyright and then you could –

Jill Powlick: Copyright.

Bob Barrett: Yeah, that's a different thing?

Jill Powlick: That is a different thing. Copyright is a much longer term, trademarks protect a term that is used in commerce, and trademarks can be good as long as you are using it.

Bob Barrett: Well, let's talk about just what can you patent, can you patent anything, what types of things are under the patent umbrella?

Jill Powlick: The definition of patentability is very broad and basically the courts have interpreted the patent statute to include anything under the sun made by man. But there are some caveats to that: it must be new, it must be useful and it must be non-obvious, you can patent improvements on preexisting objects, but the improvement must be non-obvious from what went before, and they must be inventions.

I often get situations where people have gone traveling abroad, particularly to some place remote and they come back and say, hey, I saw this really cool gadget, can I patent it? I have never seen anything like it in the United States; and no, they can't patent it, they didn't invent it, that's copying. You must be the inventor or a group of inventors to patent something.

There are a number of things that you cannot patent however, you cannot patent obvious improvements. You cannot patent things that exist in nature. If you are out rock-hounding and you find a new rock or mineral that nobody has discovered before that's a discovery and not an invention, you cannot patent that mineral you didn't make it.

Now if you were to synthesize something in a laboratory that was identical to something that might exist out nature, you can patent your synthesized version, you might be able to patent the process of making it or a way of extracting that mineral from its natural environment, but you can't patent that natural item

And this is one of the things that courts are struggling with right now in several recent lawsuits: is where is the line between what is nature -- what is natural, and what is patentable.

Bob Barrett: And I guess the next question would be, what do you have to describe or do to get to patentable subject matter?

(00:05:03)

Jill Powlick: A patent consists of several parts. There is usually a set of figures, although some biotech patents don't need any figures and you might not have any, there's usually figures, there is a description and there is this set of numbered paragraphs at the end called the claims.

I've seen patents with as few as one claim and as many as several hundred. And the claims describe the boundaries of the invention, and what you need for patentable subject matter is enough information to let somebody of ordinary skill in the art of that invention to make or use the invention.

You don't have to describe every single step in the process if those steps are ordinary and somebody in that field would recognize it. But you have to have enough detail in the patent itself to allow somebody of ordinary skills of the art to practice the claims at the end.

Bob Barrett: Well now that the Prometheus patent has been found to be invalid by the Supreme Court, can anyone practice the methods described for measuring Thiopurine metabolites and adjusting Thiopurine dosages?

Jill Powlick: That's an interesting question and the answer is not a yes or no answer. Prometheus has lost their patent, the Supreme Court has decided, there are very few options left. If a doctor were to perform the steps involved in their methods, Prometheus could not go after them for patent infringement because the patent has been declared to be invalid.

However, as I said before, patents are a negative right and other people may have patents on various other steps in the Prometheus process or may have patents on steps that a specific doctor might use in performing the basic invention.

And I haven't done the research on that, I don't know what patents are out there, so I can't say with any certainty that yes you can practice this invention. What I can say is, yes, you can practice this invention with respect to these Prometheus patents.

Bob Barrett: Well here is the big one now; can you patent a DNA sequence?

Jill Powlick: Currently, yes you can. And this relates to another lawsuit that is working its way through the courts. And that's the Myriad Genetics case. Myriad has a number of patents on genes relating to the BRCA1 and BRCA2 genes, these are the breast cancer and ovarian cancer genes, and their patents have been challenged in court; and initially some of the claims were found to be invalid by the Federal District Court that's Trial Court.

Myriad challenged that ruling to the Federal Circuit, and the Federal Circuit found the DNA sequences isolated or purified DNA sequences are patentable subject matter.

So currently, yes, DNA sequences are patentable. However, the Prometheus case was decided in March of 2012 and a few days after the Supreme Court handed down their decision in the Prometheus case, they asked the Federal Circuit, the Court of Appeals for patents to reconsider their decision in light of the Supreme Court's decision in Prometheus.

So that case has now gone back to the Court of Appeals and will -- however it's decided, likely be appealed to the Supreme Court, we'll see if the Supreme Court takes it and what they do with it. So, like I said, currently the answer is, yes, but that may change.

Bob Barrett: So if the Supreme Court ultimately finds that Myriad's patents are invalid, then are all DNA patents invalid?

Jill Powlick: No, I don't think so. Certainly the ruling would apply to Myriad patents and any patents that are similar to Myriad's. The Myriad claims that issue -- there were several different types, but I am going to talk specifically about the isolated DNA claims.

There are many patents that exist that are similar to that, but there are many other patents that are formulated in different ways. For example, many patents claim kits for testing specific DNA sequences, and those kits may contain some isolated DNA, they usually contain an enzyme such as Taq polymerase, which is a bacterial enzyme, and then some other components for amplifying the DNA to test it.

That kit itself, with that combination of perhaps human or other species DNA, with the bacterial enzyme does not exist in nature, and while I do not sit on the Supreme Court and don't know how the Supreme Court would ultimately decide a negative finding for Myriad, if finding that their patents are invalid would not necessarily affect this type of kit claim or any other type of patent that has subject matter where you have different products from perhaps different species or some synthetic and some naturally occurring products. Those patents in my opinion would be valid even if a Myriad had a negative finding.

Bob Barrett: They wouldn't be automatically invalid but might this be used as precedent?

(00:09:56)

Jill Powlick: It could be and certainly there will be people who will try to challenge various types of kit claims, but it would take years to get through the courts.

The Myriad case has been going on for a few years, I don't have the dates in front of me, but it started a few years ago, and many of these cases can take six, eight, ten years before they are completely resolved.

So in the near term, kit claims and various types of method claims that are outside of any potential negative finding from Myriad would still be valid for years to come.

Bob Barrett: Jill Powlick is Legal Counsel and a Patent Attorney at Idaho Technology. She has been our guest in this podcast from Clinical Chemistry.

I am Bob Barrett, thanks for listening!

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