



## Podcast Transcript

# Navigating the Fine Line Between Obviousness and Obviousness-Type Double Patenting

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**Kattman:** Patent exclusivity is essential if a pharmaceutical company intends to seek regulatory approval of a drug. While drug discovery, pre-clinical development, formulation, and clinical development will culminate in one FDA-approved drug, that new drug often embodies several inventions, each of which can be entitled to patent protection. But if patent applications for those inventions are not filed with an understanding of how each application may affect the others, applicants may unwittingly be surrendering potentially valuable patent coverage.

I'm Amy Kattman, and you're listening to BakerHosts.

On today's episode, we discuss two common rejections seen in United States patent prosecution: obviousness and obviousness-type double patenting. Although they sound similar, they differ in a few significant ways. To provide us with insight into this topic, we have Stephanie Lodise. Stephanie is a partner in BakerHostetler's Intellectual Property Group. She has a Ph.D. in organic

chemistry and co-leads our firm's Biotechnology, Chemical and Pharmaceutical Practice team. Also joining Stephanie is patent agent, Tracy Palovich. Tracy has a Ph.D. in organometallic chemistry and prepares and prosecutes patent applications before the United States Patent and Trademark Office, primarily for clients in the biotechnology, chemical and pharmaceutical arena.

Welcome to the show, Stephanie and Tracy.

Lodise: It is great to be here.

Palovich: Wonderful to speak with you, Amy.

Kattman: Tracy, I'd like to begin with you. Could you explain what is obviousness?

Palovich: Obviousness is a legal construct in patent law. It is quite different from how we may use the term in everyday terms. In patent law, there is a statutory basis for obviousness, and that is 35 U.S.C. 103. The statutory language for obviousness is pretty wordy. Basically, obviousness means that even if the invention was never previously described or known, it still does not warrant patent exclusivity protection. Basically, obviousness implies that people who are skilled in the art would have made the invention in light of all the information available in the art. Now, by referring to people skilled in the art, that means someone who is skilled in the particular invention being described. That person of skill in the art will vary from technology to technology and from invention to invention.

Now, obviousness is a United States patent law concept. It is pretty similar to inventive step or inventiveness in other countries. Now, in order to reject the patent claim for being obvious, an examiner must point to at least one piece of prior art and basically provide reasons that that patent claim is obvious in view of that art. Now, the prior art can be a patent, it can be a published application, a journal or a magazine article or an internet posting, even. The prior art can actually also be an offer to sell the invention or an actual sale of the invention. However, it is critical that the prior art is, it must have been published before the filing date of the patent, or the offer to sell must have been prior to the filing date of the patent.

Further, it doesn't matter who is the author or owner of the prior art or part of the prior sale or the actual sale. It can even be the inventor's own publication or the inventor's own sale.

Kattman: Stephanie, what is obviousness-type double patenting?

Lodise: Unlike obviousness, even though it has the same words, obviousness-type double patenting is a little different in that there is no statutory basis for it in U.S. patent law. It is entirely judge-made. What is also different about this part of the U.S. patent law is that it is a U.S. construct. No other country in the world has obviousness-type patenting, especially as we have it here. So, I mentioned that it is something that is not found in a statute. It is judge-made.

Nonstatutory-type double patenting is grounded in equity and it is intended to prevent prolongation of patent term by prohibiting claims in one patent that are not patentably distinct from claims in another patent, where the two patents have a common inventor or a common owner. The biggest difference between obviousness and obviousness-type double patenting is that neither patent that is at issue is prior art to the other. So, around the world, the patents would be, the patent applications are separately patentable. You can get two patents. Generally, not an issue. But the United States, you can have this rejection where you might be told by the patent office that you cannot have a separate patent application.

One of the reasons for this is that we don't want patent owners to have more patent term than that which they are entitled. And another reason that the justices talk about when they're developing this law, is they don't want the possibility of multiple suits from different entities to occur to the public. They want the public to know that if they're going to be sued, it will be by one entity and they don't have to appear in court against multiple parties.

So, the way that the rejection typically comes up is that an examiner will allege that the claims of the patent application being examined are not patentably distinct from the claims of another U.S. patent or even a pending patent application. The examiner is only supposed to be looking at the claims, and that is an important distinction. The examiner is not supposed to base the rejection on what the applications disclose, which is something very different from obviousness. Again, they're not prior art to each other, so the filing and the issue dates, not really something that the examiner is looking for, but they are looking for this commonality of a common inventor or a common assignee.

Something else that I think many of our colleagues around the world recognize is that obviousness double patenting, since it is entirely a U.S. construct, it can be very confusing. Another thing to keep in mind is that since it is not statutory, since it is something that the judges have made up along the way, and contours of it have developed over time, the case law is evolving. And at any point in time, what we thought about what it was five years ago may be different today.

Kattman: Thanks, Stephanie. So, you really have to pay attention.

Lodise: Mm-hmm.

Kattman: Could you explain how can an applicant prevent its own earlier-filed patent applications from becoming prior art to its later-filed patent applications?

Lodise: Sure. So, this is important because when Tracy talked to us about what obviousness was, the big takeaway is that there is prior art. Are you separately patentable over what is prior art? Prior art are publications, things that happened in the world before you filed your patent application. Now, what is generally problematic, sometimes, when there is an ongoing project for one of our clients, say that one that goes on for many years, perhaps even decades, it is common for the project to yield new discoveries throughout its lifetime. The challenge to

patentability arises when there has been a patent application filed and new discoveries occur after that first patent application is published, and it has become part of the prior art. Now, there are many strategies that we can employ for our clients to prevent the earlier-filed applications from negating patentability of later discoveries. And Tracy, I think there is one that you follow practically every day.

Palovich: Absolutely. We track publication dates whenever possible. We like to file on further discoveries prior to any publication of the applicant's patent applications. We can also take advantage of some prior art exceptions, particularly that the exception under 35 U.S.C. 102(b) for any applications filed within a year of the applicant's patent application publication.

Lodise: Yes, that is very important to do, track your publication dates. At least you should know when your owner is publishing and that is certainly trackable. There is the 18-month rule, and we know that patent applications always publish in the U.S. on a Thursday and U.S. patents publish on Tuesday. Another thing that we try is perhaps we don't publish anything at all. And by that I don't mean that we don't file on anything, I mean that we take advantage of the U.S. provision that allows for nonpublication of patent applications.

The United States is certainly one of the most important markets around the world. If there is an applicant's small company really trying to make something of itself, if it thinks that it might perhaps forgo foreign patent protection, and it believes that giving up that right might be beneficial to protecting later discoveries as the project goes on, it can file its applications with a nonpublication request. That means that its patent applications do not become public until they are actually patented. And I think Tracy, you have some drafting strategies that we follow.

Palovich: Absolutely. Another strategy is to not over-describe in the earlier filings. In other words, don't go too broad. Save descriptions of discoveries for the actual discovery, not something that you may be doing in two or three years. For example, a more evolving strategy is to claim narrowly, and this really provides less opportunity for an examiner to issue a double patenting rejection over the earlier patent, since there is less of a chance that the claims will overlap.

Kattman: These are great tips. Stephanie, back to you. If the applicant successfully timed its application so as to avoid the earlier application from being prior art to the later-filed applications, the applicant should be entitled to a patent, right?

Lodise: You'd think, but in the United States that is not necessarily the case, and this is absolutely the place where our European, our Japanese, our Chinese counterparts come to us asking, what happened here? And this is where obviousness-type double patenting comes in. Our client has two patent applications, they're from the same project, one is not prior art to the other. Outside of the United States, there is no problem for our client. They're getting multiple patents granted, but in the U.S. the examiner has issued this obviousness-type double patenting rejection and we're forced to address it. And

this is where the examiner is saying that even though one is not prior art to the other, it is probably not fair for you to get two separate patents. So, we take these all very seriously and we consider with our client, what are your goals of the two applications? What do you need from this other application? And it is especially acute now because the examining court is very keen to issue obviousness-type double patenting rejections, even when just looking at the faces of the claims they don't seem related to each other at all.

Kattman: Thank you. Tracy, how can an applicant prevent obviousness-type double patenting rejection from being raised during prosecution?

Palovich: Well, unfortunately we can't prevent the rejection from being raised. Unfortunately, applicants should expect that it will be raised, and they need to be proactive in their drafting and prosecution strategies if they would like to avoid filing terminal disclaimers.

Lodise: Another thing that we can do is we can take advantage of the divisional practice that we have in the United States. In the United States, U.S.C. 121 says that divisional applications, if they have been designated as divisionals by the United States Patent Office, can't be used as obviousness-type double patenting rejections over each other. So, we try as much as we can to prompt the office to give us those types of rejections if we think that we might have issues in the future because then we are in the safe harbor provision of the law, and we don't have to worry about having to address an obviousness-type double patenting rejection in the future.

Kattman: So as a final question, Tracy, what can an applicant do if the obviousness-type double patenting rejection can't be overcome?

Palovich: Well, as I previously noted that we, you can, the rejection can be obviated with a terminal disclaimer. And briefly, the terminal disclaimer establishes permanent co-ownership of the two patents. The terminal disclaimers also ensure that the patentee will not get a longer patent term than that which is entitled in equity.

Lodise: One thing that has come up, and Tracy and I have had to deal with this sometimes, is when there has been sort of like a movement of patents. Say like a university sells patent property to its inventor. Sometimes you can't do that terminal disclaimer because the two patent properties cannot be co-owned, and that could be a real bummer because that obviousness-type double patenting rejection will still stand, and unless you can overcome it just based on argument you will not be entitled to a patent, and you will not be able to file the terminal disclaimer in order to obviate that rejection.

So, when we have situations like this there are certain things that we consider. One thing that we can do is have the patent properties co-owned but to have one exclusively licensed to the other party that wants it. Now that is not ideal, but it is certainly a better situation to be in as opposed to one where there will not be another patent granted.

Another thing to think about if the terminal disclaimer isn't an option. So, like I mentioned if you couldn't get them co-owned or where you don't want to disclaim the additional patent term. That was part of the strategy for filing the additional application, you're really looking to have that extension of patent term, you do feel that this is a separate invention from what has been previously described. It is really hard to get a patent examiner to withdraw the rejection. They really do like to stick to their guns. So, something to think about is during prosecution to be able to supply evidence of distinction to the examiner, so that the examiner can see that these claims that we're now presenting to examiner are distinct. This is a separate invention that is worthy of its own separate patent term.

We file declarations, we can file journal articles, the like. Sometimes that is not enough for an examiner, and sometimes we go to appeal. When you're thinking about appeal you want to be very sure, like you absolutely want to do this, you need that additional patent term or they can't be co-owned. You want to make sure that you have a fulsome record before going to the appeals board, so that you have everything already on the record that you can use to convince the board that these are separate inventions worth a separate patent term.

And I'll just say that this is all very complicated. I mentioned that at the beginning, and it is just something to always keep in mind. It is something that we speak to our clients about all the time when they're considering whether to file a second application or follow-on application, or they have an application on file but they might have missed something. We're always talking about the possibility of there being an obviousness-type double patenting rejection, and how it might be best to address it. So, always remember, speak to your U.S. patent attorney or patent agent, and think all these issues through so that you're drafting your applications properly and that you're responding to office actions appropriately.

Kattman: Stephanie and Tracy, thank you for providing us with this really valuable information.

Palovich: You're welcome. This was a lot of fun.

Lodise: Thanks so much.

Kattman: If you have any questions for either Stephanie or Tracy, their contact information is in the show notes. As always, thanks for listening to BakerHosts.

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