
Patents: Post-Grant Podcast: New Developments in Obviousness-Type Double Patenting and Original Patent Requirements

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Andrew Zappia:

Greetings. And welcome to Troutman Pepper's Post-Grant podcast series. My name is Andy Zappia. And I'm joined today by my partners, Meg O'Gara and Duke Fitch. In this installment, we're going to take a look at recent developments in obvious type double patenting and the original patent requirements. And how they might impact strategies in post-grant proceedings. Duke, just to set the table on the first topic, what is obvious type double patenting, and which is often called ODP?

Duke Fitch:

Sure. Thanks, Andy. Obviousness-type double patenting is a judicially created doctrine. It's judge-made law that the patent office even refers to as non-statutory double patenting. It's been around for more than a hundred years and was intended to address two primary concerns when an inventor or patent owner has more than one patent covering a particular invention.

This is where the claims are not patentably distinct. In other words, they're obvious variants of one another. The first concern is the unjustified time-wise extension of exclusivity over the invention. In other words, unfairly extending the monopoly on the invention because you have multiple patents that expire on different dates.

And the second concern is the potential for multiple infringement suits being brought by different assignees. This is where the inventor or patent owner sells rights to each patent to different parties and each new owner brings a separate infringement claim against the same alleged infringer.

Andrew Zappia:

And what's the typical strategy to deal with ODP rejections during prosecution?

Duke Fitch:

Well, the easiest way to address the issue in prosecution is for the patent owner to file a terminal disclaimer. This is a statutory fix for ODP. Currently, and we'll talk about a recent proposal from the patent office to change the rules. But, currently, the patent owner must agree to sacrifice any term of the patent which extends beyond the expiry of the other patent over which they're disclaiming. And the patent can't be enforced unless it remains co-owned with the other patent. Now the courts have held that the filing of a terminal disclaimer is not an admission that the claims are obvious over the claims of the other patent. It's simply a mechanical device to resolve the ODP issue.

Andrew Zappia:

Now we had a recent decision, it's called *In Re Collect*, on the topic of ODP. Meg, before we get into that case, can you just explain what PTE and PTA are?

Megan O'Gara:

Sure. Absolutely, Andy. Very briefly, patent term adjustment, PTA, and patent term extension, PTE, are statutory mechanisms that compensate a patentee with additional patent term for certain types of delays. PTA, patent term adjustment, compensates for administrative delays by the USPTO during patent prosecution. For example, where the office takes longer than four months to mail an action following an applicant's response. And that PTA is offset by the patent applicant's own delays.

PTE on the other hand, patent term extension, compensates a drug or a medical device patent owner for the period of delay caused by the regulatory review process before a product can be commercially marketed. It aims to restore the period of patent term that is essentially lost because the product couldn't be commercially marketed until approval from that regulatory agency like the FDA.

Why are we talking about PTA and PTE? I'm going to ask that question for you, Andy. Because we need to know how these term adjustments that extend the expiration date of a patent affect that core ODP inquiry. That's whether the claims of a later expiring patent would be obvious over those of an earlier expiring patent. What we'll talk about today is that PTA and PTE are provided for under different statutes. And they're ultimately treated differently in the ODP case law we're discussing.

Andrew Zappia:

Duke, what did the *Collect* case hold that so many people are talking about with respect to PTA and PTE?

Duke Fitch:

Well, before we get to the *Collect* holding, I just wanted to mention an earlier case called *Gilead v. Natco*. It was decided a little over 10 years ago. And the federal circuit said that for ODP, it doesn't matter when the patents are filed or even when they grant. The only things that matter are the expiry dates. If a patent has claims that are obvious over an earlier expiring patent from the same inventor or patent owner, then the later expiring patent is invalid for ODP unless the patent owner files a terminal disclaimer.

That case, along with some dicta in another federal circuit case from 2014 called *AbbVie v. Kennedy* had the patent community concerned about what would happen if a patent owner had more than one patent covering an invention and the patents expired on different dates due to patent term adjustment, which, as Meg just mentioned, is statutorily granted. This was the issue that was before the federal circuit in *In re Collect*.

Collect owned five patents, they were all derived from the same patent application and all expired on different dates due to varying amounts of patent term adjustment. Despite an earlier

decision from the federal circuit in a 2018 case called *Novartis v. Ezra Ventures*, which held that ODP does not invalidate a validly obtained patent term extension. The court in *Collect* distinguished between patent term extension and patent term adjustment and held that the expiration date used for ODP where a patent has received patent term adjustment is the expiration date after the PTA has been added.

The impact of this is that where, for example, two patents with patentably indistinct claims in the same family differ in their expiration dates due to PTA. The later expiring patent is automatically invalid for ODP unless a terminal disclaimer is filed. I just want to add that *Collect* has filed a petition for writ of certiorari with the Supreme Court, which is currently pending. We'll see if they take up the case. But for now, this is law.

Andrew Zappia:

And what impact does that have on prosecution strategy? For example, divisional practice? Meg, do you want to take this one?

Megan O'Gara:

Sure. Our listeners likely appreciate that there's certain advantages of divisional filings that are made in response to a restriction requirement. 35 USC Section 121 provides a safe harbor from ODP for the parent case and the divisional filing in those situations. According to statute, that's strictly limited to divisional applications filed as a result, that statutory language, as a result of a restriction requirement.

And given the developments in case law, applicants will likely be far more conscious of drawing restriction requirements. Perhaps presenting fuller claim sets and paying excess claims fees they wouldn't normally pay. And actively and immediately pursuing divided subject matter and divisional applications to take advantage of this ODP shield. This isn't a new practice. But we're likely to see more vigilance around it.

Now, in my experience and I'm sure in Duke's, entities with portfolios covering products important to business are already vigilant in drawing restriction requirements and filing those divisional applications. That said, the developments in ODP case law and the proposed rule package that we're going to talk about today puts even greater emphasis on this vigilance.

There are other prosecution practices apart from divisional filings that we do see commonly, including a reluctance to issue continuation subject matter, where an issued and related case has PTA. Allowing continuations like this to issue presents a potential ODP trap, which Duke referred to, that applicants are quite cautious about especially post-*Collect*.

Andrew Zappia:

Meg, from your comments, I take it that there's an incentive now to include bigger claim sets with subject matter that might draw restriction crime, because you almost want to get the restriction requirement.

Megan O'Gara:

Yeah. You really do want those fuller claim sets with as many distinct categories as you can provide for in that initial filing. You want to draw that very comprehensive restriction requirement from the office. And you also want to be cautious about maybe cutting off your nose despite your face by sort of deleting subject matter in order to save claims fees. Maybe you pay those excess claims fees and you draw a more fulsome restriction requirement.

Andrew Zappia:

From a portfolio perspective, Duke, what if you don't handle your portfolio correctly as far as looking at it in totality and trying to manage this issue of PTA, and PTE, and restriction requirements?

Duke Fitch:

Yeah. Say, for example, you have a granted patent that's received patent term adjustment and you have a continuation from the same family that's been granted with patentably indistinct claims and either less or no PTA. As soon as the continuation granted, you now have an ODP issue. And the only way to cure it is to proactively file a terminal disclaimer on a later expiring patent.

In that example, the later expiring patent actually granted first with prosecution having ended long ago. And so, there's nothing telling you that you need to go back and file a terminal disclaimer. But if you do end up filing that terminal disclaimer, you could be giving up a lot of exclusivity value.

In certain industries, for example, pharma and biotech, that additional patent term can be incredibly valuable. It could mean millions of dollars every single day on a billion-dollar drug. And so, giving it up can be a major sacrifice. Potentially, an even bigger problem exists as it did in the *Celllect* case if the earlier expiring patent has already expired. In that situation, you actually can't file a terminal disclaimer. And the later expiring patent is simply invalid for ODP. Potentially, significant consequences if you don't make efforts to mitigate the risk during prosecution or proactively manage the risk when reviewing your patent portfolio.

Andrew Zappia:

And you really have to think about your whole portfolio and the status of all the patents in it when you make these decisions, it sounds like.

Duke Fitch:

That's right.

Andrew Zappia:

And obviousness-type double patenting invalidity argument can be raised in post-grant proceeding. And like an IPR, for example, or a requester could raise it in a re-exam. Suppose

there are scenarios where that could be a problem in view of some of these recent developments, Meg, maybe you want to talk about that a bit?

Megan O'Gara:

Sure. You're right that ODP can form the basis of a post-issuance challenge in an IPR or a re-exam. But backing up just a bit and sort of dovetailing on what Duke was mentioning, it's more important than ever post-Collect for applicants to proactively police their portfolios, especially with regard to ODP.

Applicants shouldn't take comfort or refuge in an examiner's failure to reject claims on an ODP grounds. And we see this day-in and day-out, we should all be proactive in conducting our own analysis citing potential ODP reference patents and applications to the office. And perhaps filing proactive terminal disclaimers while weighing the benefits and risks of doing so as Duke was discussing.

Doing all of these things won't necessarily insulate a patent from attack on ODP grounds. But it does ensure that patentees will be better prepared to defend or file a terminal disclaimer assuming that's actually possible at that point once the issue presents itself in a post-issuance setting.

On the other hand, to speak to the dangers of not doing those things as your question gets to, Andy, a patentee could be caught really flat-footed in a case where they had not considered ODP and actively policed their portfolio. For example, there could be a lack of vigilance relating to maintaining ownership of the two patents in a portfolio creating a situation where a terminal disclaimer is not possible because there's a lack of common ownership. And the only reply to a post-issuance ODP challenge at that point would be based on non-obviousness.

Andrew Zappia:

Right. You have to say it's not the earlier related patent or does not make the patent under challenge obvious. Right?

Megan O'Gara:

Yeah. That's right. You'd be in a position where you'd have to argue the claims are not obvious variants of the earlier expiring patent.

Andrew Zappia:

Now, just to make things even more complicated, Duke, there's a new proposed rule from the PTO on terminal disclaimers. Just in general, what is that proposed rule?

Duke Fitch:

Yeah. In addition to the current requirements for terminal disclaimer that we've already discussed, the patent office has proposed that the disclaimer must include an agreement the patent will be unenforceable if it's tied directly or indirectly to another patent that has any claim invalidated or canceled based on prior art.

If even one claim is invalidated, then any patent that's been terminally disclaimed over the challenge patent cannot be enforced. For example, if a patent owner has three patents, patents A, B, and C, that granted in a family, and patent B has been terminally disclaimed over patent A including this new requirement, and patent C has been terminally disclaimed over patent B, and a challenger successfully invalidates, say, for example, claim five of patent A based on the prior art, then patents B and C are unenforceable. Even though the remaining claims of patent A are still valid and enforceable. It's a very odd result.

Andrew Zappia:

Yeah. And it kind of goes against the well-accepted notion that you look at patentability claim-by-claim. Meg, do you view this kind of waiver requirement is something new from the PTO?

Megan O'Gara:

Oh, yeah. This is a new approach. It's a new angle from the office. It's essentially asking, like you say, for an agreement from the applicant for a domino-like unenforceability of its related portfolio. And there has been a resounding rejection by practitioners who see the potential for this practice to tie the unenforceability of an entire patent family to validity findings of a single and likely the weakest claim in the patent family. There's been a visceral reaction from stakeholders. And I think that's shown in the comments to the proposed rule-making. That comment period closed July 9th with several hundred comments.

Andrew Zappia:

Duke, why do you think the PTO is trying to do this?

Duke Fitch:

Well, for some time now, the patent office has expressed concern around patent owners particularly in the pharma and biotech space obtaining a large number of patents covering a single invention. This is often pejoratively referred to as a patent thicket. And some believe it limits competition by increasing the cost and complexity of litigation.

Many patent practitioners will recall an effort by the patent office back in 2007, 2008 to restrict the number of continuation applications that can be filed. That led to litigation. And the court held that patent office has no substantive rule-making authority. And so, they can't restrict the number of continuations filed.

In the present context, the patent office explicitly stated this action is being taken to prevent multiple patents directed to obvious variants of an invention from potentially deterring competition and to promote innovation and competition by allowing a competitor to avoid enforcement of patents tied by one or more terminal disclaimers to another patent having a claim finally held unpatentable or invalid over prior art. In other words, you can successfully challenge one claim in a patent and knock out every patent tied to it.

Andrew Zappia:

Well, there's going to be a lot more said on this proposed rule. But to stay on the topic of new developments, Meg, we also have had news on something called the original patent requirement. What is that?

Megan O'Gara:

Sure. Thanks, Andy. We're moving now to another post-issuance topic, which is reissue.

Taking a step back, reissue of a patent is provided for under 35 USC Section 251, which permits reissue of a patent on the basis of certain errors. Among those errors is claiming more or less than a patentee had a right to claim. Specifically, section 251 in part states whenever any patent is through error deemed wholly or partly inoperative or invalid, by reason of the patentee claiming more or less than he had a right to claim in the patent, the director shall reissue the patent for the invention disclosed in the original patent. The current original patent requirement that we are discussing today flows from that very language in section 251. The director shall reissue the patent for the invention disclosed in the original patent.

In reissue practice we've been seeing a resurgence of these original patent rejections under 251, particularly since the *Antares Pharma* case that came down from the federal circuit in 2014. This case held that the original patent must "clearly and unequivocally" disclose the newly claimed subject matter of the reissue claims as a separate invention. This case and others we'll talk about today are part of a line of cases distinguishing section 251's original patent requirement from the written description requirement of section 112. Now the *Antares* case and other cases we'll discuss today apply the original patent requirement in the context of a broadening reissue application, where you expand your claim scope in reissue. Although the statute doesn't limit the original patent requirement to only broadened claims, certain case law suggests it is limited to broadening reissue and we are going to talk about it in that context where it is most often applied.

Andrew Zappia:

Right. And most of our listeners probably know this. This issue of a broadening reissue request, that has to be made within two years of grant, right?

Megan O'Gara:

Yeah. That's right. The statute requires that you actually file a broadened reissue application within two years from the issuance of the original patent. You can file it on the anniversary. But it has to be within two years.

Andrew Zappia:

Now how does the original patent requirement come up in reissues? Can you explain that a bit and how the requirement has been applied in sort of reissue proceedings?

Megan O'Gara:

Absolutely. The original patent requirement is applied to these broadened reissue claims, like we said, and requires that, in addition to that 2-year limit, the original patent must clearly and unequivocally disclose the newly claimed invention as a separate invention.

In practice, the way we're seeing this is a rejection under 35 USC Section 251 for failure to comply with the original patent requirement. And, ultimately, I think of this as something akin to the more strict basis requirement in Europe. It requires more explicit support than the written description requirement of 35 USC Section 112.

Andrew Zappia:

Basically, to put it in simple terms, you can't use a broadening reissue to sort of claim something that's a new invention. It has to be within the scope of the original patent.

Megan O'Gara:

Yeah. And it's probably something more than that even, Andy. It's got to be something that's really explicitly called out in that original patent. Which patent practitioners are accustomed to making support arguments under 35 USC Section 112. This is a more strict requirement than that. You really need to point to a section of the original patent that describes the new invention that's claimed in the reissue case explicitly.

Andrew Zappia:

Gotcha. And I know there have been some other recent cases on this, including one in the last two years. Have they changed the landscape at all?

Megan O'Gara:

Yes. There's been several cases in the last few years that have dealt with the original patent requirement, including *Forum US, INC v. Flow Valve*. That was decided by the federal circuit in 2019. The *Float'N'Grill* case decided by the federal circuit in 2023. And which has made news as of late, the *Ikorongo* case.

In each case, the claims that issue were held to violate the original patent requirement. In *Ikorongo*, the reissue patent claims were invalidated by the district court for violation of the original patent requirement. And the federal circuit summarily affirmed the ruling. It really captured attention, because *Ikorongo* petitioned for cert to the Supreme Court, which was denied just in May in 2024.

However, to me, the *Float'N'Grill* case which was decided by the federal circuit in 2023 was a significant clarification of the original patent requirement. Really drawing the line between the original patent requirement of section 251 and the written description requirement of section 112.

Andrew Zappia:

As a reissue practitioner, Meg, how do you try to navigate this original patent requirement question?

Megan O'Gara:

I should say that as a part of the diligence prior to filing a broadening reissue application, we look carefully at a number of things, including the prosecution history to determine whether or not there might be issues of recapture. Surrender and recapture that we might be facing and we should be prepared for. We look carefully at the time bar, of course. Immediately, that's probably the number one thing we look for. And we also identify support for all reissue claims when we're looking at going into reissue. Not just broadening reissue. But we look at those broadened reissue claims and the support for those claims in a special way considering the original patent requirement.

You're required, when you file any amendments in a reissue case, to provide a statement of status and support. And that gives you sort of a heightened bar for enumerating to the patent office where you see support for those reissue claims. And we're really vigilant when it comes to the broadened reissue claims that we're identifying where in that original patent we have support that would satisfy the original patent requirement in that exercise.

Andrew Zappia:

Well, these are some really complicated and interesting issues that aren't commonly discussed in the context of post-grant proceedings. Thanks a lot, Meg and Duke, for walking us through these.

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Duke and Meg, thanks a lot. And we hope you all enjoyed the podcast.

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