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Double-Patenting Ruling Shows Terminal Disclaimers' Value

By Jane Love and Robert Trenchard (May 8, 2024, 12:53 PM EDT)

The U.S. Court of Appeals for the Federal Circuit's In re: Cellect LLC decision last year has been read by some to rob patent owners of lawful patent term, that is, the time period when a patent provides exclusive right to the invention.[1]

Indeed, a recent Law360 article seems to take that position.[2]

But Cellect in fact identifies how patent owners can protect themselves using terminal disclaimers, a common tool in patent prosecution. Appropriate terminal disclaimers should shield the full term of many patents Cellect is now being used to attack.



The base patent term in the U.S. is 20 years from the application filing date.[3]

That period can be extended in some circumstances, including via a patent term adjustment, or PTA, to account for U.S. Patent and Trademark Office delays examining the application.[4] That added term — sometimes years-long — can be critical to ensuring patent owners obtain the full exclusivity Congress intended.

In Cellect, however, PTA was no boon. It instead led to the demise of several patents due to obviousness-type double patenting, or ODP. Under that doctrine, patent owners cannot use one patent to extend the term of another on essentially the same invention.[5]



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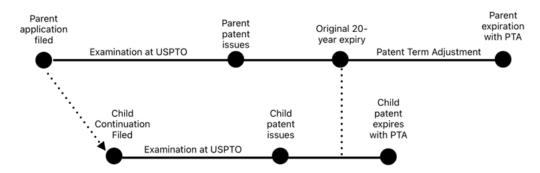
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Cellect held for the first time that this analysis should take account of PTA. In other words, if one patent expires later than an obvious variant due to PTA, the later-expiring patent is at risk of an ODP challenge based on the earlier-expiring patent.

Some say Cellect now outlaws important aspects of routine patent practice.[6] Often, a patent applicant will submit a first parent application followed by child applications pursued later, called continuations or divisionals.

The 20-year patent term for all patents is measured from the initial application. The parent usually takes the longest to pursue; the examiner may have to learn new technology and a new body of art for the first application, whereas child applications do not present the same learning curve.

As a result, the parent often will be granted more PTA and have a longer term than the later-filed children. Here is a picture of a common relationship between patents:



According to some, Cellect would always render the parent patent invalid in this scenario, if the parent and child claim obvious variants of the same invention.[7] But that position cannot be right. It would take from the patent owner lawfully granted PTA on the parent patent.

True, child continuations could be limited only to nonobvious variants as a solution. Yet the law has never imposed such a requirement. Just the opposite — the law has long allowed claims on obvious variants.[8]

So how can Cellect be squared with this longstanding, lawful practice? As Cellect observes, terminal disclaimers are a solution to the ODP problem.[9]

The Terminal Disclaimer Solution

Applicants and owners file terminal disclaimers to effectively make two patents into a single set of claims with a single maximum patent term.[10]

Used to tie a child to a parent, this device would preserve the parent patent's full PTA, while also precluding the sort of conduct the Federal Circuit found troubling in Cellect.

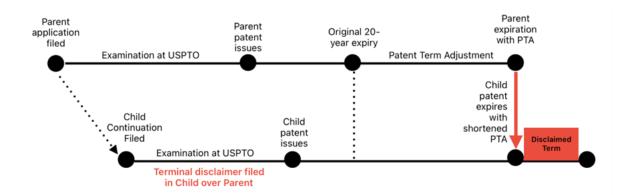
Functionally, terminal disclaimers limit the term of one patent to no greater than that of another, and permanently require that they be owned together.[11]

These steps eliminate any ODP issue — the two purposes of the ODP doctrine are to limit a patent owner to a single patent term for a single invention, and to prevent claims to the same invention from being split among different owners requiring serial enforcement.[12]

For instance, imagine parent patent A is given 200 days of PTA to compensate for delays during examination. Child application B seeks obvious variant claims. Patent office regulations would require the examiner to reject application B under ODP.[13]

But the applicant could obviate that rejection with a terminal disclaimer legally binding B to A and disclaiming any patent term beyond A. B's claims would thus never have more term than A's — no matter how long the delay in examining B.

Any B term, PTA included, beyond A would be disclaimed. The patent owner would get two patents, but only one fully adjusted term — no more — as follows:



That situation contrasts with the facts in Cellect. There, the patentee had pursued five applications on obvious variants of the same invention. The examiner took longer to review some applications than others, resulting in different PTA awards.

The first-granted patent had 45 days of PTA, and the others ranged from zero to 759 days. Despite all patents claiming obvious variants, the examiner did not reject the claims for ODP, and no terminal disclaimers were filed.

The patent owner ended up with over 700 added days of term beyond the first-granted patent — term that would have been disclaimed had the patent owner filed terminal disclaimers.[14]

This clearly troubled the Federal Circuit. To an outside observer, this pattern could appear like a patent applicant taking advantage of an overworked patent office to get more term via multiple shots on goal — that is, pursuing multiple applications on the same invention, and then hoping that an overworked examiner would delay in examining the applications and miss any ODP issue.

Perhaps that is why the Federal Circuit was displeased with the patent owner's argument that no terminal disclaimers were filed because the examiner never asked.[15]

In any event, the Cellect facts are not the typical pattern, and the patent office itself, as appellee, said that the usual parent-child issue was not present in Cellect at all.[16] Typically, the child would be terminally disclaimed against the parent, and ODP would be avoided.

The Significance of Terminal Disclaimers in Ongoing Litigation

Cellect has spawned several follow-on cases and arguments.

In one, Allergan U.S. Inc. v. MSN Laboratories Private Ltd. in September 2023, a U.S. District Court for the District of Delaware judge invalidated a parent patent with more PTA than a child, holding that Cellect "recognizes no exception to the rule it announced."[17]

This holding was curious — one of the child patents had been terminally disclaimed against the parent patent with greater term.[18] The opinion ignores that fact, however, and it is not the focus of the now-pending appeal.[19]

That being said, arguments have been made about what the Federal Circuit meant in holding that

terminal disclaimers are the solution to the ODP problem. One argument is that Cellect simply requires disclaiming the patent with more PTA against an obvious variant with less.

On that view, after a child patent is granted with less PTA, the patent owner must terminally disclaim the parent patent's added term, or face an ODP attack.[20]

Terminal disclaimers can be applied to patents after they are granted but before they expire.[21] Those advancing this argument point out that, in Cellect, every patent that had received PTA was found invalid for ODP against the one with no PTA.[22]

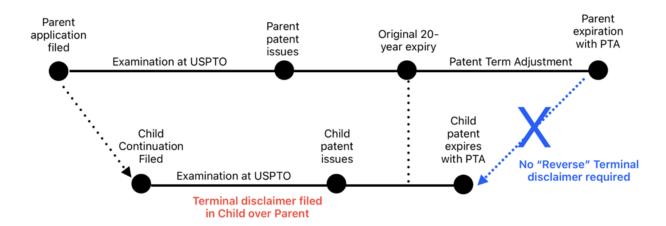
But nothing in Cellect says that the parent PTA would need to be disclaimed, and adopting this view would effectively force the patent owner to give up the PTA on the parent patent, contrary to Congress's intent.

If a terminal disclaimer already exists tying the child to the parent patent, then the patent owner has received only one maximum term, the claims are forever tied together and the goals of ODP have been vindicated.

In Cellect, the patent owner did not file any terminal disclaimers and could no longer do so because the patents had all expired. [23] The unecumbered claims thus could be split freely and result in serial litigation, directly contrary to one of ODP's two goals.

Unable to prevent that result, the Federal Circuit was left with no choice but to limit the patent owner to the patent with the shortest term, and no PTA. If later-issued patents had been terminally disclaimed against earlier-issued patents, there would have been no need for that result.

The contrary reading would appear to require a patent owner to file a second reverse terminal disclaimer, from parent to child, once relative expiration dates were clear. The following diagram illustrates this:



Given that the first terminal disclaimer already created a single set of claims under Braithwaite, and bound the two patents together as to ownership, requiring yet another reverse terminal disclaimer would be unnecessary, illogical and contrary to the purposes of the patent laws.

Requiring double disclaimers would create massive uncertainty for patent owners and the public about

an invention's lawful period of exclusivity.

Another objection could be that binding a child to a parent patent in the typical scenario in truth gives up nothing — the child already has less PTA than the parent. This, too, is wrong. The two patents are bound together legally.

The patent owner thus gives up the freedom to split up claims to the same invention among different owners. As for the extended term, when the terminal disclaimer is filed in the child application before issuance, the applicant does not know how much PTA will be forfeited. Examination is not over.

It is possible — and indeed would have been true in Cellect itself — that the applicant is giving up more term than what it received as PTA for the parent patent. Only with the benefit of hindsight can one definitively say the PTA is a certain number of days, and then judge whether the applicant actually sacrificed any term.

It should go without saying that a terminal disclaimer's effect must be assessed when filed, not in hindsight. As noted, any other result would inject unacceptable uncertainty into patent rights, hurting the patent owner and the public.

The parent patent with PTA would always be at risk of having to be terminally disclaimed if a child application issued with less term.

The patent owner would be perpetually at risk, and the public in the dark about when the patent will actually expire — it would all depend on facts beyond the patent owner's control, namely delays in examination by the patent office. That is exactly opposite of what the law demands.[24]

In short, as the Federal Circuit said in Cellect itself, terminal disclaimers are the solution to the problem of obviousness-type double patenting. Patent owners and litigants should embrace that solution to avoid the damaging implications of a different reading.

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- [1] In re Cellect, LLC, 81 F.4th 1216 (Fed. Cir. 2023).
- [2] See Austin Lorch & Jeff Wolfson, Practical Pointers After Fed. Circ. Double-Patenting Decision, IP Law360 (April 19, 2024).
- [3] 35 U.S.C. § 154(a)(2) (patent term "20 years from the date on which the application for the patent was filed").
- [4] 35 U.S.C. § 154(b).
- [5] Cellect, 81 F.4th at 1226.

- [6] See, e.g., Allergan U.S., Inc. v. MSN Labs. Pvt. Ltd., Civil Action 19-1727-RGA, Dkt. No. 483 at 40 (D. Del. Sep. 27, 2023) (accepting argument attacking parent patent with PTA); Acadia Pharmaceuticals, Inc. v. Aurobindo Pharma Ltd., No. 22-cv-1387-GBW, 2023 WL 8622111 (D. Del. Dec. 13, 2023) (rejecting argument); see also, e.g., Amgen, Inc., et ano. v. Sandoz Inc., Case 1:23-cv-02406-CPO-EAP, Dkt. No. 352 (Opposition to Preliminary Injunction) at 4-7 (D.N.J. Feb. 16, 2024) (arguing that Cellect invalidates parent patent with PTA).
- [7] See, e.g., cases in note 6; see also IP Law360 April 19, 2024 article in note 3 (arguing that patent owners should disclaim the PTA given to the later-expiring patent).
- [8] See, e.g., Application of Braithwaite, 379 F.2d 594, 601 (C.C.P.A. 1967) (describing "advantage" to "the public" from adding "considerable disclosure" in continuation applications on obvious variants, and "all [the patent owner] is getting from this application and for only the remainder of the same term are additional, more specific claims which would serve as a second line of defense if the dominating claims should prove to be vulnerable").
- [9] Cellect, 81 F.4th at 1228 ("As the Board stated, ODP and terminal disclaimers are 'two sides of the same coin: the problem and the solution."").
- [10] See Braithwaite, 379 F.2d at 601 ("When a terminal disclaimer causes two patents to expire together, a situation is created which is tantamount for all practical purposes to having all the claims in one patent.").
- [11] 35 U.S.C. § 253(a); 37 C.F.R. § 1.321 (2023).
- [12] Cellect, 81 F.4th at 1229-30.
- [13] See United States Patent Office, Manual of Patent Examining Procedure (MPEP), 9th Edd (Revision July 2022), 804, 1490.
- [14] Id. at 1220.
- [15] Id. at 1222.
- [16] In re Cellect, Fed. Cir. Case No. 22-1293, Dkt. No. 174 (Dec. 14, 2023 USPTO Resp. in Opposition to Rehearing) at 12 n.3 (Dec. 18, 2023) ("[H]ere, the challenged claims are not themselves 'parent' claims; rather they are 'child' claims that claim priority to the same parent application, and thus the scenarios presented by amici are not implicated.").
- [17] Allergan U.S., Inc. v. MSN Labs. Pvt. Ltd., Civil Action 19-1727-RGA, Dkt. No. 483 at 40 (D. Del. Sep. 27, 2023).
- [18] Allergan U.S., Inc. v. MSN Labs. Pvt. Ltd., Civil Action 19-1727-RGA, Dkt. No. 482-1 (D. Del. Sep. 6, 2023).
- [19] See, e.g., Allergan USA, Inc., et al. v. MSN Labs. Pvt. Ltd., Fed. Cir. Case 24-1061, Dkt. No. 14 (Allergan Appeal Brief).
- [20] See, e.g., Allergan U.S., Inc. v. MSN Labs. Pvt. Ltd., Civil Action 19-1727-RGA, Dkt. No. 482 (Joint

Status Report) at 1-3 (D. Del. Sep. 6, 2023); see also IP Law360 April 19, 2024 article in note 3.

- [21] Boehringer Ingelheim Int'l GmbH v. Barr Lab'ys, Inc., 592 F.3d 1340, 1348 (Fed. Cir. 2010).
- [22] See, e.g., Amgen, Inc., et ano. v. Sandoz Inc., Case 1:23-cv-02406-CPO-EAP, Dkt. No. 352 (Opposition to Preliminary Injunction) at 4-7 (D.N.J. Feb. 16, 2024) (arguing that Cellect invalidates parent patent with PTA).
- [23] Cellect, 81 F.4th at 1229-30.
- [24] Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 150 (1989) ("[L]ike any property right, [a patent's] boundaries should be clear. This clarity is essential to promote progress, because it enables efficient investment in innovation. A patent holder should know what he owns, and the public should know what he does not.")