



Mind Your Ps and Qs, and Your PTAs Too

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Last week, the Federal Circuit held that obviousness-type double patenting trumps patent term adjustment, opening the door for invalidity attacks that to date had been questionable.

In re Collect[1] was an appeal from a Patent Trial and Appeal Board decision affirming a patent examiner's finding that claims across four patents owned by Collect LLC were unpatentable because of obviousness-type double patenting (ODP).

ODP is a judicially created doctrine that precludes a patentee from lengthening its 20-year patent term by later filing additional patent applications to obvious variants of the invention earlier claimed. This doctrine renders invalid claims from a later-expiring patent that are patentably indistinct from claims of an earlier-expiring patent. One defense against ODP is to file a terminal disclaimer, disclaiming any patent term that extends beyond the underlying patent's term. Because we now calculate a patent's expiration date from filing and not issuance, and ODP is most commonly found in continuation practice, the term of both patents involved in the ODP are often the same. But in some cases, the challenged patent can have a later expiration date than the underlying patent due to patent term adjustment (PTA). One question, unanswered to date, was whether filing a terminal disclaimer to obviate ODP in that case would also disclaim the portion of patent term arising from PTA. The Federal Circuit answered that question this week, holding that it does.

Because a patent's expiration date is calculated from the date of filing—rather than the date of issuance—delays in prosecuting the patent application reduce the enforceable term of the patent. Congress enacted PTA to restore that enforceable term lost due to Patent Office delay. It is more often awarded in the first-filed application in a family, which can take some time to prosecute. Typically, once

patentable subject matter is identified in the first filed application, follow-on applications move through the Patent Office more quickly. That said, one can never predict in advance whether and how much PTA may accrue in any patent application, first-filed or continuation.

The Federal Circuit previously held that ODP does *not* trump the statutory-based Patent Term Extension (PTE),^[2] which is awarded to patents in the biotech and pharmaceutical fields to restore term lost through the protracted US Food and Drug Administration (FDA)-approval process. In other words, if the patentee files a terminal disclaimer to obviate an ODP, any PTE term would be added back to the patent's new expiration date, maintaining the restored term. *Collect* argued that the same rationale in that decision should apply here, meaning that judicially created ODP should not trump statutorily awarded PTA. The Federal Circuit disagreed, relying on the fact that PTE and PTA came from different statutes, "each [having] its own independent framework" and "quite distinct purposes." Following that rationale, the Federal Circuit held that statutorily-awarded PTA term would not be added back to the new expiration date that arose from filing a terminal disclaimer to obviate ODP.

While *Collect* was a high-tech case – directed to devices comprising image sensors – this decision has the potential to significantly impact the pharmaceutical industry. In high tech, improvements occur so quickly that patents often become obsolete long before their term ends. In contrast, lengthy clinical trials combined with the FDA-approval process means that pharmaceutical patents hold most value at the end of their term, and every day that term is extended is lucrative.

Many existing portfolios likely include at least one patent with PTA that, after *Collect*, is now at risk of invalidation under ODP. One potential defense against ODP is to argue patentable distinctness between the claim sets at issue. Another potential fix is to file a terminal disclaimer, which disclaims any patent term extending beyond the expiration date of the underlying patent. While a terminal disclaimer may appear on its face to be a quick and easy fix, it comes at the expense of that extra term, so the costs and benefits of this approach should be weighed carefully. And there may be cases where a terminal disclaimer is not an option,^[3] removing that potential defense in its entirety.

For pharmaceutical patents in particular, PTA may be baked into PTE term, that is,

the PTE term awarded is added to the expiration date that includes PTA. This raises the question of whether this decision puts that portion of the PTE term at risk. For example: I have a patent that would have expired on January 1, 2029, but 365 days of PTA means it expires January 1, 2030. An award of three years of PTE would be added to the January 1, 2030 date, meaning that my patent term would expire on January 1, 2033. If, however, my patent is subject to an ODP over a continuation application with no PTA that expires on January 30, 2029, and I file a terminal disclaimer disclaiming patent term beyond that date, does *Collect* mean that my PTE term now ends on January 1, 2032?

While it is expected that *Collect* will be further appealed, patent owners should nonetheless take stock of their and their competitors' patent portfolios in the meantime to look for patents having PTA that are now potential targets for an ODP challenge.

[1] *In re Collect*, 2022-1293-1296 (Fed. Circ. August 28, 2023)

[2] *Novartis AG v. Ezra Ventures LLC*, 909 F.3d 1367 (Fed. Cir. 2018)

[3] See Emily Tkac, Deborah Sterling, Gaby Longworth, and Eric K. Steffe, *Collaborative Research and "Reverse" Obviousness-Type Double Patenting*, *Intellectual Property & Technology Law Journal*, July 2022

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