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The Federal Circuit Affirms That Obviousness-type Double Patenting is Available for Patents Whose Expiration Dates Differ as a Result of Patent Term Adjustment

In Re: Cellect, LLC
Decided August 28, 2023

Nearly a decade ago, the Federal Circuit held that "the doctrine of obviousness-type double patenting continues to apply where two patents that claim the same invention have different expiration dates." *AbbVie Inc. v. Mathilda & Terence Kennedy Inst. of Rheumatology Tr*., 764 F.3d 1366, 1374 (Fed. Cir. 2014). In *Mathilda*, the two patents at issue had different expiration dates, *inter alia*, as a result of different priority dates. In dicta, the *Mathilda* court noted that "[p]atents claiming overlapping subject matter that were filed at the same time still can have different patent terms due to examination delays at the PTO," as a result of patent term adjustment (PTA). The Mathilda decision created much uncertainty with respect to the impact of obviousness-type double patenting (ODP) in a situation where two patents have differing expiration dates solely as a result of PTA.

In 2018, however, the Federal Circuit held that an earlier-filed, earlier-issued patent that had a later expiration date as a result of a statutory patent term extension (PTE) resulting from regulatory delays before the Food & Drug Administration (FDA) was not subject to ODP invalidation. *Novartis AG v. Ezra Ventures LLC*, 909 F.3d 1367 (Fed. Cir. 2018). The Novartis court held that a PTE was valid "so long as the extended patent is otherwise valid without the extension." The *Novartis* court noted that using ODP to shorten the PTE term would mean that "a judge-made doctrine would cut off a statutorily-authorized time extension." Since *Novartis*, patent owners held out some hope that PTA terms, which are also statutorily-authorized time extensions, would likewise be immune to the judge-made ODP doctrine.

The Federal Circuit dashed any such hopes earlier this week and held that the ODP analysis "for a patent that has received PTA … must be based on the expiration date of the patent after PTA has been added." *In re Cellect, LLC*, Docket No. 22-1293, *slip op* at 21.

Cellect, LLC ("Cellect") appealed to the Federal Circuit from four *ex parte* reexamination decisions of the United States Patent and Trademark Office ("USPTO") Patent Trial and Appeal Board ("the Board") affirming the unpatentability of certain claims for ODP. In each reexamination proceeding, the USPTO Examiner issued a Final Office Action determining that the challenged claims were obvious variants of Cellect's previously expired patented claims (one of which was not subject to any PTA). In each Office Action, the challenged claims were rejected over a later?filed, earlier-expiring reference patent. Cellect appealed the ODP rejections to the Board, which affirmed the Examiner's rejections.

Before the Federal Circuit, Cellect, citing to *Novartis*, argued that the Board erred in relying on the PTA extended expiration date in its ODP analysis. Cellect argued that, like PTE, PTA provides a statutorily-authorized time

extension, such that it would be improper for the judge?made ODP doctrine to cut off the extension.

The court found Cellect's argument unpersuasive and pointed to differences in the statutes governing PTE and PTA, 35 U.S.C. §§ 156 and 154, respectively. Specifically, the court noted that the PTA statute (35 U.S.C. § 154(b)(2)(B)) provides that "[n]o patent the term of which has been disclaimed beyond a specified date may be adjusted under this section beyond the expiration date specified in the disclaimer." In other words, in drafting the PTA statute, Congress intended a terminal disclaimer to cut off any PTA extension, such that the extended patent may not be extended beyond the disclaimed expiration date. By contrast, the PTE statute does not contain similar language. The court further noted that Cellect's reliance on *Novartis* was misplaced because the *Novartis* holding explicitly relied on the differences between the PTE and PTA statutes in determining that the PTE term was valid "so long as the extended patent is otherwise valid without the extension."

Further, because the *ex parte* reexamination requests were filed after the expiration date of the earliest expiring Cellect patent, Cellect could not have filed a terminal disclaimer during the reexamination proceeding. Cellect argued that any invalidation should only be for the PTA term and not the entire term of the patent. The Federal Circuit disagreed because such a result "would be tantamount to issuing a retroactive terminal disclaimer, which would be improper" and "would in effect give Cellect the opportunity to benefit from terminal disclaimers it never filed." Accordingly, the court held that the challenged claims were invalid *for their entire term*.

The court did note that the non-challenged claims were entitled to their full term, including the granted PTA, unless they are later found to be obvious variations of earlier-filed, commonly owned claims.

In developing their patent portfolios, patent owners whose patents have been extended by PTA should carefully develop their continuing application strategy to avoid or minimize the likelihood of any future ODP challenges that would reduce or eliminate the PTA extensions. Further, while ODP is evaluated on a claim-by-claim basis, a terminal disclaimer cuts off the PTA for every claim in the patent. Accordingly, patent owners in litigation should make sure that any ODP allegation is applicable to all claims in challenged patent (or at least all asserted claims) before filing a terminal disclaimer because those claims that are not subject to ODP will enjoy the benefit of the PTA if no terminal disclaimer is filed. Patent owners should also consider addressing the substance of any alleged ODP on the merits before filing a terminal disclaimer.

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