



## In Wake of In re Collect, District Court Interprets Safe Harbor Statute and Finds Patent Not Invalid for Obviousness-Type Double Patenting

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The District Court for the District of Delaware recently held on summary judgment that a patent with 2,295 days of combined patent term adjustment (PTA) and patent term extension (PTE) was not invalid for obviousness-type double patenting (OTDP). First, the court held that the challenged patent could not be invalidated by a subsequent divisional patent because of the safe harbor provision in 35 U.S.C. § 121. Importantly, the court narrowly interpreted the “filed before” language of the safe harbor provision, refusing to apply it where the challenged patent issued from the application in which the restriction requirement was entered. Second, the court held that, as a threshold question, the filing date of the reference patent (along with the expiration date) must be considered before OTDP can apply.

### Key Holdings:

- The requirement that the “divisional application is **filed before** the issuance of the patent...” is inapplicable when the challenged patent issues from the original application.
- The filing date of the reference patent may be considered in determining whether OTDP applies.

In this Hatch-Waxman case, both parties filed cross-motions for summary judgment regarding the validity of U.S. Patent No. 7,601,740 for obviousness-type double patenting in view of U.S. Patent No. 9,566,271. The '740 Patent was issued on October 13, 2009, and was granted 980 days of PTA and 1,315 days of PTE. The '271 Patent was filed on November 6, 2015, and claims

priority to a series of continuation applications that ultimately claim priority to a divisional of the '740 Patent.

The parties generally agreed that, if the '271 Patent was a proper OTDP reference to the '740 Patent, then the relevant claim would be invalid. The parties' dispute focused on whether the '740 Patent was entitled to the benefit of the safe harbor provision of 35 U.S.C. § 121 as a result of a restriction requirement that was entered during prosecution.

The § 121 safe harbor provision states:

A patent issuing on an application with respect to which a requirement for restriction . . . has been made, or on an application filed as a result of such requirement, shall not be used as a reference either in the Patent and Trademark Office or in the courts against **a divisional application** or **against the original application** or any patent issued on either of them, **if the divisional application is filed before the issuance of the patent on the other application.**

The main point of dispute before the district court was whether the safe harbor could apply to the '740 Patent even though the reference patent, the '271 Patent, was not filed **before** the '740 Patent issued. The patentee argued that the statute distinguishes between divisional applications and original applications, and only requires that patents from divisional applications that are being challenged on OTDP grounds have been “filed before” issuance of the original application. Stated differently, the “filed before” requirement does not apply to the application in which the restriction requirement is entered—it only applies to subsequently filed divisional applications.

The accused infringer argued that the “filed before” requirement applies to the invalidating reference patent. That is, for a divisional application to fall within the scope of the safe harbor, it must be filed before the issuance of the patent being challenged. Under this interpretation, any divisional applications that are filed after the original patent issues are available OTDP references against that original patent (and any others that issue before its filing).

The district court agreed with the patentee, and held as a matter of statutory interpretation that the “filed before the issuance of the patent” requirement does not apply when the challenged patent issues from an original application where the restriction requirement was entered. The district court reasoned that the application in which the restriction requirement is entered is where the rights are first created and, therefore, claims that issue in that

application are unlikely to be the result of gamesmanship. The district court further observed that it would be an odd result to have claims invalidated simply because the patentee filed another application when the patentee could not predict a particularly advantageous outcome between filing amended claims versus a divisional application. Accordingly, the district court found the challenged patent fell within the safe harbor provision.

The district court also found that, in the alternative, the '740 Patent was not invalid for OTDP because the '271 Patent did not qualify as a proper OTDP reference, because it was filed later than the '740 Patent. The district court explained, “[i]f a later-filed patent is used as a reference, the logic and purpose of OTDP is flipped on its head: rather than preventing a patent owner from unjustifiably extending the term of a patent, OTDP would operate to cut off a patent term that would have been valid but for a later-filed patent.” The court distinguished its finding from the result of the recent Federal Circuit decision *In re Collect*, 81 F.4th 1216 (Fed. Cir. 2023), where a later-filed patent was used as an invalidating OTDP reference against an earlier-filed patent. The court observed that the patent owner did not challenge the use of a later-filed patent as a reference, but instead focused its argument on whether OTDP could cut short a grant of patent term adjustment. But note, a different judge in the District of Delaware held earlier this year, “The ‘first-filed, first-issued’ distinction is immaterial. When analyzing ODP, a court compares patent expiration dates, rather than filing or issuance dates.” *Allergan USA, Inc. v. MSN Lab’ys Priv. Ltd.*, 2023 WL 6295496, \*22 (Sep. 27, 2023) (citing *Gilead Scis., Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208, 1215-17 (Fed. Cir. 2014).

**Practice Tip:** Although this area is still somewhat unsettled, this decision could answer one question regarding the scope of the OTDP safe harbor provision. If upheld, patents issuing from an original application that receive PTA grants may have some protection against OTDP challenges that rely on subsequent divisional applications.

*Acadia Pharms. Inc. v. Aurobindo Pharma Ltd.*, C.A. No. 20-985-GBW (D. Del.)

## Categories

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Patent Infringement

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