

Federal Circuit Decision Clarifies Obviousness-Type Double Patenting and Patent Term Adjustments in *Allergan v. MSN Laboratories*

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Summary

On August 13, the Federal Circuit issued a [precedential ruling](#) in *Allergan v. MSN Laboratories* (Case No. 24-1061). This decision **reversed** the District of Delaware's application of the Federal Circuit precedent in *In re: Cellect LLC* to invalidate a claim in an earlier-filed parent application over admittedly patentably indistinct claims in later-filed (and earlier-expired) child patents. This decision has resolved some substantial questions about the application of obviousness-type double patenting (ODP) that had been raised by last year's *In re Cellect* decision.

Case Background

Allergan, Janssen, and Eden Biodesigns (collectively, Allergan) asserted patent infringement against Sun Pharmaceuticals Industries (Sun) after Sun filed an abbreviated new drug application (ANDA) seeking U.S. Food and Drug Administration (FDA) approval to market and sell a generic version of Allergan's bowel treatment drug, Viberzi.

Following a three-day bench trial focusing on the Viberzi patents, the district court held that the asserted claim in parent patent [7,741,356](#) (the '356 Patent) was invalid for ODP over claims of two later-filed child patents. ODP is a judicially created rule that, in the absence of a terminal disclaimer, prevents the same inventor from obtaining multiple patents for a single invention. See [Manual of Patent Examining Procedure \(MPEP\) § 804](#). The doctrine's primary goal is to prevent an unjustified extension of patent exclusivity beyond the life of a patent. (Opinion at 11.)

The earlier-filed '356 Patent received a 467-day patent term adjustment (PTA)[\[1\]](#), resulting in a patent term that extended *beyond* the expiration dates of two later-filed and later-issued child patents. In finding the asserted claim of the '356 Patent invalid, the district court applied the ruling in *Cellect*[\[2\]](#) to conclude that the expiration dates of the challenged and reference patents, rather than the filing or issuance dates, should be compared in the analysis of whether ODP applies.[\[3\]](#) (*Id.* at 14) (stating that *Cellect* establishes that "when it comes to evaluating ODP on a patent that has received PTA, the relevant expiration date is the expiration date including PTA – not the original expiration date measured twenty years from the priority date). Because the '356 Patent expired after the admittedly patentably indistinct child patents, the district court concluded that the ODP doctrine operated to invalidate the asserted claim of the '356 Patent.

Allergan appealed the district court's decision.

Federal Circuit's Decision

On appeal, the Federal Circuit asked a slightly different question than the one addressed in last year's *In re Collect* case: "[C]an a first-filed, first-issued, later-expiring claim be invalidated by a later-filed, later-issued, earlier-expiring reference claim having a common priority date?" In a precedential opinion, the three-judge panel held it **cannot**. (Opinion at 19) (noting, "[i]n many ways this case is 'a prime example' of when ODP does not apply.)

The Federal Circuit first took note of historical changes to the way in which patent terms are measured. Specifically, prior to 1995, patent terms were measured from their date of issuance. (*Id.* at 12.). As a result, courts looked to issuance dates of commonly owned, patentably indistinct patents to determine whether ODP should be applied. (*Id.*)

After a change in law in 1995, patent terms began to be measured from the effective filing date, or priority date, of the patent. (*Id.*). Thus, patent terms for all patents filed after the change in law in 1995, and that share a priority date, are expected to expire on the same day, absent some specifically calculated reason to extend that expiration date. (*Id.* at 12-13).

One such reason to extend the expiration date of a patent filed after 1995 is to account for patent term lost due to delays in prosecution that are not caused by the applicant. Congress specifically addressed this concern by codifying adjustments to patent terms to account for such delays. (*Id.* at 13.) The term of the '356 Patent was adjusted as a result of this congressionally allowed PTA, thereby extending the life of the '356 Patent beyond that of later-issued child patents. As a result, and expressly pursuant to *In re Collect*, the district court found that the parent claim of the '356 Patent was invalid in view of the patentably indistinct subject matter contained in the later-issued but earlier-expired child claims. (*Id.* at 15).

The Federal Circuit reversed the district court. In doing so, it clarified that invalidating a first-filed, first-issued parent patent with PTA in view of a later-filed, later-issued child patent with less or no PTA would run counter to the fundamental purposes of ODP and negate the benefit Congress intended with PTA.

"To hold otherwise ... would not only run afoul of the fundamental purposes of ODP, but effectively abrogate the benefit Congress intended to bestow on patentees when codifying PTA ... such a holding would require patent owners, in order to preserve the validity of the parent patent, to file a terminal disclaimer disclaiming any term of the parent that extends beyond that of the child, which, given that the patents share a priority date, would amount to the disclaimer of only PTA. That parent patent, then ... would instead be limited to the, presumably shorter, term of its own child. Such a result would be untenable."

(Opinion at 20.)

The court emphasized that the expiration dates should not be the sole factor in ODP analysis, especially when the claims in the child patent did not exist until after the parent patent issued. (*Id.* at 16-17.)

Implications

This ruling clarifies the application of ODP, particularly with respect to patent families with multiple patents with different expiration dates resulting from PTA. Key points to note under this decision:

- A parent patent is entitled to its entire term, including PTA even if this extends the patent's life beyond that of a child patent. (Opinion at 17.)
- Filing a terminal disclaimer disclaiming any term of the *parent* that extends beyond that of a *child* is not necessary to preserve the validity of the parent. (*Id.* at 20.)
- Whether ODP applies requires a careful analysis of more than just a patent's expiration date. A fulsome invalidity analysis under ODP must consider whether the patent extends the monopoly of the invention beyond the period allowed by law. (*Id.* at 17.)

In many ways, *Allergan* confirms that ODP typically applies to later-filed and later-issued patent applications, and not the other way around. That said, we recommend a careful review of current practices and consultation with legal counsel to confirm whether terminal disclaimers are necessary, or whether ODP may be properly raised as a basis of invalidity for any particular patent. Our team at Troutman Pepper is ready to assist in navigating these developments.

[Allergan USA Inc. et al. v. MSN Laboratories Private Ltd. et al.](#), Case Number 24-1061, U.S. Court of Appeals for the Federal Circuit

[1] The '356 Patent actually received PTA of 1,107 days, but the patent owner disclaimed all but 467 days of the awarded PTA during the process of securing patent term extension (PTE) under 35 U.S.C. § 156.

[2] For a detailed discussion of ODP and *In re: Collect*, see Troutman Pepper's [Patents: Post-Grant Podcast: New Developments in Obviousness-Type Double Patenting and Original Patent Requirement](#).

[3] The district court also found some of the asserted claims did not satisfy the written description requirement of 35 U.S.C. § 112. This alert does not address the Section 112 issues raised in the district court or appellate decisions.

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