

GIBSON DUNN

Appellate & Constitutional Law and
Intellectual Property Update

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Federal Circuit Decision in *Allergan v. MSN*

On August 13, 2024, the Federal Circuit issued a precedential decision on the issue of obviousness-type double patenting (ODP) and patent-term adjustment (PTA) in *Allergan USA, Inc. et al., v. MSN Laboratories Private Ltd., et al.*, No. 24-1061 (Fed. Cir. Aug. 13, 2024). While the decision also addressed other issues, this update focuses on summarizing the Court's holding on the ODP issue.

Allergan markets and sells eluxadoline tablets under the brand name Viberzi®. Allergan owns patents that cover the drug compound and composition; specifically, claim 40 of the '356 patent recites the eluxadoline compound. The '356 patent was awarded 1,107 days of PTA due to delays in its prosecution. All but 467 of those PTA days were disclaimed. Continuing applications were filed claiming the same priority date as the '356 patent (the '011 and '709 patents). Neither received PTA, and each was therefore set to expire before the '356 patent. Defendant argued based on *In re Collect, LLC*, 81 F.4th 1216, 1228–29 (Fed. Cir. 2023), that the '011 and '709 patents were ODP references that rendered the '356 patent invalid. The district court agreed, and Allergan appealed.

The Federal Circuit (Lourie, J., joined by Dyk^[1] and Reyna, J.J.) [reversed](#), concluding that the claims of the '011 and '709 reference patents were not proper ODP references that could be used to invalidate claim 40 of the '356 patent. The Court held that a “first-filed, first-issued, later-expiring claim cannot be invalidated by a later-filed, later-issued, earlier-expiring reference claim having a common priority date.” The Federal Circuit distinguished the facts and questions presented in *In re Collect* from *Allergan* and stated that “*Collect* does not address, let alone resolve, any variation of the question presented here—namely, under what circumstances can a

claim properly serve as an ODP reference—and therefore has little to say on the precise issue before us.” The Court then held that a “later-filed, later-issued” patent cannot be an ODP reference to “the first-filed, first-issued patent in its family,” stating: “[t]hat is the only conclusion consistent with the purpose of the ODP doctrine, which is to prevent patentees from obtaining a second patent on a patentably indistinct invention to effectively extend the life of a first patent to that subject matter.” The Court further asserted that “the first-filed, first-issued patent in its family . . . is the patent that sets the maximum period of exclusivity for the claimed subject matter and any patentably indistinct variants.”

The Court provided the following further rationale for its decision:

“When seeking patent protection, it is not atypical for a patent applicant to first seek to protect the most valuable inventive asset (*e.g.*, a pharmaceutical genus claim) before filing continuing applications on enhancements or modifications to that inventive asset (*e.g.*, a particular compound in that genus, a method of using the compounds of that genus, etc.). And it is unsurprising that prosecution of a first-of-its-kind invention can be protracted, requiring greater time and effort by the applicant and examiner alike, such that any eventual patent on that invention is awarded some amount of PTA. Nor is it surprising that, for one reason or another (*e.g.*, the examiner’s newfound familiarity with the subject matter), a subsequently filed continuing application claiming the same priority date and covering a modification of that invention proceeds much more efficiently through prosecution such that any patent awarded to that modification receives little to no award of PTA. As a result, that later-filed, later-issued continuing, or “child,” patent, whether subject to a terminal disclaimer over the parent or not, generally expires no later than the parent patent. That child patent does not, then, result in any extension of patent term of the invention claimed in the parent patent given that it expires first. Nor can the parent patent be said to result in an extension of patent term of the invention claimed in the child patent when, as here, the claims in the child patent did not even exist until after the parent patent issued. To hold otherwise—that a first-filed, first-issued parent patent having duly received PTA can be invalidated by a later-filed, later-issued child patent with less, if any, PTA—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. That is because 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 not receive the benefit of its congressionally guaranteed patent term, *see* 35 U.S.C. § 154(b), and would instead be limited to the, presumably shorter, term of its own child. Such a result would be untenable.”

After this decision, there could be more proceedings forthcoming, including a petition for panel rehearing, a petition for rehearing *en banc*, and/or a petition for certiorari. Please stay tuned for further developments on this front.

[1] Judge Dyk joined this portion of the majority opinion. He dissented with respect to other issues addressed by the Court, which have not been summarized in this update.

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Gibson Dunn's lawyers are available to assist in addressing any questions you may have regarding developments at the Federal Circuit. Please contact the Gibson Dunn lawyer with whom you usually work, any leader or member of the firm's Appellate and Constitutional Law or Intellectual Property practice groups, or the authors:

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