



LEGAL UPDATES

Federal Circuit Overrules ODP Rejection of Parent Patent Based on *In re Collect*

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In a new precedential decision issued August 13, 2024, the Court of Appeals for the Federal Circuit in *Allergan USA. v. MSN Labs*, 24-1061, held that a first-filed, first-issued parent patent that receives a patent term adjustment (PTA) due to delays by the Patent Office during prosecution cannot be invalidated for obviousness-type double patenting (ODP) by a later-filed, later-issued child patent that receives less, if any, PTA, and expires earlier.

The Federal Circuit decision in *Allergan* overruled the judgment by the U.S. District Court of Delaware that asserted claim 40 of U.S. Pat. No. 7,441,356 was invalid for ODP. The '356 patent is owned by Janssen Pharmaceutica NV and licensed exclusively to Allergan, and covers Allergan's VIBERZI® eluxadoline tablets approved for the treatment of irritable bowel syndrome with diarrhea ("IBS-D") in adults. Allergan filed suit in 2020 against Sun Pharmaceutical Industries Ltd. alleging infringement of the '356 patent. That suit was consolidated with two other suits against Sun and MSN for alleged infringement of several patents based on their ANDA filings seeking FDA approval to sell generic versions of VIBERZI®.

The Delaware District Court ruled that claim 40 of the '356 patent was invalid for ODP over the claims in two later-filed patents in same family that were not patentably distinct and had the same priority date, but expired earlier due to the PTA awarded to the '356 patent. The District Court stated it was bound by the Federal Circuit holding in *In re Collect* (Fed. Cir. 2023) that "ODP for a patent that has received PTA, regardless whether or not a terminal disclaimer is required or has been filed, must be based on the expiration date of the patent after PTA has been added." According to the District Court, "the 'first-filed, first issued' distinction is immaterial," because "a court compares patent expiration dates, rather than filing or issuance dates."

The Federal Circuit in *Allergan*, which consisted of the same panel of three judges that decided *In re Collect*, stated that the "situation presented here of ODP with respect to a first-filed, first-issued patent" was factually distinguishable, and that *Collect* "does not address, let alone resolve . . . 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 appellate court stated that, where the purported ODP reference patents were later-filed and

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later-issued patents in the same family as the challenged patent, and shared the same priority date, they were “not proper ODP references that can be used to invalidate claim 40 of the ‘356 patent.” The later-filed patents were “unquestionably ‘second’ to that patent,” and the claims of the earlier-filed ‘356 patent “do not extend or prolong the monopoly [on eluxadoline] beyond the period allowed by law.”

This precedential decision by the Federal Circuit in *Allergan* is of particular significance considering the controversy surrounding the application ODP following the decision in *In re Cellect*, including the petition for certiorari in that case that is still pending before the U.S. Supreme Court.

It should be noted that the court in *Allergan* explained that 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.” The court also noted that “prosecution of a first-of-its-kind invention can be protracted,” resulting in an award of PTA, while a “subsequently filed continuation application claiming the same priority date . . . proceeds much more efficiently . . . [and] receives little to no award of PTA.” The court’s decision makes clear that under this typical scenario ODP cannot be used to invalidate a first-filed, first-issued parent patent, and thereby “abrogate the benefit Congress intended to bestow on patentees when codifying PTA.”

If you have any questions about patent prosecution, please contact [James DeGiulio](#), [James Velema](#), [William Scofield, Jr.](#) or your regular Lathrop GPM contact.