Double Trouble? Some Double Patenting Woes Resolved

Allergan USA v. MSN Laboratories Private Ltd., No. 2024-1061 (Fed. Cir. Aug. 13, 2024)

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On August 13, 2024, the Federal Circuit reversed a district court's decision that a patent was invalid for obviousness-type double patenting ("ODP") and held that *In re: Cellect LLC*, 81 F.4th 1216, 1228–29 (Fed. Cir. 2023) did not require the invalidation of a related earlier patent even though it expired later. ODP is a judicially created doctrine to prevent an inventor from receiving an unjustified timewise extension of an

invention by filing multiple patents for the same invention but where each patent has different expiration dates. A patent owner can avoid ODP by filing a terminal disclaimer in the later expiring patent disclaiming any portion of the patent term that extends beyond the expiration of the earlier expiring patent. This case addressed what happens when the term of the earlier filed patent extends beyond the expiration of the later filed patent.



Sun Pharmaceutical Industries ("Sun") filed an abbreviated new drug application ("ANDA") for a generic version of Viberzi, which is covered by U.S. Patent No. 7,741,356 ("the '356 patent") owned by Allergan USA, Inc et al. ("Allergan"). Allergan then sued Sun alleging that Sun infringed the '356 patent and two patents claiming priority to the '356 patent: U.S. Patent Nos. 8,344,011 ("the '011 patent") and 8,609,709 ("the '709 patent"). Of these patents, the '356 patent was the first filed and first-to-issue, but due to a patent term adjustment ("PTA") of 467 days, it was the last of these patents set to expire. Sun argued that the '356 patent was invalid under ODP because it expired after the '011 and '709 patents. Allergan argued that ODP did not apply because the '356 patent was filed first and issued first. That is, at the time the '365 patent was being prosecuted, the inventor did not (and could not) know that the '356 patent would expire after any other patents that it may file in the future. The district court, relying on *Cellect*, found that Allergan's distinction was immaterial and invalidated the '356 patent, finding that "[w]hen analyzing ODP, a court compares patent expiration dates, rather than filing or issuance dates." Allergan appealed.

The Federal Circuit held that ODP cannot invalidate a first-filed, first-issued, later expiring patent. The Federal Circuit explained that *Cellect* held that PTA should be considered when analyzing ODP, but *Cellect* did not answer the question presented here—namely whether an ODP analysis is applicable to an earlier issued but later expiring patent. Analyzing the facts of this case, the Federal Circuit found that the '011 and '709 patents were not proper ODP references because they were later filed and later issued patents. ODP is meant to prevent an inventor from obtaining a *second* patent that is indistinct from the *first* patent to prevent the inventor from improperly extending the life of the first patent. Because the '011 and '709 patents were later filed and later issued, it was improper to use them in an ODP analysis to invalidate the earlier issued '356 patent. Therefore, the Federal Circuit reversed the district court's decision.

After *Cellect*, there was concern that ODP would invalidate earlier filed, earlier issued patents in a patent family. This was problematic because when a patent is filed, its expiration date relative to later filed patents is unknown as PTA can vary for each patent and that it would be difficult for owners to monitor their patent families to determine when terminal disclaimers are needed. Although this case provides one instance where ODP does not apply, questions still remain regarding whether ODP is applicable in other situations.