

Publication

09/13/2024

Federal Circuit Weighs in Again on Obviousness-Type Double Patenting to Limit *In re Collect* and Preserve PTA for First-Filed, First-Issued Patents

Obviousness-type double patenting (ODP), a judicially-created ground of patent invalidity, has become the subject of intense interest after the Federal Circuit issued two decisions refining the application of the doctrine in a little over a year. This update discusses these recent developments, which impact the amount of U.S. patent terms that may be enjoyed by patent owners.

Born from the principle that each invention should be limited to a single patent term, ODP is intended to prevent an unjust timewise extension of patent rights that would result from obtaining multiple patents on patentably indistinct inventions. In the United States, patent rights naturally expire twenty years from the date of the original non-provisional application or PCT application filing. That term is automatically extended pursuant to 35 U.S.C. § 154(b) for delays of the United States Patent and Trademark Office (PTO) in examining the application. This automatic extension for PTO delay is referred to as patent term adjustment (PTA).

Consequently, related patents, claiming priority to the same original filing, can, and often do, expire on different days due to PTA. Until recently, it was an open question as to whether PTA should be considered by courts in ODP analyses.

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The Federal Circuit appeared to answer that question last year in *In re Collect, LLC (Collect)* when it held that the expiration date of the patent, including any PTA, is the key date in the ODP analysis. Applying that rule, the Court held that *Collect's* patents were invalid for ODP because, due to the PTA awarded, they expired later than the reference patents, which were part of the same patent family. Ordinarily, the patent owner could cure this flaw by filing a terminal disclaimer so the later-expiring patent would expire on the same day. However, *Collect* could not cure the ODP defect by filing a terminal disclaimer because it was too late – the reference patents had already expired.

In *Allergan USA, Inc. v. MSN Labs. Pvt. Ltd. (Allergan)*, a case arising under the Hatch-Waxman act, defendant Sun challenged the validity of the U.S. Patent No. 7,741,356 ("356 patent"), covering Allergan's IBS drug, Viberzi (eluxadoline) on the grounds of ODP. Sun argued that the single asserted '356 patent claim was invalid because, due to an award of PTA, it expired 467 days *after* two later-filed and later-issued patents in the same family. The parties did not dispute that the '356 parent patent was patentably indistinct over the earlier expiring child patents. The district court agreed with Sun and invalidated the '356 patent claim. In doing so, the district court held that it was bound by the Federal Circuit's prior decision in *Collect*, which, according to the district court, did not recognize any exception to the rule that the ODP analysis is to be based solely on comparison of patent expiration dates after PTA was applied.

On appeal, the Federal Circuit reversed the district court and clarified its holding in *Collect*. According to the Federal Circuit, *Collect* merely answered the question of what the proper expiration date is to use for the ODP analysis, whereas the different question in *Allergan* was under what circumstances can a patent claim properly serve as an ODP reference. To answer that question, the court examined the purpose of ODP, which is to prevent

patentees from obtaining a *second* patent on a patentably indistinct invention to effectively extend the life of a *first* patent covering the same subject matter. Since the '356 patent was the first-filed, first-issued patent covering eluxadoline in the family, the court held that it set the maximum period of exclusivity for any patentably indistinct claims. In other words, the fact that the '356 patent expired later than other patentably indistinct claims in the same family is irrelevant because it was not a *second*, later expiring patent for the same invention. As a result, Sun's ODP challenge to the '356 patent failed because a first-filed, first-issued, later-expiring patent claim cannot be invalidated by a later-filed, later-issued, earlier-expiring reference claim having a common priority date. The court explained that to hold otherwise would effectively remove the benefit Congress intended to bestow on patentees when codifying PTA.

Although the Federal Circuit in *Allergan* limited the scope of its holding in *Collect* and provided some guidance regarding what a proper ODP reference under the specific facts is presented, many questions remain as to the proper scope of ODP. For example, the Federal Circuit did not address whether a *later*-filed but first-issued patent would also set the term of maximum exclusivity and could be used to invalidate a first-filed but later-issued parent that is awarded more PTA. The court also failed to address that in *Collect*, a later-filed, earlier-expiring patent was used to invalidate *both* an earlier-filed, earlier-issued, later-expiring patent and an earlier-filed, later-issued, later-expiring patent. Instead, the Federal Circuit insisted that this issue had not been before the *Collect* court since the patent owner did not challenge whether the reference claims used to invalidate the asserted claims were proper ODP references.

Meanwhile, the patent owner in *Collect* has filed a petition for a writ of certiorari with the Supreme Court, which has been followed by a plethora of amicus briefs. It remains to be seen whether the recent *Allergan* decision



will tip the balance in favor of the Supreme Court granting certiorari. In the absence of further clarity from the courts, a prudent course for patent owners to fend off ODP challenges to patents with PTA may be to ensure that the most valuable patent claims in a family are both first-filed and first-issued, if possible.

If you have any questions regarding the decisions discussed in this update or the application of ODP, please contact Emer Simic, Joseph Sherling, or your Neal Gerber Eisenberg attorney.

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