

RECENT DEVELOPMENTS IN OBVIOUSNESS-TYPE DOUBLE PATENTING

Christopher Wheeler



Overview

- In August 2024, the Federal Circuit ruled on an obviousness-type double patenting (“ODP”) issue in *Allergan USA, INC. v. MSN Laboratories Private LTD.* (Fed. Cir. August 13, 2024), appealed from D. Del. (Judge Andrews). Before Lourie, Dyk, and Reyna.
- The issue was whether a first-filed, first-issued, later-expiring claim can be invalidated by a later-filed, later-issued, earlier-expiring reference claim having a common priority date (*i.e.*, “same family”).

Background

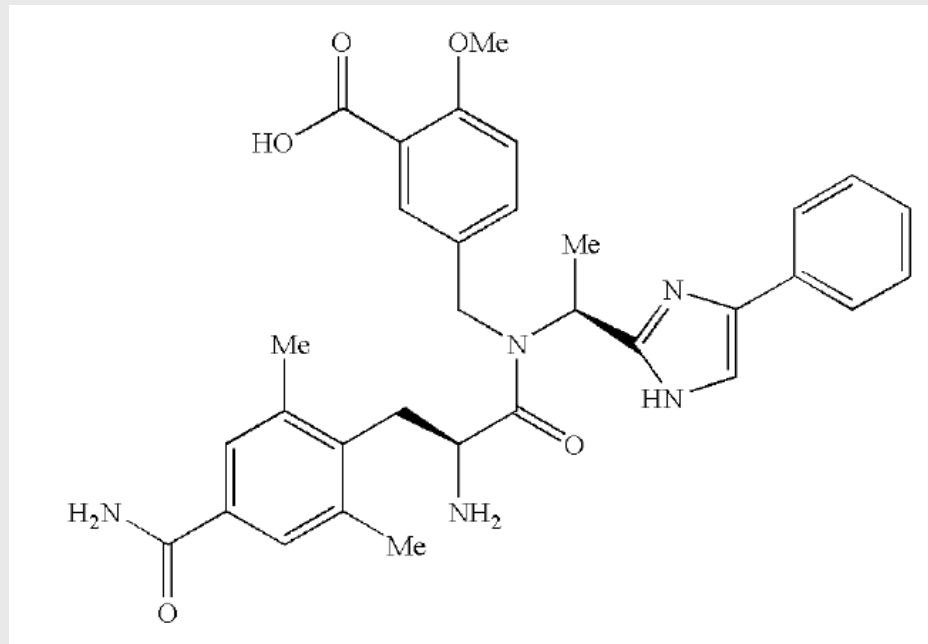
- Janssen (co-Appellant) owned a patent directed to eluxadoline, which is marketed under the brand name Viberzi®.
- Viberzi® is indicated for treatment of IBS-D and works by activating opioid receptors in the gut to reduce bowel contractions.
- There are a number of patents associated with eluxadoline, one being U.S. Patent 7,741,356 (“the ’356 patent”), filed March 14, 2005 -- the first ever patent application to cover eluxadoline.

Background

- Janssen filed a number of continuing applications that each claimed priority from the March 14, 2005 filing date of the '356 patent, including U.S. Patent No. 8,344,011 (“the '011 patent”) and U.S. Patent No. 8,609,709 (“the '709 patent”).
- The application leading to the '011 patent was filed on July 19, 2010, as a divisional of an application which was a continuation of the '356 patent.
- The application leading to the '709 patent was filed on November 30, 2012, as a continuation of the '011 patent.

Background

- The relevant claim in the '356 patent was claim 40, which recited several compounds, including eluxadoline shown below:



Background

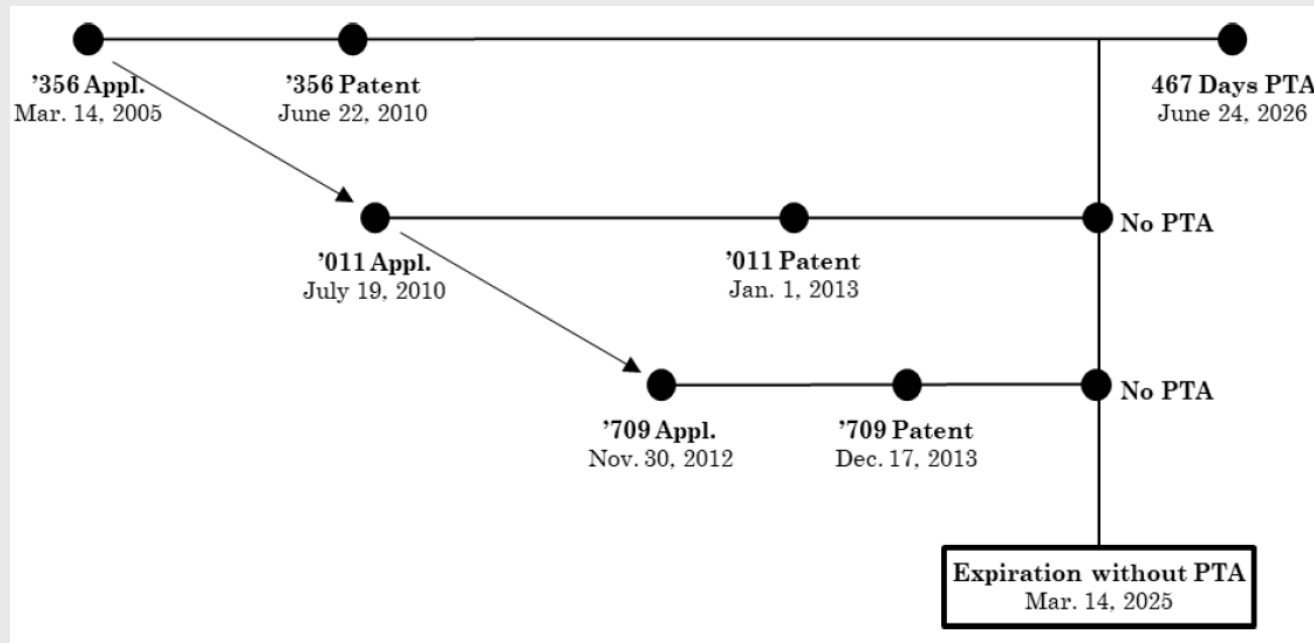
- The relevant claim in the '011 patent was claim 33, which recited a method for treating pain or gastrointestinal disorder comprising administering to a patient in need thereof eluxadoline or one of seven other compounds.
- The relevant claim in the '709 patent was claim 5, which explicitly recited the eluxadoline compound.

Background

- The '356 patent issued on June 22, 2010, and **after accounting for patent term adjustment, the expiration date of the '356 patent was June 24, 2026.**
- The '011 patent issued on January 1, 2013, and with no PTA, the expiration date of the '011 patent was March 14, 2025 (*i.e.*, 20 years from the filing date of the application corresponding to the '356 patent).
- The '709 patent issued on December 17, 2013, and with no PTA, the expiration date of the '011 patent was also March 14, 2025.

Background

- Because all three patents shared a priority date, all would expire on the same day but for the PTA awarded to the '356 patent.



Background

- Sun Pharmaceutical (co-Appellee) filed an ANDA for Viberzi[®] asserting invalidity of the '356 patent based on ODP over the '011 patent and the '709 patent.
- The parties stipulated that Sun would infringe all the asserted claims if those claims were valid.
- The District Court found the claims of the '356 patent invalid based on ODP.
- Allergan appealed, and the Federal Circuit reversed.

District Court Proceedings

- Sun argued that claim 40 of the '356 patent was invalid for ODP over claim 33 of the '011 patent and claim 5 of the '709 patent because the claims were allegedly not patentably distinct and because claim 40, having been awarded 467 days of PTA, expired after the reference claims of the '011 and '709 patents.
- In response, Allergan argued that because the '356 patent was the first patent claiming eluxadoline to be filed and the first patent to issue, claim 40 is not subject to ODP over the later-filed, later-issued claims of the reference patents.
- Allergan did not contest Sun's argument that claim 40 is not patentably distinct from the reference claims.

District Court Proceedings

- The District Court agreed with Sun, finding Allergan’s “first-filed, first-issued” distinction to be immaterial.
- It stated that “[w]hen analyzing ODP, a court compares patent expiration dates, rather than filing or issuance dates.” *Id.* (citing *Gilead Scis., Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208, 1215–17 (Fed. Cir. 2014), and *In re Collect, LLC*, 81 F.4th 1216, 1228–29 (Fed. Cir. 2023)).
- Because the District Court read *Collect* and prior Federal Circuit case law as binding it to consider expiration dates *alone* in the ODP analysis, it concluded that claim 40 of the ’356 patent was invalid.

The Federal Circuit Discussion

- ODP is an issue of law premised on underlying factual inquiries and is therefore reviewed *de novo* for clear error.
- Since Allergan conceded that the asserted claim was not patentably distinct over the reference claims, the only question before the Federal Circuit was one of law, *i.e.*, “Can 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?”

The Federal Circuit Discussion

- Under 35 U.S.C. § 154(a)(2), a patent's term is measured from its effective filing, or priority, date, *i.e.*, the earlier of (1) the filing date of the application and (2) the filing date of an application from which the patent claims priority.
- In practice, there is little risk of an unjustified extension of term subject to ODP because all patents to an invention that share a priority date are expected to expire on the same day.
- But of course, due to an award of PTA, two commonly-owned patents that would otherwise expire on the same day due to a shared priority date may nevertheless have different expiration dates, which is circumstance that is normally resolved with a Terminal Disclaimer.

The Federal Circuit Discussion – *In re Collect*

- The District Court relied on the Federal Circuit's decision in *Collect*.
- In *Collect*, the patent owner had obtained a number of interrelated patents to admittedly patentably indistinct subject matter which each claimed priority from a single application.
- Accordingly, but for individual grants of PTA awarded to each patent, each would have expired on the same day.
- Yet, none of the asserted patents were subject to a terminal disclaimer, and all the patents had expired.

The Federal Circuit Discussion – *In re Collect*

- In a reexam, it was determined that the claims of the since-expired asserted patents were invalid for ODP because the various awards of PTA had resulted in the patent owner receiving an unjustified timewise extension of patent term (up to 759 days) on patentably indistinct inventions.
- On appeal, the Federal Circuit affirmed the asserted patents' invalidity, holding 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."
- Accordingly, *Collect* established a rule 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.

The Federal Circuit Discussion – *In re Collect*

- The District Court in *Allergan* found itself bound by *Collect* and held that because claim 40 of the '356 patent expired after the reference claims of the '011 and '709 patents due to PTA, it was invalid for ODP.
- The Federal Circuit noted that the problem with this result was that *Collect* answered a different question than that at issue here.
- The holding in *Collect* was only controlling in this case to the extent that it required considering, in the ODP analysis, the '356 patent's June 24, 2026 expiration date (*i.e.*, the expiration date after the addition of PTA), not the March 24, 2025 expiration date that it would have shared with the '011 and '709 reference patents in the absence of a PTA award.

The Federal Circuit Discussion – *In re Collect*

- The Federal Circuit found that it does not follow that the '356 patent *must* be invalidated by the '011 and '709 reference patents simply because it expires later.
- It 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 had little to say on the precise issue at hand.
- The Federal Circuit opined that the purpose of the ODP doctrine 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. *Miller v. Eagle Mfg. Co.*, 151 U.S. at 198 (1894).

The Federal Circuit Discussion – *In re Collect*

- The Federal Circuit concluded that the claims of the '011 and '709 reference patents were not proper ODP references that can be used to invalidate claim 40 of the '356 patent.
- It found this to be the only conclusion consistent with the purpose of the ODP doctrine.
- The contrary position would require concluding that the '356 patent—the first-ever patent covering eluxadoline—extended Allergan's period of exclusivity to the subject matter claimed in the '011 and '709 continuation patents simply because it expired later.
- The Federal Circuit found this position to be antithetical to the principles of ODP.

The Federal Circuit Discussion – *In re Collect*

- The '356 patent was undoubtedly the “first” patent to cover eluxadoline, whether measured by filing date or by issuance date.
- And each of the '011 and '709 patents was unquestionably “second” to that patent.
- The Federal Circuit found that the claims of the '356 patent did not “extend or prolong the monopoly [on eluxadoline] beyond the period allowed by law,” and therefore were not subject to ODP over the '011 and '709 patents.
- The fact that the '356 patent expired later was of no consequence here because it is not a “*second*, later expiring patent for the same invention.”
- As the first-filed, first-issued patent in its family, it was the '356 patent that set the maximum period of exclusivity for the claimed subject matter and any patentably indistinct variants.

The Federal Circuit Holding

- Therefore, the Federal Circuit 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 did not find anything in this holding inconsistent with other Federal Circuit case law.

The Federal Circuit Discussion – *Gilead*

- In *Gilead*, the Federal Circuit recognized that use of issuance date alone to determine whether a patent was invalid for ODP had several shortcomings including the possibility of significant gamesmanship during prosecution.
- In that case, the patent owner had crafted a separate chain of applications, not tied to the priority date of an earlier-filed patent that claimed patentably indistinct subject matter.
- Because the later-filed, earlier-issued asserted patent did not claim priority from the earlier-filed, later-issued patent, it did not share an expiration date with that patent, and instead expired twenty years from its own, later filing date.
- This resulted in the asserted claim having nearly two years of additional term as compared to the patentably indistinct reference claim.

The Federal Circuit Discussion – *Gilead*

- Under those circumstances, the Federal Circuit observed that, between issuance date and expiration date, the latter serves as the better benchmark in determining the application of ODP.
- Accordingly, the Federal Circuit held that a later-issued but earlier-expiring patent can qualify as an ODP reference to invalidate an earlier-issued but later-expiring patent.

The Federal Circuit Discussion – *Gilead*

- In the present matter, Sun argued that the holding in *Gilead* applied, where the later-issued, earlier-expiring claims of the '011 and '709 patents are relied upon as ODP references to invalidate the earlier-issued but later-expiring claim of the '356 patent.
- But the court in *Gilead* focused its inquiry only on whether issuance dates should remain the most relevant benchmark for evaluating ODP, according to the Federal Circuit in *Allergan*.
- It did not address the role of filing dates.

The Federal Circuit Discussion – *Gilead*

- The holding in *Gilead*, which was expressly limited to the circumstances of that case, was not pronounced in a vacuum.
- Unlike here, the challenged claims of the asserted patent in *Gilead* were filed after, claimed a later priority date than, *and* expired after the reference claims, which resulted in an unwarranted extension of patent term for an invention that had already been the subject of an earlier-filed, earlier-expiring claim.
- In contrast, claim 40 of the '356 patent was filed before, shares a priority date with, and issued before the claims of the '011 and '709 patents.
- Because the '356 patent was the first patent in its family to be filed and to issue, it did not *extend* any period of exclusivity on the claimed subject matter.

The Federal Circuit Discussion – *Abbvie*

- Similarly, in *Abbvie Inc. v. Mathilda & Terence Kennedy Inst. of Rheumatology Tr.*, 764 F.3d 1366, 1373 (Fed. Cir. 2014), the asserted claims were filed later, claimed a later priority date, issued later, and expired later than the patentably indistinct reference claims.

The Federal Circuit Discussion – Other Notes

- The Federal Circuit noted that 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.
- 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.
- In the eyes of the Federal Circuit, this result would be untenable.

Recent Developments/Future Outlook

- In late September 2024, Sun filed a *Petition for Rehearing En Banc* in *Allergan*.
- The Supreme Court denied *certiorari* in *Collect* in early October 2024.
- Therefore, the broad holding in *Collect* will stand.
- But the law surrounding limitations on *Collect*, such as the safe harbor in *Allergan*, is far from settled.

Questions and Comments





Birch
Stewart
Kolasch
Birch LLP

Christopher Wheeler
christopher.wheeler@bskb.com
(703) 205-8008