Allergan USA, Inc. v. MSN Laboratories Private Ltd., 2024-1061 (Fed. Cir. 8/13/2024)

By, Rick Neifeld, Neifeld IP Law

This is a decision on an appeal from the District of Delaware district court case Nos. 1:19-cv-01727-RGA, 1:20-cv-01479-RGA, 1:21-cv-01064-RGA, 1:21-cv-01065-RGA. Allergan appealed. The Federal Circuit reversed the district court holding of obviousness-type double patenting invalidity, and a majority reversed the district court holding of written description invalidity.

Legal Issue: Non-statutory obviousness-type double patenting, requirements for reference claims.

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 discussed and logically distinguished its prior precedents.

> "Obviousness-type double patenting is an issue of law premised on underlying factual inquiries." *Ezra*, 909 F.3d at 1372 (citation omitted). We therefore review the district court's ultimate conclusion on ODP de novo, and its predicate findings of fact for clear error. *Id.* Here, where Allergan concedes that the asserted claim is not patentably distinct over the reference claims, the only question before us is one of law. Namely, 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? We hold that it cannot. [Allergan Usa, Inc. v. MSN Laboratories Private Ltd., 2024-1061 (Fed. Cir. 8/13/2024).]
>
> Here, we conclude that the claims of the '011 and '709 reference patents are not proper ODP references that can be used to invalidate claim 40 of the '356 patent. That 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. *See Miller*, 151 U.S. at 198 ("[T]he power to create a monopoly is exhausted by the first patent . . . a new and later patent for the same invention would operate to extend or prolong the monopoly beyond the period allowed by law."); *Abbvie*, 764 F.3d at 1373 (citing Miller for the "crucial purpose" of ODP: "prevent[ing] an inventor from securing a second, later expiring patent for the same invention"); *Cellect*, 81 F.4th at 1226 ("A crucial purpose of ODP is to prevent an inventor from securing a second, later-expiring patent for non-distinct claims."). Sun's contrary position would require us to conclude that the '356 patent—the first-ever patent covering eluxadoline—extends Allergan's period of exclusivity to the subject matter claimed in the '011 and '709 continuation patents simply because it expires later. That position is antithetical to the principles of

ODP. [Allergan Usa, Inc. v. MSN Laboratories Private Ltd., 2024-1061 (Fed. Cir. 8/13/2024).]

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. Accordingly, claim 40 of the '356 patent is not invalid for ODP over claim 33 of the '011 patent or claim 5 of the '709 patent. [Allergan Usa, Inc. v. MSN Laboratories Private Ltd., 2024-1061 (Fed. Cir. 8/13/2024).]

Despite Sun's assertions to the contrary, our conclusion is consistent with our case law. *E.g., Cellect*, 81 F.4th at 1230 ("We do, however, note that the non-asserted claims in the challenged patents are entitled to their full term, including the duly granted PTA, unless they are found to be later-filed obvious variations of earlier-filed, commonly owned claims."); *Ezra*, 909 F.3d at 1374 (noting that "the traditional concern with obviousness-type double patenting" is not raised where "it is the earlier-filed, earlier issued . . . patent, not the later-filed, later-issued . . . patent, that has the later expiration date"); *see Breckenridge*, 909 F.3d at 1366 ("In this particular situation where we have an earlier-filed, earlier-issued, pre-URAA patent that expires after the later-filed, later-issued, post-URAA patent due to a change in statutory patent term law, we decline to invalidate the challenged pre-URAA patent by finding the postURAA patent to be a proper obviousness-type double patenting reference.") [Allergan Usa, Inc. v. MSN Laboratories Private Ltd., 2024-1061 (Fed. Cir. 8/13/2024).]

We acknowledge Sun's position that our holding in *Gilead* appears to apply here, 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*, guided by the parties' arguments, focused its inquiry only on whether issuance dates should remain the most relevant benchmark for evaluating ODP post-URAA. *See id.* at 1214–15. It did not address the role of filing dates. And most importantly, our holding in *Gilead*, which was expressly limited to the "circumstances of [that] case," *id.* at 1212, 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 reference 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 does not extend any period of exclusivity on the claimed subject matter. [Allergan Usa, Inc. v. MSN Laboratories Private Ltd., 2024-1061 (Fed. Cir. 8/13/2024).]

For similar reasons, we are unpersuaded by Sun's reliance on *Abbvie*, in which the asserted claims were filed later, claimed a later priority date, issued later, and expired later than the patentably indistinct reference claims. As we have recognized, *Abbvie* "is a prime example of the post-URAA scenario we contemplated in Gilead where an inventor, seeking to prolong his exclusivity rights over his invention, applies for a second patent on an obvious variant of his invention protected by a first patent" and achieves a later expiration date by choosing a different, later priority date than the one relied upon for the first patent. *Breckenridge*, 909 F.3d at 1365. For the reasons already explained, that is not the case here. [Allergan Usa, Inc. v. MSN Laboratories Private Ltd., 2024-1061 (Fed. Cir. 8/13/2024).]

Note: While the panel split on the written description issue, the reasoning there does not provide significant case law.