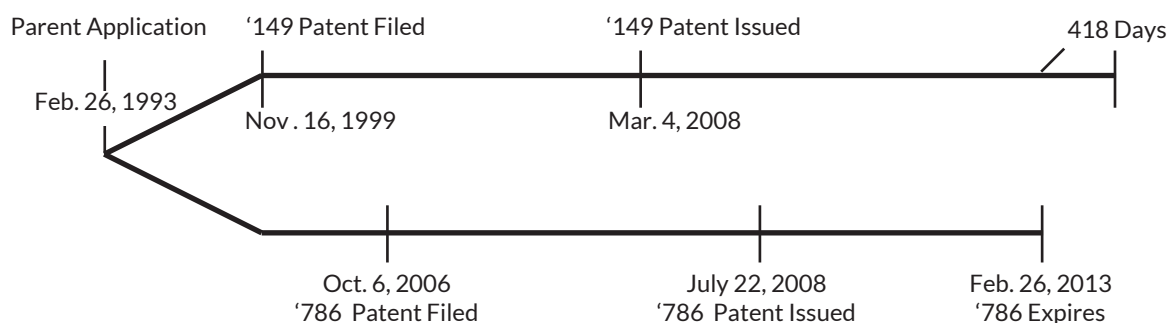


Whether Obviousness Type Double Patenting Can Be Used to Invalidate Patents That Expire Later Because of Patent Term Adjustment

July 12, 2021

We write to advise you on an issue currently before the Federal Circuit in a case of first impression, namely whether a later-filed, earlier-expiring patent can be used as a reference for obvious-type double patenting (OTDP) to invalidate a patent that was filed earlier but expires later because of a patent-term adjustment (PTA). *Mitsubishi Tanabe Pharma Corp. v. Sandoz Inc.*, Case No. 21-1876 (Fed. Cir. 2021). Below is a visual example of this situation:



Magna Elecs., Inc. v. TRW Auto. Holdings Corp., 2015 WL 11430786, at *2 (W.D. Mich. Dec. 10, 2015). The question is whether the '786 patent can serve as a reference to invalidate the PTA-adjusted '149 patent. While the *Magna* case involved car technology, the *Sandoz* action shows that the upcoming decision impacts the pharmaceutical sector (e.g., where an earlier-filed compound patent issues and expires after a later-filed polymorph patent because of PTO delays in prosecution of the compound patent).

Whether OTDP applies where a patent expires later because a PTA has not been considered by the Federal Circuit, but it has been considered by two district courts — who have reached different conclusions. The first court to address this issue was the Western District of Michigan in *Magna*. There, the court conducted an extensive analysis into the history and purpose of the OTDP doctrine. OTDP applies where two patents claim the same invention but have different expiration dates, unless the two inventions are patentably distinct. *Magna*, 2015 WL 11430786, at *2 (citing *AbbVie Inc. v. Mathilda & Terence Kennedy Inst. of Rheumatology Tr.*, 764 F.3d 1366, 1374 (Fed. Cir. 2014)). The doctrine is designed to prevent an inventor from securing a second, later-expiring patent for the same invention. *Id.*; see also *AbbVie*, 764 F.3d at 1373. Thus, it prevents a patent owner from controlling the public's right to use the patented invention beyond the statutorily allowed patent term of that invention. *Id.*; see also *Gilead Scis., Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208, 1216-17 (Fed. Cir. 2014). ("Permitting any earlier expiring patent to serve as a double patenting reference for a patent subject to the URAA guarantees a stable benchmark that preserves the public's right to use the invention (and its obvious variants) that are claimed in a patent when that patent expires").

In *Magna*, the court focused on the expiry of the earlier reference (the '786 patent) and the public's right to practice that invention, finding that OTDP applied where a patent expired later because of a PTA. *Id.* The *Magna* decision was seemingly in line with dicta of the Federal Circuit in *AbbVie*, which suggested OTDP had continuing viability to address where "[p]atents claiming overlapping subject matter that were filed at the same time still can have different patent terms due to examination delays at the PTO." *Id.* (citing 35 U.S.C. § 154(b)). But, the case settled before appeal, and so the Federal Circuit did not rule directly on the issue.

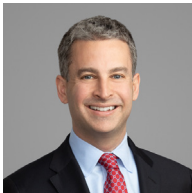
After *Magna* (and *Gilead* and *AbbVie*), the Federal Circuit considered whether OTDP applied where the first-filed patent expired later because of a patent term extension (PTE), as contrasted to a PTA. *Novartis AG v. Ezra Ventures LLC*, 909 F.3d 1367 (Fed. Cir. 2018). In *Ezra*, the Federal Circuit considered the specific purpose of the PTE provisions of the Patent Act and held that OTDP did not apply. *Id.*

In *Sandoz*, the issue of application of OTDP caused by a PTA was again presented to a district court, this time before the district of New Jersey in an ANDA action. *Sandoz*, No. 3:17-cv-05319-FLW-DEA, at 61 (D.N.J. Mar. 22, 2021). The court essentially sought to determine which was more applicable, the *AbbVie-Gilead-Magna* line of cases applying OTDP broadly while focusing on patent expiry or *Ezra's* finding of an exception to OTDP, where a PTE is granted. Ultimately, the court held that a PTA is akin to a PTE, and thus patents expiring later because of a PTA are safe from the OTDP doctrine. *Id.*

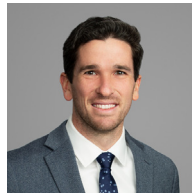
In *Sandoz*, the last remaining defendant — Zydus — appealed to the Federal Circuit. Zydus has raised as the sole issue on appeal whether OTDP applies to a patent expiring later because of a PTA. If you would like to discuss this issue or how this decision may impact projects you are working on, please feel free to reach out.

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