Proskauer

Why Obviousness-type Double Patent Analysis Isn't Obvious

Proskauer in Life Sciences Blog on **August 6, 2021**

Over the last seven years there has been commotion in Obviousness-type Double Patenting ("ODP") practice. One of the latest cases to spur a considerable amount of interest is *Mitsubishi Tanabe Corp. v. Sandoz, Inc.*, which is currently on appeal to the Federal Circuit ("CAFC"). While a detailed review of this case is not the intent of this post, as a fair number of practitioners have provided insightful coverage, an historical overview is helpful for framing the decision and issues that need clarification from the CAFC.

The upheaval in ODP jurisprudence began with *Gilead Sciences, Inc. v. Natco Pharma Ltd.* (2014). Reversing the district court, the CAFC found that a *later-issued but earlier-expiring* patent could serve as an ODP reference. The court discussed in detail the policy concerns behind the judicially-created ODP doctrine, namely preventing extension of a patent monopoly based on later expiring patents on obvious variations of the same invention. The panel held that the relevant inquiry for an ODP analysis is the expiration dates of the patents at issue, a shift from the practice of looking at the issue date. Following *Gilead*, the CAFC has continued to refine the updated ODP architecture, including what can be considered an ODP reference.

In *Abbvie Inc. v. Mathilda and Terence Kennedy Institute of Rheumatology Trust* (2014) the CAFC made *Gilead* explicit: ODP "appl[ies] where two patents . . . claim the same invention [and] have different expiration dates." In rejecting the patent owner's arguments that ODP does not apply after the Uruguay Round Agreements Act ("URAA") the court noted, in *dicta*, that "[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."

In *Novartis Pharma. Corp. v. Breckenridge Pharma. Inc.* (2018) ("*Novartis I*") the CAFC reversed the district court and held that ODP did not apply when there was no evidence of "gamesmanship" and the difference in patent expiration dates was a result of an intervening change of law. There, the defendant argued that a post-URAA patent that had expired on Sept. 23, 2013 invalidated a pre-URAA patent with an expected expiration of Sept. 9, 2019. The original expiration date of the pre-URAA patent was Sept. 9, 2014, but an additional 5-years of Patent Term Extension ("PTE") was awarded for regulatory delay.

In *Novartis AG v. Ezra Ventures LLC* (2018) ("*Novartis II*"), a case critical to the *Mitsubishi* decision, the defendant argued that a post-URAA patent that had expired on Sept. 23, 2017 invalidated a pre-URAA expiring Feb. 18, 2019. The original expiration date of the pre-URAA patent was Feb. 18, 2014, but an additional 5-years of PTE was awarded for regulatory delay (like the *Novartis I* pre-URAA patent). The defendant also argued that the PTE awarded to the pre-URAA patent should be truncated to have expired at the same time as the post-URAA patent.

The CAFC affirmed the district court's judgment, holding that the post-URAA patent was not a proper ODP reference. Further, the CAFC extended its holding *in* *Merck & Co., Inc. v. Hi-Tech Pharmacal Co., Inc.* (2007) and held that "PTE . . . is valid if the extended patent is otherwise valid without the extension." The CAFC noted that there was no evidence of trying to orchestrate longer patent monopolies and the policy concerns at the heart of ODP were not present. Underlying to the *Mitsubishi* decision, the CAFC refused to use a judge-made doctrine to limit a statutorily grounded PTE.

In *Mitsubishi* the two patents of concern were both post-URAA patents, shared a common priority chain, and were originally expected to expire on the same date (July 30, 2024). However, one patent had received 256 days PTE while the other received 1079 days of Patent Term Adjustment ("PTA"). The defendant argued that the patent benefiting from PTA was invalid based on ODP in view of the earlier expiring, PTE-extended patent. Relying on *Novartis I* and *II*, the district court found that the earlier expiring, PTE-extended patent was not a proper ODP reference—the traditional ODP policy concerns were not present and the term extension was based in statute. The court dismissed the statements in *Abbvie* regarding examination delays at the PTO as *dicta* and discounted the defendant's attempt to distinguish PTA and PTE in footnotes.

Many practitioners are looking forward to the CAFC's decision in the case. Given the uncertainties surrounding ODP, clarification from the CAFC would be a welcome development.

To what extent is it proper to analogize between cases that involve PTE with cases that involve PTA?

In *Mitsubishi*, the district court analogized to *Novartis II* (a PTE case) to reach its conclusion. However, in *Merck* (mentioned above in relation to *Abbvie*) the CAFC contrasted §§ 154 and 156 while construing the later. The district court discounted the incongruence by distinguishing *Merck* as involving terminal disclaimers, which were not at issue.

Another consideration here is that the scopes of impact for PTE and PTA are very different. Any patent—covering any technology—that experiences delay during prosecution may qualify for day-for-day PTA; only one patent covering a product subject to regulatory review may receive PTE. Thus, a blanket exclusion of patents that differ only in PTA as ODP references will have much farther reaching consequences than for PTE.

What is the impact on other statutory provisions?

The *Mitsubishi* court did not engage in an in depth statutory construction reaching its conclusion and interplay between other sections need to be considered to best effectuate the Act. One area of potential impact is the § 121 safe harbor. Essentially, under the § 121 safe harbor patents that issue following proper restriction practice (*i.e.*, divisional applications) cannot be used as references against one another. In *Mitsubishi* a continuation application was found uncitable against a related application.

The interplay between the network of statutory provisions and judge-made doctrine is nuanced and can change over time. In the end there is a need to find the right balance and the CAFC should provide very much appreciated clarification and guidance shortly.

View Original

Related Professionals

- **Fangli Chen, Ph.D.**

Partner

- **Nicholas C. Prairie**
  Associate