

Obviousness-type Double Patenting Does Not Limit an Otherwise Validly Obtained Patent Term Extension

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The United States Court of Appeals for the Federal Circuit has ruled that obviousness-type double patenting does not invalidate an otherwise validly obtained patent term extension (PTE) under 35 U.S.C. § 156. The decision in *Novartis AG v. Ezra Ventures LLC* affirmed the Delaware District Court's similar judgment, and demonstrates that a patent with an earlier expiration date, including one that is terminally disclaimed over other patents, can be extended beyond one or more patents with later expiration dates.

In the U.S., a single patent covering a pharmaceutical product can be extended for up to five years to make up for patent term lost during clinical trials for regulatory (i.e., FDA) approval. This was part of the landmark Hatch-Waxman Act of 1984, which balanced branded drug exclusivity with generic competition. However, there are statutory and judicial doctrines that prevent a patent owner from extending the life of a first patent to an invention with further patents on the same invention, or obvious variants of the same invention. This case addresses what happens when these doctrines appear to conflict.

In this case, plaintiff-appellee Novartis owned at least two patents covering the same pharmaceutical product. The first patent expired in 2017. A second patent was scheduled to expire in 2014. However, with the addition of a PTE, its expiration date was extended to 2019, beyond the expiration date of the first patent.

The two patents covered the pharmaceutical product Gilenya® (fingolimod) for the treatment of relapsing-remitting multiple sclerosis. The first patent, U.S. Patent No. 6,004,565, claimed methods of using fingolimod related to the treatment of multiple sclerosis. Its patent term expired in 2017. The second patent, U.S. Patent No. 5,604,229 was filed in 1992 and issued in 1997 with claims directed to compounds including fingolimod and claims directed to methods of their use related to the treatment of multiple sclerosis. Because it was filed in 1992, the '229 patent was entitled to a 17-year patent term, and it was expected to expire in 2014. But the plaintiff-appellee obtained a PTE extending the termination date of the '229 patent for five years to 2019, i.e. beyond the 2017 termination date of the '565 patent.

According to 35 U.S.C. § 156(c)(4), "in no event shall more than one patent be extended... for the same regulatory review period for any product." Defendant-appellee Ezra Ventures argued that the

PTE on the '229 patent “effectively” extended the patent term of the expired, '565 patent claiming the same subject matter. The District Court and Federal Circuit rejected this argument under principles of statutory construction and legislative history.

Separately, Defendant-appellee argued that the doctrine of obviousness-type double patenting rendered the PTE-extended '229 patent invalid, because it was not patentably distinct over the claims of the '565 patent. The District Court and the Federal Circuit also rejected this argument. According to the Federal Circuit, “if a patent, under pre-PTE expiration date, is valid under all other provisions of the law, then it is entitled to the full term of its PTE.” Since the '229 patent, pre-PTE, would have expired before the '565 patent, the Federal Circuit found no obviousness-type double patenting concern like the one raised in *Gilead v. Natco Pharm*, 753, F.3d 1208 (Fed. Cir. 2014).

Finally, Defendant-appellee argued that the PTE violated the “bedrock principle” that the public may practice an expired patent. The District Court found no authority for this “bedrock principle,” and the Federal Circuit did not comment on this position when affirming the District Court’s final judgment.

With this decision, patent owners should be sure to consider all possible patents for PTE on a pharmaceutical product. So long as the patent itself is valid as of its original expiration date, a PTE should provide valuable extension of patent life.

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