



## Federal Circuit Partially Clarifies Obviousness-Type Double Patenting Law in Two Opinions Released the Same Day

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In the first opinion, the court held that, because the Uruguay Round Agreements Act (URAA) changed the law for calculating patent term expiration dates, a later-filed, earlier-expiring, post-URAA patent cannot serve as a double patenting reference for an earlier-filed, later-expiring, pre-URAA patent.

In this first case, *Novartis Pharms. Corp. v. Breckenridge Pharm. Inc.*, Nos. 2017-2173, 2175-2180, 2182-2184 (Fed. Cir. Dec. 7, 2018) (JJ. Prost, Wallach, Chen), Novartis owned two patents in the same family that share a common specification and effective filing date. One of the patents, U.S. Patent No. 5,665,772 (the “772 Patent”), was filed pre-URAA and is entitled to a 17-year patent term calculated from the 772 Patent’s issuance date. The other patent, U.S. Patent No. 6,440,990 (the “990 Patent”), was filed post-URAA and is entitled to a 20-year patent term calculated from its earliest effective filing date. Due to this intervening change in the law, the 990 Patent, which was filed and issued after the 772 Patent, expired about a year before the 772 Patent.

Before the district court, the parties stipulated that, if the 990 Patent, which covers methods of treatment using everolimus, is a proper double patenting reference, the 772 Patent, which claims the compound everolimus, is invalid for OTDP. Novartis sells Zortress<sup>®</sup> and Afinitor<sup>®</sup>, both of which contain everolimus as the active ingredient. The district court applied the reasoning of *Gilead Sciences, Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208 (Fed. Cir. 2014) to conclude that a later-filed, later-issued, earlier-expiring patent can properly serve as a double

patenting reference for an earlier-filed, earlier-issued, later-expiring patent, and it did not take into account the change in patent term calculations under the URAA.

The Federal Circuit reversed. Judge Chen, writing for the panel, stated that, while *Gilead* properly set a patent's expiration date as the "benchmark" for an OTDP analysis, that decision is limited to situations where both patents are subject to post-URAA patent terms. Under the facts in *Breckenridge*, the court found that *Gilead* does not control. Instead, the court applied "traditional pre-URAA [OTDP] practice," which considers the pre-URAA 772 Patent's issuance date "as the reference point for [OTDP]." Under this framework, and because a change in patent term law should not truncate the term "statutorily assigned" to the 772 Patent, the court held that the post-URAA 990 Patent is not a proper double patenting reference for the 772 Patent.

In the second December 7 opinion, the court held that a patent owner may seek a patent term extension (PTE) for any patent that it is statutorily permitted to do so, regardless of other relevant patents it owns. The court also held that OTDP does not invalidate validly obtained PTE, if the unextended patent would have been otherwise valid.

In this second case, *Novartis AG, et al. v. Ezra Ventures LLC*, No. 2017-2284 (Fed. Cir. Dec. 7, 2018) (JJ. Moore, Chen and Hughes), Ezra had filed an application seeking approval to market a generic version of Novartis's drug Gilenya<sup>®</sup>. Novartis asserted U.S. Patent No. 5,604,229 (the "229 Patent"), which covered the compound used in Gilenya<sup>®</sup>. The 229 Patent's original term had been set to expire on February 18, 2014, but, due to regulatory delays in the approval of Gilenya<sup>®</sup>, the 229 Patent received five years of PTE pursuant to 35 U.S.C. § 156, extending its term until February 18, 2019.

In the district court, Ezra argued that the 229 Patent was invalid in light of Novartis' U.S. Patent No. 6,004,565 (the "565 Patent"), which covered a specific use of the same compound and expired on September 23, 2017. The 229 and 565 Patents do not share a common specification or effective filing date. Ezra argued that Novartis violated 35 U.S.C. § 156(c)(4), which prohibits extension of more than one patent for any product, because extending the term of the 229 Patent "effectively" extended the term of the 565 Patent (which one cannot practice without practicing the 229 Patent). Ezra also argued that the earlier-filed, earlier-issued, later-expiring (because of PTE) 229 Patent was invalid for OTDP over the 565 Patent. The district court disagreed. Ezra stipulated to infringement and appealed.

The Federal Circuit affirmed. In an opinion also written by Judge Chen, the court held that there was no reason to read the word “effectively” into 35 U.S.C. § 156(c)(4). The fact that the 565 Patent cannot be practiced during the 229 Patent’s extended term is a permissible consequence of the 229 Patent’s legal term extension. The Federal Circuit also held that OTDP does not invalidate a validly obtained PTE under these circumstances. The court relied heavily on *Merck & Co. v. Hi-Tech Pharmacal Co.*, 482 F.3d 1317 (Fec. Cir. 2007), where it had held that a patent challenged in litigation was not invalid, even though its term had been disclaimed during prosecution to overcome an OTDP rejection, and then extended under 35 U.S.C. § 156. In *Merck*, the court stressed the fact that § 156 says a patent’s term “shall” be extended, distinguishing it from 35 U.S.C. § 154 (patent term adjustment for PTO delay), which excludes patents in which a terminal disclaimer had been filed from term adjustment due to PTO delay. See § 154(b)(2)(B) (“No patent the term of which has been disclaimed beyond a specified date may be adjusted under this section beyond the expiration date specified in the disclaimer.”) Ultimately, the Federal Circuit explained that, where a patent, pursuant to its pre-PTE expiration date, is valid under all provisions of law, then it is entitled to the full term of its PTE.

Practice Note: Innovators seeking to protect a new drug product should carefully select the patent for which they seek PTE. These cases do not fully address the outcome of an OTDP challenge against a patent whose term was adjusted due to PTO delay and then further extended for PTE. Because a patent whose term can be further extended by PTE will often be extended to the same date regardless of whether that patent’s term was extended due to PTO delay, patent owners should consider seeking PTE for a patent that does not already have a patent term adjustment due to PTO delay.

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