

Federal Circuit Delivers Two Important Decisions on Obviousness-Type Double Patenting

December 10, 2018

Life Sciences

On December 7, 2018, the Federal Circuit issued two highly-anticipated decisions clarifying the application of the obviousness-type double patenting doctrine: *Novartis AG v. Ezra Ventures LLC*¹ (patent term extension ("PTE")), and *Novartis Pharmaceuticals Corp. v. Breckenridge Pharmaceutical Inc.*² (pre-Uruguay Round Agreements Act ("URAA") versus post-URAA patents). In both cases, the Federal Circuit declined to extend the reasoning of *Gilead Sciences Inc. v. Natco Pharma Ltd.*³ to the factual scenarios presented.

In *Ezra*, the Federal Circuit rejected an obviousness-type double patenting attack premised on a grant of PTE under 35 U.S.C. § 156. The court held that PTE in itself does not create an obviousness-type double patenting issue, "so long as the extended patent is otherwise valid without the extension."⁴

In *Breckenridge*, the Federal Circuit rejected an obviousness-type double patenting attack on a pre-URAA patent, which used a post-URAA patent as the purportedly invalidating reference. According to the court, *Gilead* did not control because that case is "limited to the context of when both patents in question are *post*-URAA patents."⁵

Novartis v. Ezra

Novartis owned at least two patents, U.S. Patent No. 5,604,229 ("the '229 Patent") and U.S. Patent No. 6,004,565 ("the '565 Patent"), covering its multiple sclerosis drug Gilenya®. In connection with the product, Novartis sought and was granted five years of PTE, under 35 U.S.C. § 156, on the '229 Patent, rather than the '565 Patent. The '565 Patent expired on September 23,

¹ No. 2017-2284, 2018 WL 6423564 (Fed. Cir. Dec. 7, 2018) (hereinafter "*Ezra*").

² Nos. 2017-2173, 2017-2175, 2017-2176, 2017-2178, 2017-2179, 2017-2180, 2017-2182, 2017-2183, 2017-2184, 2018 WL 6423451 (Fed. Cir. Dec. 7, 2018) (hereinafter "*Breckenridge*").

³ 753 F.3d 1208 (Fed. Cir. 2014). *Gilead* held that a later-filed, earlier-expiring patent can be used as a double patenting reference to invalidate an earlier-filed but later-expiring patent.

⁴ *Ezra*, 2018 WL 6423564, at *6 (Fed. Cir. Dec. 7, 2018).

⁵ *Breckenridge*, 2018 WL 6423451, at *2 (Fed. Cir. Dec. 7, 2018) (emphasis in original) (citing *Gilead*, 753 F.3d at 1216).

2017, while the '229 Patent (including its PTE period) expires on February 18, 2019. Without PTE, the '229 Patent would have expired on February 18, 2014.

Ezra filed an ANDA related to a generic version of Gilenya[®] and Novartis filed suit, asserting the '229 Patent. Ezra attacked the validity of the claims of the '229 Patent, arguing that the PTE period of the '229 Patent was an improper extension of the term of the earlier-expiring '565 Patent that violated the PTE statute and that the '229 Patent was invalid for obviousness-type double patenting over the '565 Patent. The district court rejected these arguments, and the Federal Circuit affirmed, rejecting each argument in turn.

First, the Federal Circuit rejected Ezra's argument that the PTE on the '229 Patent violated 35 U.S.C. § 156(c)(4), which states that "in no event [may] more than one patent be extended . . . for the same regulatory review period for any product." Ezra argued that, because the '229 Patent "covers a compound necessary to practice the methods claimed in the '565 Patent,"⁶ the PTE period of the '229 Patent "effectively" and improperly extended the term of the '565 Patent. The court concluded that Novartis had complied with the legal requirements of § 156 by selecting one patent, the '229 Patent, to receive PTE. The court's analysis noted that the PTE statute intentionally gives patentees the flexibility to choose which of the patents covering the product should receive PTE. The court declined to impose a requirement on patentees to ensure that selection of a patent for PTE would not "effectively" extend the term of any other patent.

Second, the Federal Circuit concluded that, although the PTE Novartis obtained on the '229 Patent caused the '229 Patent to expire after the '565 Patent, the '565 Patent was not a proper obviousness-type double patenting reference for the '229 Patent. In reaching this conclusion, the Court relied heavily on *Merck & Co., Inc. v. Hi-Tech Pharmacal Co., Inc.*,⁷ in which the Federal Circuit upheld the validity of PTE granted to a patent that had been terminally disclaimed during prosecution to overcome an obviousness-type double patenting rejection.⁸ The Federal Circuit explained that, in the factual scenario presented in *Merck*, a terminally disclaimed patent with PTE "necessarily will expire after the patent to which it had been subject to an obviousness-type double patenting rejection."⁹ The court held that, "if a patent, under its pre-PTE expiration date, is valid under all other provisions of law, then it is entitled to the full term of its PTE."¹⁰ The court found it significant that the prosecution history of the '229 and '565 Patents did not raise concerns of gamesmanship like those present in *Gilead*, and cautioned that a "judge-made doctrine [should not] cut off a statutorily-authorized time extension."¹¹

Novartis v. Breckenridge

Novartis owns U.S. Patent No. 5,665,772 ("the '772 Patent"), which claims the compound everolimus, and 6,440,990 ("the '990 Patent"), which claims methods of treatment using everolimus and specific compositions comprising everolimus. The '772 Patent was filed prior to the effective date of the URAA, entitling it to a term of 17 years from issuance. Accordingly, its original expiration date was September 9, 2014, before application of a five-year PTE period that

⁶ *Ezra*, 2018 WL 6423564, at *4 (Fed. Cir. Dec. 7, 2018).

⁷ 482 F.3d 1317 (Fed. Cir. 2007).

⁸ *Id.* at 1318-19, 1324.

⁹ *Ezra*, 2018 WL 6423564, at *5 (Fed. Cir. Dec. 7, 2018).

¹⁰ *Id.* The court recognized, however, that if a patent should have been terminally disclaimed due to double patenting concerns but was not, that patent would be susceptible to an obviousness-type double patenting challenge. *Id.*

¹¹ *Id.* at *6.

extended the term to September 9, 2019.¹² The '990 Patent was filed after the effective date of the URAA and therefore had a term of 20 years from the earliest effective filing date (making its expiration date September 23, 2013). Thus, even though the '990 Patent was both filed after and issued after the '772 Patent, it expired before the '772 Patent. Novartis sued Appellees¹³ for infringement of the '772 Patent after Appellees sought FDA approval to market generic versions of Zortress[®] and Afinitor[®], products using everolimus as the active ingredient.

Relying on the Federal Circuit's decision in *Gilead*, the district court found that the '990 Patent was a proper double patenting reference against the '772 Patent. The district court's analysis focused on the language in *Gilead* indicating "that the expiration date is the benchmark of obviousness-type double patenting."¹⁴

The Federal Circuit reversed, concluding that *Gilead* was limited to instances in which both patents at issue are post-URAA patents, and did not apply to the case at hand because Appellees sought to use a *post*-URAA patent as a double patenting reference against a *pre*-URAA patent. The Federal Circuit found it significant that the '772 Patent's expiration after the '990 Patent was a result of an intervening change in patent term law, not any attempts by Novartis to engage in what the court termed "patent prosecution gamesmanship." The court concluded that the later-filed, later-issued, post-URAA '990 Patent was not a proper double patenting reference for the earlier-filed, earlier-issued, pre-URAA '772 patent, and instead used the issuance dates of the patents as the reference point for the analysis. The court indicated that focusing on the issuance dates was in accordance with the pre-*Gilead* approach which was to be applied to a pre-URAA patent. The Federal Circuit found this result was consistent with Congress's intent to allow patent owners who had filed patent applications before the URAA transition date to enjoy the longest possible patent term available under either pre-URAA or post-URAA patent term law.

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This alert summarizes the Federal Circuit's decisions in *Novartis AG v. Ezra Ventures LLC and Novartis Pharmaceuticals Corp. v. Breckenridge Pharmaceutical Inc.* It does not contain any opinions, characterizations, or conclusions by or of Covington & Burling LLP. As a result, the information presented herein does not necessarily reflect the views of Covington & Burling LLP or any of its clients. This information is not intended as legal advice. Readers should seek specific legal advice before acting with regard to the subjects mentioned herein.

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¹² The Federal Circuit explicitly noted that the PTE extension in this case does not affect the obviousness-type double patenting analysis because, even without the PTE granted to the '772 Patent, that patent's original expiration date of September 9, 2014, was still later than the '990 Patent's expiration date of September 24, 2013. *Breckenridge*, 2018 WL 6423451, at *4 n.2 (Fed. Cir. Dec. 7, 2018).

¹³ Appellees included Breckenridge Pharmaceutical Inc., Par Pharmaceutical, Inc., and West-Ward Pharmaceuticals International Limited.

¹⁴ *Breckenridge*, 2018 WL 6423451, at *2 (Fed. Cir. Dec. 7, 2018).