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IP Client Alert – § 156 Patent Term Extension Does Not Conflict With Obviousness-Type Double Patenting

**Novartis AG v. Ezra Ventures LLC,
909 F.3d 1367 (Fed. Cir. 2018).**

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For patents filed after June 8, 1995, the term of a patent is typically twenty years from the filing date of the patent application. 35 U.S.C. §154. However, Congress has provided avenues to extend the twenty-year term in circumstances involving agency delay. See 35 U.S.C. §§ 154, 156. Under the Hatch Waxman Act of 1984, § 156 gives patent owners an opportunity to extend a drug's patent term to compensate for the delay of obtaining Food and Drug Administration (FDA) approval. When the patent owner has multiple patents that cover a drug, the patent owner may select only one patent for patent term extension under § 156. In particular, § 156(c)(4) specifies that "in no event shall more than one patent be extended...for the same regulatory review period for any product." *Id.* The Federal Circuit, in *Novartis*, addresses the conflicts that arise when multiple patents having different patent terms cover the same drug. *Novartis AG v. Ezra Ventures LLC*, 909 F.3d 1367 (Fed. Cir. 2018).

Novartis owned U.S. Patent No. 5,604,299 (the '229 Patent) directed to its multiple sclerosis drug Gilenya®, and U.S. Patent No. 6,004,565 (the '565 Patent) directed to a method for administering Gilenya®. *Id.* at 1369. The patent term of the '229 Patent was set to expire on February 18, 2014, however, Novartis secured a patent term extension ("PTE") of five years on the '229 Patent to compensate for delays from the FDA, giving it an expiration date of February 18, 2019. *Id.* The patent term of the '565 Patent expired on September 23, 2017. *Id.*

Ezra Ventures LLC ("Ezra") filed an Abbreviated New Drug Application to introduce a generic version of Gilenya®, prompting Novartis to file a patent infringement suit against Ezra. Ezra filed a motion to dismiss under Fed. R. Civ. Pro. 12(c), which the District Court denied. Ezra appealed the District Court's holding for Novartis on the grounds that (1) Novartis was required to choose a patent from the multiple patents covering Gilenya® that would not extend the term of more than one patent from the related patents, and (2) the '229 Patent was invalid for obviousness-type double patenting. *Id.* Ezra argued that the PTE for the '229 Patent also extended the term of the '565 Patent because the '229 Patent covers a compound necessary to practice the methods claimed by the '565 Patent. *Id.* at 1372.

The Federal Circuit, however, rejected Ezra's arguments and held that the PTE for the '229 Patent past that of the '565 Patent is permissible under § 156. Additionally, a patent owner has no obligation to select the patent that is least likely to extend the terms of related patents. *Id.* at 1373 ("that the method of the '565 patent cannot be practiced during the '229 patent's extended term is a permissible consequence of the legal status conferred upon the '229 patent by §156"). Following its holding in *Merck*, the Federal circuit reiterated that obviousness-type double patenting does not invalidate a validly obtained PTE. *Id.* at 1374 (articulating that since the '229 Patent, pre-PTE, would have expired before the '565 Patent, there could be no finding of obviousness-type double patenting); see also *Merck & Co. v. Hi-Tech Phramacal Co.*, 482 F.3d 1317 (Fed. Cir. 2007).

Take away: Patent owners commonly own multiple patents that cover the same product undergoing the same regulatory overview. The Federal Circuit's recognition that protections for related patents may occur as a natural consequence of protecting a single patent under § 156 leaves the door open for patent owners to strategically protect multiple patents under the umbrella of one §156 extension. Since the benefit of an extension under § 156 is limited to one patent in that family of related patents, patent owners should take care in their selection of the patent for such extension.

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