NOVARTIS AG v. EZRA VENTURES LLC, Appeal No. 2017-2284 (Fed. Cir. December 7, 2018) (Moore, Chen, and Hughes). Appealed from D. Del. (Judge Stark).

Background:

Novartis owns the '229 Patent and the '565 Patent that are both directed to the same multiple sclerosis drug. The '229 Patent was initially set to expire prior to the '565 Patent. However, under 35 U.S.C. §156 (Hatch-Waxman Act), the '229 Patent qualified for a patent term extension (PTE) of five years. Meaning, the '229 Patent expired after the expiration of the '565 Patent due to the PTE applied to the '229 Patent.

Ezra argued that the PTE applied to the '229 Patent was impermissible because the PTE de facto extended the life of the '565 Patent, which violates §156 of the Hatch-Waxman Act. Ezra also argued that the PTE applied to the '229 Patent invalidated the '229 Patent for statutory and non-obviousness-type double patenting because the claims of the '229 Patent and the '565 Patent are not patentably distinct. The district court disagreed and held that the PTE applied to the '229 Patent was proper, and the claims of the '229 Patent and the '565 Patent do not raise a double patenting issue. Ezra appealed.

Issues/Holdings:

Did the district court err in holding that the PTE applied to the '229 Patent satisfied §156 of the Hatch-Waxman Act? - No, affirmed.

Did the district court err in holding that the claims of the '229 Patent and the '565 Patent do not raise a double patenting issue? - No, affirmed.

Discussion:

The Federal Circuit held that the PTE applied to the '229 Patent did not "de facto" extend the term of the '565 Patent. 35 U.S.C. §156(c)(4) states "in no event shall more than one patent be extended under subsection (e)(1) for the same regulatory review period for any product." Ezra argued that the '229 Patent extended the term of the '565 Patent because both patents covered the same product. However, the Federal Circuit found that §156 does not restrict selection between the two patents for PTE, and thus Novartis was free to select either the '229 Patent or the '565 Patent to apply to PTE, regardless of the impact of the patent term on products covered by the patents. The Federal Circuit stated "[t]hat 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."

The Federal Circuit also held that obviousness-type double patenting does not invalidate a validly obtained PTE when the PTE causes the '229 patent to expire after Novartis's allegedly patentably indistinct '565 patent. Under *Merck & Co. v. Hi-Tech Pharmacal Co.*, the Federal Circuit stated that "§ 154 'expressly excludes patents in which a terminal disclaimer was filed from the benefit of a term adjustment for PTO delays,' but § 156 contains 'no similar provision that excludes patents in which a terminal disclaimer was filed from the benefits of Hatch-Waxman extensions.'" Thus, the Federal Circuit similarly held that the '229 Patent, which was valid prior to applying the PTE, remains valid after applying the PTE provided by §156.