United States Court of Appeals for the Federal Circuit

NOVARTIS AG, NOVARTIS PHARMACEUTICALS CORPORATION, MITSUBISHI TANABE PHARMA CORPORATION, MITSUI SUGAR CO. LTD.,
Plaintiffs-Appellees

v.

EZRA VENTURES LLC,
Defendant-Appellant

2017-2284

Appeal from the United States District Court for the District of Delaware in Nos. 1:15-cv-00150-LPS, 1:15-cv-00975-LPS, Chief Judge Leonard P. Stark.

Decided: December 7, 2018

JANE M. LOVE, Gibson, Dunn & Crutcher LLP, New York, NY, argued for all plaintiffs-appellees. Plaintiffs-appellees Novartis AG, Novartis Pharmaceuticals Corporation also represented by ROBERT TRENCHARD; ALEXANDER N. HARRIS, San Francisco, CA; MICHAEL A. VALEK, Dallas, TX.

JOSEPH M. O'MALLEY, JR., Paul Hastings LLP, New York, NY, for plaintiffs-appellees Mitsubishi Tanabe

Pharma Corporation, Mitsui Sugar Co. Ltd. Also represented by ERIC WILLIAM DITTMANN.

SHASHANK UPADHYE, Amin Talati Upadhye LLP, Chicago, IL, argued for defendant-appellant. Also represented by BRENT ALLEN BATZER, JOSEPH CWIK, JONATHAN JACOB KRIT, YIXIN H. TANG.

Before MOORE, CHEN, and HUGHES, *Circuit Judges.*

CHEN, *Circuit Judge*.

SUMMARY

This case concerns the interplay between a patent term extension (PTE) granted pursuant to 35 U.S.C. § 156 and the obviousness-type double patenting doctrine. The Delaware District Court concluded that, in accordance with statutory construction principles and as a logical extension of this court's holding in *Merck & Co. v. Hi-Tech Pharmacal Co.*, 482 F.3d 1317 (Fed. Cir. 2007), obviousness-type double patenting does not invalidate an otherwise validly obtained PTE under § 156. We agree and accordingly affirm.

BACKGROUND

Defendant-Appellant Ezra Ventures LLC (Ezra) filed an Abbreviated New Drug Application (ANDA) relating to a generic version of Novartis's branded multiple sclerosis drug Gilenya®. Novartis filed an infringement suit against Ezra in response, asserting claims 9, 10, 35, 36, 46, and 48 of U.S. Patent No. 5,604,229.

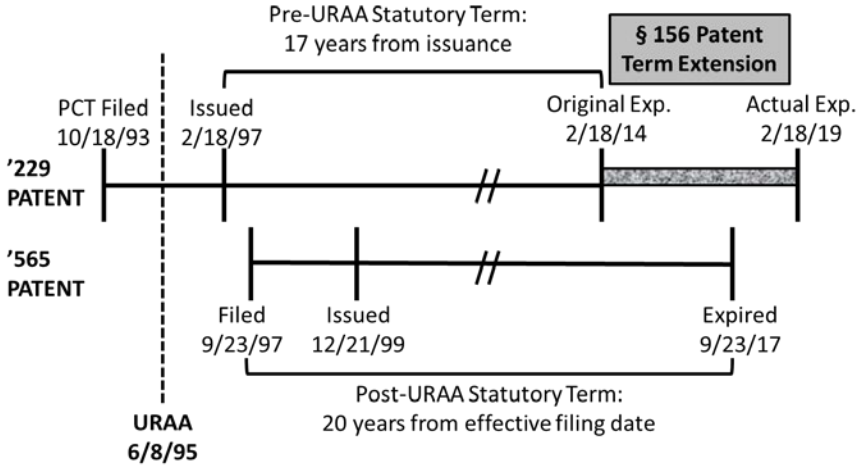
The '229 patent claims a large group of compounds, including fingolimod, the active ingredient in Gilenya®. Because the '229 patent was filed before the effective date of the Uruguay Round Agreements Act of 1994 (URAA), its patent term is governed by the law in effect at that time—the rule of 17 years from issuance. Pub. L. No.

103-465, §532, 108 Stat. 4809, 4983–85. The '229 patent thus was set to expire on February 18, 2014, 17 years from its issuance date, but Novartis secured a PTE of five years on the patent pursuant to 35 U.S.C. § 156. Section 156 was part of the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act) and was enacted to restore the value of the patent term that a patent owner loses during the early years of the patent because the product cannot be commercially marketed without approval from a regulatory agency (e.g., Food and Drug Administration approval). Pub. L. No. 98-417, 98 Stat. 1585, 1598. Section 156 allows a term extension of up to five years, equal to the regulatory review period, on a patent covering a product subject to regulatory review. *See* 35 U.S.C. §§ 156(a), (c), (g)(6). Section 156(a) sets forth the requirements for a patent to qualify for a PTE, the details of which are not relevant here.

A patent owner often owns multiple patents that cover the same product that has been subject to regulatory review, but only one patent's term can be extended. *See* 35 U.S.C. § 156(c)(4). The patent owner makes a choice among its qualifying patents. "Congress chose not to limit the availability of a patent term extension to a specific parent or continuation patent but instead chose a flexible approach which gave the patentee the choice." *Merck*, 482 F.3d at 1323; 130 Cong. Rec. 23765 (1984) ("[O]ne patent on a product, not necessarily the first, can be extended . . . ."); *id.* at 24444 ("Under this amendment, the patent holder would be allowed to select the patent to be extended. . . . I believe this amendment is acceptable because it gives the patentholder the flexibility to select the most important patent for extension.").

Here, Novartis owned at least two patents covering Gilenya® that could qualify for PTE under § 156(a): the '229 patent and U.S. Patent No. 6,004,565, which claims a method of administering fingolimod. Novartis chose to apply for PTE on the '229 patent. With the PTE granted

to the '229 patent, the '229 patent now expires on February 18, 2019. Because the '565 patent issued from a patent application filed after the effective date of the URAA, its term expired on September 23, 2017—20 years from its earliest effective filing date. *See Merck & Co. v. Kessler*, 80 F.3d 1543, 1547 (Fed. Cir. 1996) (explaining the post-URAA regime, citing § 154(a)(2) and § 154(c)(1)). The '229 patent is thus a pre-URAA patent whereas the '565 patent is a post-URAA patent, governed by different statutory patent term regimes. Below is a timeline of the relevant dates between the two patents.



On September 22, 2016, the district court denied Ezra's Federal Rule of Civil Procedure 12(c) motion for judgment on the pleadings, where Ezra argued that the '229 patent should be ruled invalid, or otherwise terminally disclaimed for the patent term past the expiration date of the unasserted '565 patent. Specifically, Ezra argued that the granted extension of the '229 patent's term beyond the life of the '565 patent is impermissible because it: (1) de facto also extends the life of the '565 patent, and thereby violates § 156(c)(4)'s requirement that only "one patent be extended"; (2) violates the "bedrock principle" that the public may practice an expired patent; and (3) renders the '229 patent invalid for statutory- and obvi-

ousness-type double patenting because Novartis's '229 patent claims are not patentably distinct from its '565 patent claims.

While § 156(c)(4) specifies that "in no event shall more than one patent be extended . . . for the same regulatory review period for any product," the district court concluded that Ezra's argument regarding the de facto extension of the '565 patent required reading "effectively" into the statute as a modifier of "extended." The district court found that such a reading did not make sense when compared to other uses of the word "extend" in the same statute, which the district court found to "refer to the legal status conferred upon a patent chosen to benefit from PTE." *Novartis AG v. Ezra Ventures, LLC*, 2016 WL 5334464, at *2 (D. Del. Sept. 22, 2016). Further, the district court relied on this court's decision in *Merck*, where we concluded that a terminally disclaimed patent could still have its term extended with a PTE because "Congress chose not to limit the availability of a patent term extension to a specific parent or continuation patent but instead chose a flexible approach which gave the patentee the choice." *Id.* (citing 482 F.3d at 1323). The district court reasoned that "[e]xtension of the term of a patent that has been terminally disclaimed [as allowed in *Merck*] 'de facto' or 'effectively' extends the life of the patent over which it is terminally disclaimed," much like the extension of the '229 patent's term effectively extends the life of the related '565 patent here. *Id.* at *3. Thus, the district court concluded that the '229 patent's term extension was permissible under § 156.

The district court also explained that "expiration of a patent does not grant the public an affirmative right to practice a patent; it merely ends the term of the patentee's right to exclude others from practicing the patent." *Id.* The district court then pointed to other ways in which the '565 patent subject matter could still be blocked from public use, e.g., other patent rights or contractual obliga-

tions. *Id.* Further, the district court found that Ezra had not provided authority indicating that a policy in favor of dedicating an expired patent's subject matter to the public can override Congress's express statutory language. *Id.*

Finally, the district court found that a judgment on the pleadings was improper for Ezra's double patenting challenge because the analysis included factual issues underlying a "construction of the claims in [the] earlier patent and later patent" and a "determination of whether differences between claims render them patentably distinct." *Id.* (citing *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 968 (Fed. Cir. 2001)). The district court directed Ezra to file for summary judgment based on double patenting at a later time, "should it have a good faith basis to do so." *Id.*

Five months after the district court denied Ezra's Rule 12(c) motion, Ezra stipulated that its ANDA product infringes claims 9, 10, 35, 36, 46, and 48 of the '229 patent if these claims are not invalid, expired, or unenforceable. Two months later, Ezra sent a letter to the district court stating that it would "not present further evidence on the issue of improper statutory and obviousness-type double patenting," and withdrew its other pending defenses. Ezra stated that its decision disposed of all pending triable issues and rendered a trial moot.

Following Ezra's letter, both Novartis and Ezra filed their respective proposed final judgments, and the district court issued judgment on June 9, 2017. The district court found the '229 patent valid, unexpired, and enforceable with the PTE, found infringement of the '229 patent, and imposed an injunction on Ezra's ANDA product until the expiration of the '229 patent in 2019.

Ezra now appeals on the issues of statutory construction of § 156 and obviousness-type double patenting.[1] We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

DISCUSSION

This court reviews questions of statutory interpretation de novo, without deference to the district court's interpretation. *Glaxo Operations UK Ltd. v. Quigg*, 894 F.2d 392, 395 (Fed. Cir. 1990). Obviousness-type double patenting is an issue of law premised on underlying factual inquiries. *Otsuka Pharm. Co. v. Sandoz, Inc.*, 678 F.3d 1280, 1290 (Fed. Cir. 2012). Accordingly, we consider the district court's ultimate conclusion on obviousness-type double patenting without deference, but we review any predicate findings of fact for clear error. *Eli Lilly & Co. v. Teva Parenteral Meds., Inc.*, 689 F.3d 1368, 1376 (Fed. Cir. 2012). To the extent any of Ezra's arguments are tied to the district court's denial of its Rule 12(c) motion, rather than the district court's final judgment, we review such denial according to the law of the regional circuit, which in this case calls for de novo appellate review. *McRO, Inc. v. Bandai Namco Games Am. Inc.*, 837 F.3d 1299, 1311 (Fed. Cir. 2016); *DiCarlo v. St. Mary Hosp.*, 530 F.3d 255, 259 (3d Cir. 2008).

I. The Validity of the '229 Patent's Term Extension

A. Section 156's "One Extended Patent" Rule

As stated above, § 156 was passed as part of the Hatch-Waxman Act, "establish[ing] a patent term extension for patents relating to certain products subject to regulatory delays that could not be marketed prior to

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[1] Ezra also initially appealed on standing and licensing issues in Appeal Nos. 2017-2283, -2286, and -2287, consolidated with this appeal, but those appeals were withdrawn before oral argument in this case.

regulatory approval." *Merck*, 482 F.3d at 1320. Section 156 provides an extension of up to five years if certain conditions are met. *See* 35 U.S.C. § 156(g)(6). Subsection 156(c)(4) provides that "in no event shall more than one patent be extended under subsection (e)(1) for the same regulatory review period for any product." This provision is relevant here because Novartis has multiple patents that cover the drug fingolimod. Subsection 156(e)(1) states that the Director of the U.S. Patent and Trademark Office makes the determination of a patent's term extension eligibility, and if the requirements of subsection 156(a) are met, then the Director "shall issue" the extension for that patent. *See* 35 U.S.C. § 156(e)(1).

Although § 156 recognizes that a patent owner may own multiple patents relating to a product, a method of using that product, and/or a method of manufacturing the product, nothing in the statute restricts the patent owner's choice for patent term extension among those patents whose terms have been partially consumed by the regulatory review process. Importantly, Congress did not, through § 156, compensate a loss of term for all patents affected by regulatory review. In striking a balance between the competing interests of new drug developers and low-cost generic competitors, Congress limited a PTE grant for such a patent owner to only one of its patents.

Ezra argues that Novartis violated § 156(c)(4) because, in its view, *two* patents were extended here: the extension of the '229 patent's term "effectively" extended the '565 patent's term as well, because the '229 patent covers a compound necessary to practice the methods claimed by the '565 patent.

We agree with the district court, however, that there is no reason to read "effectively" as a modifier to "extend" in the language of § 156(c)(4). As a basic principle of statutory construction, courts "ordinarily resist[] reading words into a statute that do not appear on its face." *Bates*

v. United States, 522 U.S. 23, 29 (1997). Further, as the district court found, "throughout the rest of § 156, 'extend,' 'extension,' and 'extending' refer to the legal status conferred upon a patent chosen to benefit from PTE." *Novartis*, 2016 WL 5334464, at *2 (citing 35 U.S.C. § 156(a) and (b)). This legal status is the literal changing of the patent's expiration date by the Director under § 156, ensuring a government-granted de jure exclusionary right for an extended time period—as opposed to an "effective" or "de facto" exclusion. Section 156(c)(4)'s language that "in no event shall more than one patent be extended under subsection (e)(1) for the same regulatory review period for any product" was intended to limit a legally conferred PTE (not an "effective" or "de facto" PTE) to one patent selected by the patent owner. Here, only the '229 patent was selected and then legally extended with a certificate of extension "recorded in the official file of the patent and . . . considered as part of the original patent." 35 U.S.C. § 156(e)(1). 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.

Ezra also contends that in order to comply with § 156, "Novartis had to make a choice [as to which patent to extend] in such a way as to ensure that 'in no event shall more than one' patent be extended." Appellant's Br. 22. We see nothing in the text, structure, or history of § 156 that imposes such a requirement on patent owners. In fact, we have found the opposite in *Merck*: Congress chose not to limit the availability of a patent term extension to a specific patent and instead chose "a flexible approach which gave the patentee the choice." 482 F.3d at 1323. As long as the requirements for a patent term extension recited in § 156(a) are met, the Director of the Patent and Trademark Office "shall" grant a PTE on the patent of patentee's choice. *See* 35 U.S.C. § 156(e)(1).

We thus conclude that Novartis's selection of its '229 patent for term extension does not violate § 156(c)(4).

B. The Interaction Between Section 156 and Obviousness-Type Double Patenting

This case also presents the question of whether the '229 patent is invalid due to obviousness-type double patenting because the term extension it received causes the '229 patent to expire after Novartis's allegedly patentably indistinct '565 patent. We conclude, as a logical extension of our holding in *Merck & Co. v. Hi-Tech Pharmacal Co.*, that obviousness-type double patenting does not invalidate a validly obtained PTE in such a scenario.

In *Merck*, U.S. Patent No. 4,797,413 was terminally disclaimed after the expiration of U.S. Patent No. 4,677,115 to overcome an obviousness-type double patenting rejection during prosecution. 482 F.3d at 1318–19. The '413 patent later received a PTE of 1,233 days pursuant to § 156. *Id.* at 1319. Appellant Hi-Tech Pharmacal Co. argued that "as a condition for the lifting of the double-patenting rejection and thus the grant of the '413 patent, Merck disclaimed any extension of its term beyond the expiration of the '115 patent and is thus foreclosed from obtaining a term extension under § 156." *Id.* at 1321. This court upheld the validity of the '413 patent's term extension grant. *Id.* at 1324. We first recognized that a straightforward reading of § 156 mandates a term extension so long as the other enumerated statutory requirements for a PTE are met. *Id.* at 1321–22 (citing 35 U.S.C. § 156(a)). We then noted the contrast between § 156 for PTE with the language of § 154 for patent term adjustments: § 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." *Id.* at 1322. Thus, this court concluded that

"[t]he express prohibition against a term adjustment regarding PTO delays [under § 154(b)], the absence of any such prohibition regarding Hatch-Waxman extensions, and the mandate in § 156 that the patent term shall be extended if the requirements enumerated in that section are met, support the conclusion that a patent term extension under § 156 is not foreclosed by a terminal disclaimer." *Id.*

We agree with the district court's observation that if a patent is terminally disclaimed to another patent to overcome an obviousness-type double patenting rejection and then term-extended under § 156 (as in *Merck*), it necessarily will expire after the patent to which it had been subject to an obviousness-type double patenting rejection. Such an extension would result in the situation, as here, where the term of patent protection afforded to the patentably indistinct patent to which the extended patent was terminally disclaimed is—in Ezra's words—"effectively" extended because of a PTE granted pursuant to § 156.

Ezra attempts to distinguish *Merck* by characterizing that case as involving "invalidity for obviousness-type-double-patenting . . ., not statutory construction of Section 156," and arguing that the *Merck* court's rationale only "spoke to the impact of a new PTE on preexisting terminal disclaimers." Appellant's Br. 21–22. But the bulk of the *Merck* opinion engages in a statutory construction of § 156. *See* 482 F.3d at 1321–23. And its holding on the validity of a PTE for a patent that was terminally disclaimed *in order to overcome an obviousness-type double patenting rejection* is directly relevant to the instant case.

Finally, Ezra argues that a PTE must not be granted if such an extension violates other provisions of law, such as invalidity under 35 U.S.C. §§ 102 and 103 or obviousness-type double patenting. We agree to the extent of considering a patent's validity *without* a § 156 extension.

For example, if a patent, under its original expiration date without a PTE, should have been (but was not) terminally disclaimed because of obviousness-type double patenting, then this court's obviousness-type double patenting case law would apply, and the patent could be invalidated. However, 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.

II. Ezra's Policy Concerns

This case does not raise the traditional concern with obviousness-type double patenting of a patent owner "extending his exclusive rights to an invention through claims in a later-filed patent that are not patentably distinct from claims in the earlier filed patent." *Proctor & Gamble Co. v. Teva Pharm. USA, Inc.*, 566 F.3d 989, 999 (Fed. Cir. 2009). Here, it is the earlier-filed, earlier-issued '229 patent, not the later-filed, later-issued '565 patent, that has the later expiration date, due to a statutorily-allowed term extension under § 156.

This case also does not present the concerns that drove recent decisions of this court regarding obviousness-type double patenting in the post-URAA context. For example, there is no potential gamesmanship issue through structuring of priority claims as identified in *Gilead Sciences, Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208 (Fed. Cir. 2014). In *Gilead*, where the relevant patents were both post-URAA patents, this court found that a patent that issues after, but expires before, another patent could qualify as a double patenting reference for that other, later-expiring patent. *Id.* at 1211–12, 1217. *Gilead* recognized a situation where "inventors could routinely orchestrate" longer patent-exclusivity periods by (1) filing serial patent applications on obvious modifications of an invention, (2) claiming different priority dates in each, and then (3) strategically responding to prosecution deadlines such that the application claiming the

latest filing date issues first, without triggering a terminal disclaimer for the earlier filed applications. *Id.* at 1215. This court prevented such an outcome by holding that expiration dates were what "really mattered" for an obviousness-type double patenting analysis in this context. *Id.* at 1215.[2] Here, Ezra does not identify any similar tactics on the part of Novartis. But for the § 156 PTE, the '229 patent would have expired before the '565 patent.[3] So there is also no concern that Novartis, once its '229 patent issued, sought to subsequently "secur[e] a second, later expiring patent for the same invention" as in *Abbvie Inc. v. Mathilda & Terence Kennedy Institute of Rheumatology Trust.*, 764 F.3d 1366, 1373 (Fed. Cir. 2014).

Further, this court has described obviousness-type double patenting as a "judge-made doctrine" that is intended to prevent extension of a patent beyond a "statutory time limit." *In re Berg*, 140 F.3d 1428, 1431–32 (Fed. Cir. 1998). Here, agreeing with Ezra would mean that a judge-made doctrine would cut off a statutorily-authorized time extension. We decline to do so.

CONCLUSION

By applying statutory construction principles, following this court's precedent in *Merck*, and addressing traditional obviousness-type double patenting principles, we

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[2] The effect of statutory term extensions was expressly not considered in *Gilead*. 753 F.3d at 1215 n.6.

[3] This is true of the '229 and '565 patents even though one was pre-URAA and the other post-URAA, a circumstance that can raise issues such as those addressed in *Novartis Pharmaceutical Corp. v. Breckenridge Pharmaceutical Inc.*, Nos. 2017-2173, 2017-2175, 2017-2176, 2017-2178, 2017-2179, 2017-2180, 2017-2182, 2017-2183, 2017-2184 (Fed. Cir. Dec. 7, 2018).

hold that a PTE pursuant to § 156 is valid so long as the extended patent is otherwise valid without the extension. Thus, the district court was correct in finding that the '565 patent is not a double patenting reference to the '229 patent and that the '229 patent is valid through the end of its PTE.[4] Accordingly, we affirm the district court's final judgment.

AFFIRMED

COSTS

No Costs.

[4] Because we find that the '565 patent is not a double patenting reference for the '229 patent, we need not address Ezra's arguments as to whether the '229 patent is patentably indistinct from the '565 patent. Ezra presents no other arguments as to the invalidity of the '229 patent to this court.