NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

IDORSIA PHARMACEUTICALS, LTD.,
Plaintiff-Appellant

v.

ANDREI IANCU, UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE,
Defendant-Appellee

2019-2346

Appeal from the United States District Court for the Eastern District of Virginia in No. 1:17-cv-00922-TSE-TCB, United States District Judge T. S. Ellis, III.

Decided: May 11, 2020

THOMAS HOXIE, Hoxie & Associates, LLP, Millburn, NJ, for plaintiff-appellant. Also represented by CORY S. POKER.

PETER JOHN SAWERT, Office of the Solicitor, United States Patent and Trademark Office, Alexandria, VA, for defendant-appellee. Also represented by KAKOLI

CAPRIHAN, BRIAN RACILLA, THOMAS W. KRAUSE; G. ZACHARY TERWILLIGER, KIMERE JANE KIMBALL, Office of the United States Attorney for the Eastern District of Virginia, United States Department of Justice, Alexandria, VA.

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

STOLL, *Circuit Judge*.

Idorsia Pharmaceuticals, Ltd. appeals the district court's summary judgment upholding the U.S. Patent and Trademark Office's patent term adjustment (PTA) determination for U.S. Patent No. 8,518,912. Specifically, Idorsia challenges the PTO's calculation of "A Delay," whereby a patent's term is adjusted when the PTO fails to respond to certain events or filings by statutorily enumerated examination deadlines. Because the district court correctly concluded that the PTO examiner's first of three restriction requirements satisfied the notice requirement of 35 U.S.C. § 132, and thus ended the accumulation of A Delay for the '912 patent, we affirm.

BACKGROUND

I

Idorsia's predecessor in interest in the '912 patent, Actelion Pharmaceuticals, Ltd., filed U.S. Patent Application No. 12/745,358 as a national stage application under 35 U.S.C. § 371. Following a preliminary amendment, the '358 application included independent claim 1 and dependent claims 2–14 and 16. Claim 1 is a compound claim reciting a chemical formula with the group $P(O)R^5R^8$. Claim 1 also recites various options for substituents R^5 and R^8.

On March 14, 2012, the PTO examiner issued a restriction requirement. The examiner identified six invention groups for all pending claims that were "independent

and distinct from each other because they [we]re directed to structurally dissimilar compounds that lack a common core" based on the possible variations for the group $P(O)R^5R^8$. J.A. 598. The examiner stated that "[r]estriction [wa]s required under 35 U.S.C. [§]121," J.A. 597, which grants the PTO the authority to limit a patent application claiming "two or more independent and distinct inventions" to one invention for continued prosecution. In response to the restriction requirement, Actelion notified the examiner by telephone that the examiner's defined invention groups omitted certain subject matter from the scope of the claims. The examiner agreed and indicated that he would issue a new restriction requirement. Actelion did not elect any of the invention groups in the initial restriction requirement.

About one month later, on April 18, 2012, the examiner issued a second restriction requirement that superseded and replaced the first restriction requirement. The examiner divided all pending claims into eight distinct invention groups. Actelion notified the examiner by telephone that the invention groups set forth in the second restriction requirement omitted claimed subject matter. The examiner agreed and indicated that he would issue a third restriction requirement. Actelion did not elect any of the invention groups in the second restriction requirement.

On June 21, 2012, the examiner issued a third restriction requirement, which divided all pending claims into three distinct invention groups. Actelion filed a response to the third restriction requirement, electing one of the three invention groups, and traversed the restriction.

The '358 application issued as the '912 patent on August 27, 2013. That same day, the PTO issued an initial PTA determination for the '912 patent of 314 days, which included 229 days of A Delay. The PTO awards A Delay for delays arising from the PTO's failure to act by certain enumerated deadlines. Relevant to this case, A Delay is based

on the time that passes between the date that is "14 months after" the "date of commencement of the national stage under section 371 in an international application" and the date that the PTO "provide[s] at least one of the notifications under section 132 or a notice of allowance under section 151." 35 U.S.C. § 154(b)(1)(A)(i); *see also* 37 C.F.R. § 1.703(a)(1).

Following Actelion's request for reconsideration of PTA, the PTO issued a final decision calculating a total of 346 days of PTA, including 261 days of A Delay, based on its determination that the examiner's second restriction requirement stopped the accrual of A Delay. Actelion then sued the PTO in the U.S. District Court for the Eastern District of Virginia, challenging the PTA determination. In March 2016, the district court remanded the case to the PTO to reconsider its PTA calculation in light of *Pfizer, Inc. v. Lee*, 811 F.3d 466 (Fed. Cir. 2016). Order, *Actelion Pharm. Ltd. v. Lee*, No. 15-1266 (E.D. Va. Mar. 2, 2016), ECF No. 23. Thereafter, the PTO issued its final determination of PTA for the '912 patent, which totaled 311 days of PTA, including 226 days of A Delay, based on its finding that A Delay stopped accruing after the examiner's first restriction requirement.

II

Idorsia brought the instant lawsuit pursuant to 35 U.S.C. § 154(b)(4)(A), the Administrative Procedure Act (APA), and the Fifth Amendment of the U.S. Constitution, challenging the PTO's PTA determination. Specifically, Idorsia argued that A Delay continued to accrue for an additional 99 days after the date calculated by the PTO because the first and second restriction requirements did not meet the notice requirement of 35 U.S.C. § 132.

The parties cross-moved for summary judgment. The district court granted summary judgment in favor of the PTO, holding that the first restriction requirement complied with § 132 based on the standard set forth in this

court's *Pfizer* decision. *Idorsia Pharm. Ltd. v. Iancu*, 393 F. Supp. 3d 445, 453–54 (E.D. Va. 2019).

Idorsia appeals. We have jurisdiction pursuant to 28 U.S.C. §§ 1295(a)(1), (a)(4)(C).

DISCUSSION

We review the district court's grant of summary judgment de novo, "applying the same standard as the district court." *Pfizer*, 811 F.3d at 470 (quoting *Voter Verified, Inc. v. Premier Election Sols., Inc.*, 698 F.3d 1374, 1379 (Fed. Cir. 2012)). The PTO's PTA decisions are reviewed in accordance with the APA. 35 U.S.C. § 154(b)(4)(A). Under the APA, a court may set aside the PTO's actions only if they are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). We hold that under *Pfizer*, the examiner's first restriction requirement met the notice requirement of § 132 and thus ended the accrual of A Delay for the '912 patent.

I

A Delay stops accruing when the PTO "provide[s] at least one of the notifications under section 132." 35 U.S.C. § 154(b)(1)(A)(i). A written restriction requirement qualifies as a "notification[] under section 132." *Pfizer*, 811 F.3d at 471–72. Section 132 provides, in pertinent part:

> Whenever, on examination, any claim for a patent is rejected, or any objection or requirement made, the Director shall notify the applicant thereof, stating the reasons for such rejection, or objection or requirement, together with such information and references as may be useful in judging of the propriety of continuing the prosecution of his application . . . .

35 U.S.C. § 132(a).

In *Pfizer*, we held that § 132 "merely requires that an applicant 'at least be informed of the broad statutory basis for [the rejection of] his claims, so that he may determine what the issues are on which he can or should produce evidence.'" 811 F.3d at 472 (alteration in original) (quoting *Chester v. Miller*, 906 F.2d 1574, 1578 (Fed. Cir. 1990)). We explained that § 132 also requires that the examiner's rejection be "sufficiently informative to allow [the applicant] to counter the grounds for rejection." *Id.* at 473–74 (citations omitted). As to this second requirement for notice, we reaffirmed our precedent holding that § 132 "is violated when a rejection is so uninformative that it prevents the applicant from recognizing and seeking to counter the grounds for rejection." *Id.* at 471–72 (quoting *Chester*, 906 F.2d at 1578).

II

In this case, Idorsia does not dispute that the examiner's first restriction requirement provided notice of the statutory basis for the examiner's rejection, namely, that restriction was required under 35 U.S.C. § 121. Rather, the parties' dispute focuses on whether the first restriction requirement was "sufficiently informative to allow [Actelion] to counter the grounds for rejection." *Pfizer*, 811 F.3d at 473–74. We agree with the district court and the PTO that under *Pfizer*, the examiner's first restriction requirement for the '912 patent satisfied the notice requirement of § 132.

The examiner's first restriction requirement asserted that all pending claims of the '358 application were subject to the restriction requirement. The first restriction requirement also defined the invention groups available for election, and articulated the reasons that the examiner believed that the '358 application claimed multiple distinct inventions. Moreover, Actelion was able to respond to the first restriction requirement and successfully oppose the examiner's description of the multiple invention groups,

which demonstrates that Actelion was able to understand the examiner's proposed invention groups and prepare responsive arguments. Thus, as in *Pfizer*, the first restriction requirement, when "[v]iewed as a whole," provided "adequate grounds on which" Actelion could "recogniz[e] and seek[] to counter the grounds for rejection." 811 F.3d at 472 (alterations in original) (quoting *Chester*, 906 F.2d at 1578).

Idorsia contends that neither the first nor the second restriction requirements qualifies as sufficient notice under § 132. In particular, Idorsia argues that the examiner's defined invention groups' omission of subject matter from the scope of the claims violates § 132 because "Actelion plainly lacked the necessary information to determine how to proceed." Appellant's Br. 26. Idorsia attempts to distinguish *Pfizer* on the ground that in *Pfizer*, the restriction requirement at issue omitted dependent claims from the defined invention groups, not subject matter from independent claims.

We reject Idorsia's overly narrow reading of *Pfizer*. A restriction requirement need not be correct to satisfy the statutory notice requirement. *See Univ. of Mass. v. Kappos*, 903 F. Supp. 2d 77, 86 (D.D.C. 2012) ("*UMass*") (rejecting as "irrelevant to . . . calculating A delay" the question of whether or not "it was necessary [for the applicant] to persuade the Examiner to revise the restriction requirement" to correct certain errors). Actelion's and the examiner's "exchanges concerning the challenged restriction requirement were part of the typical 'back and forth' process of patent prosecution." *Pfizer*, 811 F.3d at 475–76 (quoting *UMass*, 903 F. Supp. 2d at 86). Although this process "often involves changes in both the applicant's and examiner's positions, an examiner's reissuance of an office action in response to an applicant's suggestion does not automatically mean that an application has been 'delayed' for purposes of patent term adjustment." *Id.* at 475 (quoting *UMass*, 903 F. Supp. 2d at 86). Section 132 "does not

award additional A delay if an applicant successfully convinces the PTO that the Office action was erroneous." *UMass*, 903 F. Supp. 2d at 86–87. Indeed, the "underlying purpose of PTA is to compensate patent applicants for *certain reductions* in patent term that are not the fault of the applicant, not to guarantee the correctness of the agency's every decision." *Pfizer*, 811 F.3d at 476 (internal quotation marks omitted) (quoting *UMass*, 903 F. Supp. 2d at 86). Based on the record evidence, we agree with the PTO and the district court that Idorsia's alleged delay is "not the type of error for which the Act was intended to compensate." *Id.*

We have considered Idorsia's other arguments, but we do not find them persuasive. The PTO properly calculated the length of PTA for the '912 patent. Accordingly, we conclude that the district court did not err in granting summary judgment in favor of the PTO.

CONCLUSION

For the foregoing reasons, we affirm the judgment of the district court.

AFFIRMED

COSTS

No costs.