

**United States Court of Appeals
for the Federal Circuit**

DAIICHI SANKYO COMPANY, LTD.,
Plaintiff-Appellant

v.

MICHELLE K. LEE, Director,
United States Patent and Trademark Office,
Defendant-Appellee

2014-1280

Appeal from the United States District Court for the District of Columbia in No. 1:10-cv-00215-RWR, Judge Richard W. Roberts.

Decided: July 2, 2015

DARYL JOSEFFER, King & Spalding LLP, Washington, DC, argued for plaintiff-appellant. Also represented by ADAM CONRAD, Charlotte, NC; KENNETH H. SONNENFELD, MARGARET B. BRIVANLOU, MICHAEL P. DOUGHERTY, New York, NY.

BRIAN THOMAS RACILLA, Office of the Solicitor, United States Patent and Trademark Office, Alexandria, VA, argued for defendant-appellee. Also represented by NATHAN K. KELLEY, FARHEENA YASMEEN RASHEED; JOHN G. INTERRANTE, U.S. Attorney's Office, Washington, DC.

Before MOORE, REYNA, and TARANTO, *Circuit Judges*.

REYNA, *Circuit Judge*.

Daiichi Sankyo Company, Ltd. (“Daiichi”) brought suit in the District Court for the District of Columbia challenging patent term adjustments made by the United States Patent and Trademark Office (“PTO”) for two Daiichi patents. The district court granted summary judgment in favor of the government. Daiichi appeals from the entry of final judgment in the government’s favor. For the reasons given below, we *affirm*.

I. BACKGROUND

A. THE PATENT TERM STATUTE, 35 U.S.C. § 154

Section 154 of the Patent Act restores a patent’s term for two types of delay during patent prosecution that are attributable to the PTO. The first type of delay, “A Delay,” arises when the PTO fails to meet statutory deadlines for events that occur during prosecution, such as providing notice to the applicant of the rejection of a claim or taking action on an applicant’s reply to such a rejection. 35 U.S.C. § 154(b)(1)(A). The second type of delay, “B Delay,” arises when, through the fault of the PTO, the agency fails to issue a patent within three years after the actual filing date of the patent’s application. *Id.* § 154(b)(1)(B).¹

Two patent term adjustment determinations are made prior to the issuance of a patent. First, when the PTO determines that a patent is in condition for allow-

¹ The letter designation for the two types of delay described, A or B, corresponds to the statutory subparagraph governing how the particular delay is handled, 35 U.S.C. § 154(b)(1)(A) or (b)(1)(B), respectively.

ance, the agency will make an initial determination and will “transmit a notice of that determination with the written notice of allowance of the application” to the applicant. 35 U.S.C. § 154(b)(3)(B)(i) (2012).² At the time of issuance, and upon a timely request for reconsideration that satisfies the regulatory requirements, the PTO will make a final determination, which it then prints on the face of the patent. *See* 37 C.F.R. § 1.705(d) (2012).

B. REVIEW OF PATENT TERM ADJUSTMENTS

A patentee who is dissatisfied with the number of days restored to the term of the patent has a statutory right to both administrative and judicial review. Regarding administrative review, the statute requires the Director of the PTO to provide a patentee one opportunity to request reconsideration of any patent term adjustment determination made by the agency. 35 U.S.C. § 154(b)(3)(B)(ii). The statute instructs the Director to prescribe regulations that create the procedures for challenging the determination at the agency. *See id.* § 154(b)(3)(A), (b)(3)(B). The PTO promulgated 37 C.F.R. § 1.705, which imposes a deadline for requesting that the agency reconsider the patent term adjustment determination, stating that “any request for reconsideration of the patent term adjustment indicated in the patent must be filed within two months of the date the patent issued.” 37 C.F.R. § 1.705(d) (2012).

Additionally, a patentee can seek judicial review of the agency’s patent term adjustment determination.

² After the 2013 amendments, the current version of § 154 requires notification of a patent term adjustment at the time of issuance. Leahy-Smith America Invents Act Technical Corrections, Pub. L. No. 112-274, § 154, 126 Stat. 2456, 2457 (2013). The discussion here is about the previous version of the statute before those amendments.

Under the statute in force when Daiichi filed this action, a patentee who was dissatisfied with the determination could bring an action against the Director of the PTO in the District Court for the District of Columbia within 180 days after the issuance of the patent. 35 U.S.C. § 154(b)(4)(A) (2006) (amended 2011).

C. THE *WYETH* DECISION

Prior to 2010, the PTO's practice was to restore, upon issuance, patent term equaling the greater of the number of days of A and B Delays occurring during prosecution. *Wyeth v. Kappos*, 591 F.3d 1364, 1368 (Fed. Cir. 2010). The PTO explained this method for calculating patent term adjustments in the Federal Register in 2004. *Id.* at 1367–68 (quoting 69 Fed. Reg. 21706 (Apr. 22, 2004) (“2004 PTO Notice”)).

In 2007, a patent-holder brought a suit that challenged the PTO's practice of adjusting the patent term by the greater of the A and B Delay. *Wyeth v. Dudas*, 580 F. Supp. 2d 138 (D.D.C. 2008). The District Court for the District of Columbia rejected the PTO's practice on the basis that it effectively counts B Delay before it occurs. *Id.* at 142. We affirmed the district court's rejection of the PTO's practice in *Wyeth v. Kappos*. 591 F.3d at 1372. The effect of *Wyeth* was to require the PTO to extend a patent's term for every day of A or B Delay where those delays did not occur on the same day, and to extend the term by one day for each day the A and B Delays did occur on the same day.

On February 1, 2010, after we decided *Wyeth*, the PTO adopted an “Interim Procedure” for requesting patent term adjustments. The Interim Procedure set out the procedure by which a patentee could request reconsideration within two months of the patent issuance date. 75 Fed. Reg. 5043 (Feb. 1, 2010). The Interim Procedure also adopted an “optional” procedure (“Optional Interim Procedure”) for patents that issued before March 2, 2010.

Under the Optional Interim Procedure, patentees could file a petition for reconsideration up to 180 days after the issuance date, provided the sole basis for the request was that the patent term adjustment was made under the PTO's pre-*Wyeth* adjustment calculation method. *Id.* at 5043–44. The net result of the specified date and filing window was to make the Optional Interim Procedure available for patents that issued from August 5, 2009 (the earliest date of availability of the Optional Interim Procedure) to March 1, 2010. Petitions filed outside this 180-day window would be “den[ied] as untimely.” *Id.* at 5044. This appeal involves Daiichi's challenge to the PTO's denial of Daiichi's requests for reconsideration of the patent term adjustments for two of its patents.

D. DAIICHI'S PATENTS

Daiichi is a pharmaceutical company that owns three patents that it claims have been affected by the PTO's pre-*Wyeth* interpretation. These three patents, U.S. Patent Nos. 7,342,014 (“’014 patent”), 7,365,205 (“’205 patent”), and 7,567,135 (“’135 patent”), cover compounds that are useful for treating tissue death due to lack of oxygen, blood clots, and other ailments. The ’014 and ’205 patents issued before August 5, 2009 and, thus, did not qualify for the Optional Interim Procedure.³ According to Daiichi, in the PTO's patent term adjustment calculations for each of Daiichi's patents in this case, the agency chose to restore days for either the A or B Delay, but not both. Daiichi claims that the term of each of its patents was shortened by at least 321 days under the pre-*Wyeth* calculation method.

³ As discussed below, the ’135 patent issued after August 5, 2009. Daiichi invoked the Optional Interim Procedure for the ’135 patent.

E. PROCEDURAL HISTORY

Shortly after the district court's decision in *Wyeth*, but before the implementation of the Interim Procedure, Daiichi filed a petition requesting reconsideration of the patent term adjustments for the '014 and '205 patents under 37 C.F.R. § 1.705(d).

Because Daiichi's petitions were filed outside the two-month window set in 37 C.F.R. § 1.705(d), Daiichi concurrently filed a petition to waive the two-month window under 37 C.F.R. § 1.183. Section 1.183 allows the Director, on petition, to waive regulatory requirements in "extraordinary situations" when justice so requires. Daiichi argued that the district court's *Wyeth* decision constituted an extraordinary situation that justified waiving the normal two-month window for filing a request for reconsideration of the patent term adjustments under 37 C.F.R. § 1.705(d).

In late March and early April 2010, the PTO dismissed both of Daiichi's waiver petitions and denied both requests for reconsideration of the patent term adjustments because neither was timely filed within the required two-month window. Neither rejection mentioned the Interim Procedure.

Daiichi filed requests for reconsideration of the dismissals of its waiver petitions and its requests for reconsideration of the patent term adjustments for both the '014 and '205 patents. The PTO rejected both requests on the same grounds. The PTO explained that the Optional Interim Procedure allowed a patent owner to request recalculation of the patent term adjustment within 180 days after the grant of the patent. Further, the PTO had determined "not to accept *any* requests for PTA [patent term adjustment] recalculation initially filed more than 180 days after patent grant" because the judicial-review provision of 35 U.S.C. § 154(b)(4) evidenced "congressional

intent that PTA issues be resolved” soon after issuance. J.A. 3121, 3382. (emphasis underlined in original).

The PTO explained that it did not believe Congress intended to create a scheme “under which the time period to seek initial USPTO review of a PTA determination extends beyond the” 180-day “time period provided for a dissatisfied patentee to seek judicial review” of the PTO’s adjustment determination under § 154(b)(4). *Id.* at 3121–22, 3382. Accordingly, the PTO believed that the 180-day period of § 154(b)(4) “represent[ed] the outer limit” of its authority to conduct an administrative review of patent term adjustment determinations. *Id.* at 3122, 3383.

On February 12, 2010, Daiichi simultaneously filed the instant lawsuit seeking judicial review of the adjustments for all three patents under the Administrative Procedure Act (“APA”) and § 154(b)(4)(A) and petitioned the PTO for recalculation of the patent term adjustment for the ’135 patent. The PTO dismissed the petition for recalculation of the adjustment for the ’135 patent based on Daiichi’s challenge to that adjustment in the district court.

Because the ’135 patent was granted within 180 days of the March 2, 2010 deadline, it was eligible for the Optional Interim Procedure. The district court, thus, remanded the ’135 patent to the PTO, which recalculated the patent term adjustment from 86 days to 503 days. According to Daiichi, this made no practical difference, however, since the ’135 patent is terminally disclaimed over both the ’014 and ’205 patents. The latter two patents are also terminally disclaimed over each other, so that none of the three patents can be enforced past the earliest date of expiration of either the ’014 or ’205 patents.

Daiichi amended its district court complaint to seek relief on the ’014 and ’205 patents. It alleged the PTO violated the APA and § 154(b) by (1) miscalculating the

patent terms for the '014 and '205 patents and (2) refusing to reconsider its patent term adjustments in light of our decision in *Wyeth*. The parties filed cross-motions for summary judgment.

In its motion for summary judgment, Daiichi presented three arguments relevant to this appeal. First, it contended that 35 U.S.C. § 154(b)(4)(A)'s 180-day limitations period for judicial review does not apply to challenges to final patent term adjustment determinations, like Daiichi's challenge. Daiichi argued that § 154(b)(4)(A) governs only challenges to determinations made at the time of the allowance, i.e., initial determinations. Since B Delay takes into account delay in issuing a patent, it cannot be determined at the time of allowance. Therefore, Daiichi's challenge to the final patent term adjustments for its patents is not subject to the 180-day limitations period of § 154(b)(4)(A). According to Daiichi, the regular six-year statute of limitations of the APA applies to final patent term adjustment determinations made at the time of issuance. *Id.* at 3717–25.

Second, Daiichi argued that even if the 180-day period does apply to final patent term adjustments, that period should be equitably tolled because Daiichi relied on the 2004 PTO Notice disclosing how it would calculate A and B Delay, and because it acted promptly to seek administrative and judicial review in the wake of the district court's *Wyeth* decision. *Id.* at 3730–38.

Third, Daiichi challenged the PTO's use of a 180-day period for administrative review under the APA. According to Daiichi, 35 U.S.C. § 254 allows the PTO to correct mistakes in a patent whenever they occur. Thus, the importation of the 180-day period for judicial review into the context of administrative review of patent term adjustments was overly restrictive, and therefore arbitrary, capricious, and not in accordance with the law. *Id.* at 3725–30.

The district court rejected each of Daiichi's arguments. As to whether § 154(b)(4)(A) applies to final determinations, the district court found that this provision refers to any determination "under paragraph (3)," including those made under § 154(b)(3)(A). That section requires the Director to prescribe regulations governing procedures for the determination of patent term adjustments, without limiting the Director to creating procedures only for initial adjustment determinations. 35 U.S.C. § 154(b)(3)(A). Thus, the district court found that the plain meaning of the statute made clear that § 154(b)(4)(A) covered final determinations. *Daiichi Sankyo Co., Ltd. v. Rea*, 12 F. Supp. 3d 8, 16 (D.D.C. 2013).

On the issue of equitable tolling, the district court found that Daiichi could have brought a lawsuit making the same arguments that Wyeth did within the 180-day period, yet failed to do so. As such, Daiichi had not shown the existence of extraordinary circumstances, a prerequisite for equitable tolling. *Id.* at 20.

The district court also rejected Daiichi's argument that it was entitled to relief under the APA because the PTO's refusal to suspend the 180-day filing period of the Optional Interim Procedure as to the '014 and '205 patents was arbitrary, capricious, and not in accordance with law. The district court granted summary judgment to the government and entered final judgment in its favor.

On appeal, Daiichi challenges the district court's determinations (1) that the PTO's denial of administrative relief on Daiichi's requests for reconsideration of the patent term adjustments was not contrary to law, arbitrary, capricious, or an abuse of discretion under the APA; (2) that the 180-day limitations period applies to final patent term adjustment determinations; and (3) that 35 U.S.C. § 154(b)(4)(A) is not subject to equitable tolling. For the reasons stated below, we *affirm*.

II. DISCUSSION

We review the grant of summary judgment under the law of the regional circuit, here the D.C. Circuit. *Epos Techs. Ltd. v. Pegasus Techs. Ltd.*, 766 F.3d 1338, 1341 (Fed. Cir. 2013). The D.C. Circuit reviews the grant of summary judgment de novo. *Coal. for Common Sense in Gov't Procurement v. United States*, 707 F.3d 311, 315 (D.C. Cir. 2013). Summary judgment is appropriate when, after drawing all justifiable inferences in the nonmoving party's favor, *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986), there are no genuine issues of material fact and the movant is entitled to judgment as a matter of law, Fed. R. Civ. P. 56(a).

III. DAIICHI'S CHALLENGE UNDER THE APA

A. DENIAL OF RECONSIDERATION

Daiichi argues that the PTO's denials of its requests for reconsideration of the patent term adjustments were an abuse of the agency's discretion. Daiichi argues that the PTO's view that § 154(b)(4) prevents it from recalculating patent term adjustments more than 180 days after a patent is granted is erroneous. Daiichi contends this error is evidenced by the language of the final decisions denying its requests for reconsideration, where the PTO reasoned that the 180-day period represented the "outer limit" of PTO authority to conclude patent term adjustment determinations. Oral Arg. at 8:15–8:27, *available at* <http://oralarguments.cafc.uscourts.gov/default.aspx?fl=2014-1280.mp3>.

Daiichi provides two reasons to support its position that the PTO is incorrect that 180 days is the outer limit of its authority. First, the statute does not suggest that Congress intended that the period for judicial review should also apply to administrative review. Second, Daiichi asserts that Congress provided the PTO with authority to correct its own mistakes, "[w]henever a

mistake in a patent, incurred through the fault of the Patent and Trademark Office, is clearly disclosed by the records of the Office.” Appellant’s Br. 20 (quoting 35 U.S.C. § 254) (emphasis omitted). In other words, Congress has not limited the time for the PTO to correct mistakes in patent term adjustment determinations. Daiichi contends the only rationale advanced in the denials was that 180 days was the outer limit of the PTO’s authority. Therefore, Daiichi claims, the agency relied entirely on an erroneous view of the law, rendering the decisions “arbitrary and capricious, and an abuse of discretion, as a matter of law.” *Id.* at 22.

The government argues in response that, at the relevant time in 2010, the law offered Daiichi two separate avenues for challenging the patent term adjustments calculation. First, Daiichi could have requested reconsideration of the patent term adjustments within two months of the patent’s issuance under 37 C.F.R. § 1.705(d). Second, Daiichi could have filed suit in the federal district court within 180 days of issuance under § 154(b)(4)(A). Having failed to take advantage of either option, Daiichi should not be permitted to do so now. The government notes that the PTO noted that Daiichi cannot rely on the *Wyeth* decision to establish extraordinary circumstances warranting a waiver of the regular two-month administrative filing period because Daiichi could have made a timely challenge, as *Wyeth* did. Appellee’s Br. 23.

Regarding the agency’s adoption of the 180-day period for administrative review, the government argues that this selection was logical because it lengthened the period for administrative review to match the period for seeking judicial review. *Id.* at 25. Additionally, the government points to the abbreviated period of judicial review as evidence of Congress’ intent that questions regarding patent term adjustments be “decided quickly and soon after the issuance of the patent.” *Id.* at 26. Hence, any

extension of the period for administrative review beyond 180 days would be contrary to the statute. Finally, the government contends that to consider any recalculation request regardless of how long after issuance it was filed—as Daiichi claims is appropriate under 35 U.S.C. § 254—would run contrary to the PTO’s authority to adopt regulations governing the procedures for requesting reconsideration of patent term adjustments. *Id.* at 28 (citing 35 U.S.C. § 154(b)(3)).

Pursuant to the APA, an agency decision will be set aside if it is arbitrary, capricious, an abuse of discretion, or not in accordance with the law. 5 U.S.C. § 706. The scope of review under this standard is narrow, and the reviewing court may not “substitute its judgment for that of the agency.” *Motor Vehicle Mfrs. Ass’n of U.S., Inc. v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 43 (1983). An agency abuses its discretion when its decision is based on an erroneous interpretation of the law. *See Burandt v. Dudas*, 528 F.3d 1329, 1332 (Fed. Cir. 2008) (citation and quotation omitted). “Otherwise, an agency acts arbitrarily or capriciously only if the decision was not based on the relevant factors or it fails to ‘examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made.’” *Japanese Found. for Cancer Research v. Lee*, 773 F.3d 1300, 1304 (Fed. Cir. 2014) (quoting *Motor Vehicle Mfrs.*, 463 U.S. at 43)).

Here, we agree with the government that the PTO has not erroneously interpreted the law. Rather, the agency acted within its discretion under the statute to “prescribe regulations establishing procedures for the . . . determination of patent term adjustments,” 35 U.S.C. § 154(b)(3), in adopting the 180-day period as part of the Interim Procedure.

Similarly, the PTO acted within its discretion in denying Daiichi’s requests for reconsideration of the patent

term adjustment determinations. Both decisions provide ample reasoning for considering only requests filed within 180 days of the patent grant. The PTO points to the 180-day statutory judicial review period and notes that it is shorter than the normal six-year statute of limitations for administrative challenges under the APA. The PTO explains that this brief period for judicial review indicates Congress' intent that it resolve patent term adjustment issues more expeditiously than allowed under the full administrative challenge period. The PTO also reasoned that it was unlikely that Congress intended for the period for administrative review to extend beyond the period in which that administrative review could be challenged in the district court. *See* J.A. 3121–22, 3382.

The PTO's decisions are consistent with the law in effect at the time of the decisions, including all of § 154's provisions. The PTO's conclusion that its authority to conduct administrative reviews extends no further than the period for judicial review is also consistent with the statute, which expressly authorizes the PTO to make regulations governing the procedures of patent term adjustment reconsiderations. 35 U.S.C. § 154(b)(3)(A). As such, we find that the PTO did not abuse its discretion by determining not to accept petitions for administrative review filed more than 180 days after the patent grant.

B. DISPARATE TREATMENT OF PATENTS

Daiichi also contends that the PTO's disparate treatment of patents issued on August 5, 2009 (the earliest day on which a patent could issue and still qualify for the optional procedure) and the previous day was arbitrary and capricious. According to Daiichi, the issuance of *Wyeth* is no less of an extraordinary circumstance for patents issued before August 5, 2009 than it is for patents issued on or after that day. Daiichi contends the PTO has treated similarly situated patentees differently because one has a remedy and the other does not.

The government argues that Daiichi is not similarly situated with patentees whose patents issued during the period for which the Optional Interim Procedure was available. Rather, Daiichi was similarly situated with all patentees whose patents issued before the Interim Procedure's cutoff date. The government asserts that since the PTO did not consider the petitions of any patentees like Daiichi who failed to show extraordinary circumstances, Daiichi's disparate treatment argument fails.

We conclude that Daiichi has not shown that the PTO treated any requests for reconsideration of patent term adjustments filed for patents issuing before August 5, 2009 differently than Daiichi's petitions. All other similar requests were denied by the agency, showing that the PTO acted consistently with respect to similarly situated patentees. Accordingly, the PTO did not act arbitrarily or capriciously based on its treatment of reconsideration requests submitted by similarly situated patentees.

Through post-argument submission, Daiichi points the court to *Merck Sharp & Dohme Corp. v. Lee*, No. 10-1110, 2014 WL 5775749 (D.D.C. Nov. 6, 2014). In *Merck*, the government conceded before the district court that the facts of the case justified equitably tolling the 180-day judicial review period for a patent issued prior to the availability of the Optional Interim Procedure. Submission of Supplemental Authority, *Daiichi Sankyo Co. v. Lee*, No. 14-1280 (Fed. Cir. Jan. 16, 2015). Thereafter, the district court tolled the statute and remanded to the PTO to adjust the term of the patent. Daiichi argues that, under *Merck*, the government acts arbitrarily whenever it opposes a patentee that seeks recalculation under the agency's new calculation method for patents issued prior to the Optional Interim Procedure's earliest qualifying date. We disagree. In *Merck*, the government contested equitable tolling on legal grounds, when it should have done so on factual grounds. The Supreme Court has held that the government will "not be bound by the mistaken

representations of an agent unless it were clear that the representations were within the scope of the agent's authority." *Office of Pers. Mgmt. v. Richmond*, 496 U.S. 414, 419–20 (1990) (collecting cases supporting holding) (citations omitted). There is no indication that the government, in *Merck*, intended its concession to have any effect beyond that particular case. Further, there is no indication that counsel was acting with authority to bind the government so as to prevent it from ever disputing that a patent issuing before the earliest qualifying date for the Optional Interim Procedure is not entitled to a recalculation under the new calculation method.

We must also consider whether the agency's choice to grant extensions of the administrative review period for some patents to match the judicial review period for all patents was arbitrary and capricious. As discussed above, the statute provides for the Director's ability to prescribe the timeframe for a petition at the PTO. Daiichi was treated identically to all other patentees whose patents had issued more than 180-days prior to the deadline for filing a petition and who were unable to show extraordinary circumstances. Our decision in *Wyeth* did not obligate the PTO to create the Optional Interim Procedure. Indeed, all patentees who could take advantage of the Optional Interim Procedure could still challenge their patent term adjustment in the district court under the statute. The PTO simply provided an alternative, and more cost-effective, mechanism at the agency for attaining the same result. Choosing an administrative filing deadline that mirrors the judicial filing deadline, especially when it lengthens that deadline for some patentees, is neither arbitrary nor capricious.

In sum, we do not find that the PTO's consistent treatment of all patents issuing prior to the availability of the Optional Interim Procedure, the government's concession in *Merck*, or its selection and use of the 180-day

administrative review period amount to arbitrary and capricious action by the government.

IV. DAIICHI'S ADDITIONAL ARGUMENTS

Daiichi presents two additional arguments that it acknowledges are for preservation purposes only: (1) Daiichi argues 35 U.S.C. § 154(b)(4)(A)'s 180-day judicial review period applies only to challenges of patent term adjustment determinations that consider A Delays; and (2) the 180-day limitation period is subject to equitable tolling. We considered, and rejected, both of these arguments in *Novartis AG v. Lee*, 740 F.3d 593 (Fed. Cir. 2014), as Daiichi concedes. Accordingly, we do not address them further here.

CONCLUSION

The PTO's denial of Daiichi's requests for reconsideration was not based on an erroneous view of the law or otherwise arbitrary or capricious. Daiichi is not entitled to relief on the basis that the statute only covers A Delay. And Daiichi is not entitled to equitable tolling of the judicial review period. Therefore, the decision of the district court is

AFFIRMED

COSTS

Each party shall bear its own costs.