

No. 15-652

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**In the Supreme Court of the United States**

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DAIICHI SANKYO COMPANY, LTD., PETITIONER

*v.*

MICHELLE K. LEE, DIRECTOR,  
UNITED STATES PATENT AND TRADEMARK OFFICE

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*ON PETITION FOR A WRIT OF CERTIORARI  
TO THE UNITED STATES COURT OF APPEALS  
FOR THE FEDERAL CIRCUIT*

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**BRIEF FOR THE RESPONDENT IN OPPOSITION**

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### **QUESTION PRESENTED**

Whether the United States Patent and Trademark Office properly refused to reconsider its calculations of the terms of petitioner's patents, based on an intervening decision of the Federal Circuit, when petitioner did not seek review of the patent-term calculations within the statutory and regulatory deadlines.

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## **OPINIONS BELOW**

The opinion of the court of appeals (Pet. App. 1a-19a) is reported at 791 F.3d 1373. The opinion of the district court (Pet. App. 20a-43a) is reported at 12 F. Supp. 3d 8.

## **JURISDICTION**

The judgment of the court of appeals was entered on July 2, 2015. On September 18, 2015, the Chief Justice extended the time within which to file a petition for a writ of certiorari to and including October 30, 2015. On October 15, 2015, the Chief Justice further extended the time to and including November 13, 2015, and the petition was filed on that date. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

## STATEMENT

1. A patent generally expires 20 years after the date that the patent application was submitted. 35 U.S.C. 154(a)(2). Because it takes time to process a patent application, this means that the enforceable term of a patent is less than 20 years. The exact length of the patent term depends in part on the speed with which the parties act during the examination of the patent application and the conduct of any appeals.

The Patent Act provides that patent terms should be adjusted when certain types of delays occur during the processing of the application. When the United States Patent and Trademark Office (PTO) fails to meet certain statutory deadlines, an additional day of patent term is added for every day beyond the deadline. 35 U.S.C. 154(b)(1). The amount of the adjustment is then reduced by the period of time during which the applicant failed to engage in reasonable efforts to prosecute the application, generally known as “applicant delay.” 35 U.S.C. 154(b)(2)(C).

A patent-term adjustment may be premised on three types of PTO delay, each of which is commonly referred to by the applicable subsection of the statute. “A delay” involves a failure of the PTO to respond to certain events or filings by enumerated examination deadlines. See 35 U.S.C. 154(b)(1)(A). “B delay” involves a failure of the PTO to issue the patent within three years. See 35 U.S.C. 154(b)(1)(B). “C delay” involves delays due to interferences, secrecy orders, and appeals under certain circumstances. See 35 U.S.C. 154(b)(1)(C). If two types of delay overlap, the overlapping periods are subtracted to avoid double-counting. *Wyeth v. Kappos*, 591 F.3d 1364 (Fed. Cir. 2010). This ensures that the patent-term adjustment

does not “exceed the actual number of days the issuance of the patent was delayed.” 35 U.S.C. 154(b)(2)(A).

2. In 2007, a suit was brought asserting that PTO regulations erroneously treated certain types of delay as overlapping, resulting in erroneous calculations of the patent-term adjustments to which patent owners were entitled. Compl. at 4-5, 07-cv-1492, *Wyeth v. Dudas* (D.D.C. Aug. 17, 2007). The Federal Circuit agreed. *Wyeth*, 591 F.3d at 1369.

Many patent holders sought to obtain recalculation of their patent terms under *Wyeth*. Under the version of the statute in force at the time, the relevant limitations period for seeking administrative review was two months from the date the patent issued, 37 C.F.R. 1.705(d) (2004), and the limitations period for seeking judicial review was 180 days, 35 U.S.C. 154(b)(4)(A) (2010). A patentee who was dissatisfied with its patent-term-adjustment calculation could file suit in district court to challenge that determination without first requesting administrative review.<sup>1</sup> As a result, there was for each patent a period of approximately four months when the patentee was generally time-barred from seeking administrative review under 37 C.F.R. 1.705, but could still petition for judicial review. During that four-month window, however, the PTO could make an exception and waive the administrative time bar “[i]n an extraordinary situation, when justice requires.” 37 C.F.R. 1.183.

Relying on the “extraordinary situation” exception, the PTO created an expedited process (the “Interim

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<sup>1</sup> The statute has since been amended to require that applicants request administrative review before seeking judicial review. 35 U.S.C. 154(b)(4).

Procedure”) whereby patentees whose patent-term calculations had not yet become final, but who had missed the two-month window for requesting administrative review, could request recalculation of their patent terms in light of *Wyeth*. Pet. App. 88a-97a (reproducing 75 Fed. Reg. 5043 (Feb. 1, 2010)). A patentee could not invoke that procedure, however, if the time for seeking judicial review had expired and the patent term had become final. *Id.* at 95a (Interim Procedure “does not apply to \* \* \* any request for reconsideration of the patent term adjustment indicated in the patent filed later than 180 days after the patent was granted.”).

3. Petitioner seeks recalculation of the patent terms for two of its patents on the basis of the Federal Circuit’s *Wyeth* decision. Those patents were issued on March 11, 2008, and April 29, 2008, while *Wyeth* was pending in district court. Pet. App. 24a. The April 29 patent was still within the window for judicial review on September 30, 2008, when the district court in *Wyeth* held that the PTO’s regulations were invalid. *Wyeth v. Dudas*, 580 F. Supp. 2d 138 (D.D.C.), *aff’d*, 591 F.3d 1364 (Fed. Cir. 2010). Petitioner did not seek review of the calculation of its patent-term adjustment on either patent at that time.

In February 2009, after the deadlines for administrative and judicial review had expired, petitioner filed a petition with the PTO. That petition asked the agency to reconsider the patent-term adjustment determinations, and it sought a waiver of the two-month time limit in 37 C.F.R. 1.705(d) for filing a request for reconsideration. Pet. App. 25a; see 37 C.F.R. 1.183 (permitting waiver of regulatory requirements “[i]n an extraordinary situation, when

justice requires”). The PTO denied the requests. Pet. App. 51a, 53a. It explained that petitioner “could have filed a Request for Reconsideration of a Patent Term Adjustment as Wyeth did.” *Id.* at 49a. The agency further explained that, far from being an extraordinary situation justifying a waiver, the circumstances here were “not unlike any other situation where a patentee (or applicant) challenges a final agency decision and the decision upon judicial review could have had applicability to another patentee (or applicant) had they taken such action.” *Ibid.*

After the Federal Circuit affirmed the district court’s decision in *Wyeth*, petitioner filed several further requests for reconsideration of the denial of reconsideration, asserting that it should be permitted to access the post-*Wyeth* Interim Procedure. The PTO declined to revisit its prior denial of reconsideration. Pet. App. 57a, 66a, 69a. The agency reiterated that this case did not present an extraordinary situation, *id.* at 64a-65a, and it concluded that any request for recalculation of patent-term adjustment in light of *Wyeth* was required to be submitted within 180 days of the patent issue date, *id.* at 58a, 65a-66a, 70a.

4. Petitioner brought suit challenging the denials of its requests for reconsideration. Pet. App. 26a. Petitioner argued that challenges to final patent-term-adjustment determinations should be governed by the general six-year statute of limitations in the Administrative Procedure Act (APA), 28 U.S.C. 2401(a), rather than by the specific limitations period for patent terms set forth in 35 U.S.C. 154(b)(4)(A) (2010). Pet. App. 28a. Petitioner also asserted that the time for filing should be equitably tolled during the periods

between the issuance of the relevant patents and the district court's decision in *Wyeth*. *Ibid.*

The district court granted summary judgment to the government. The court held that the 180-day time limit set out in the then-applicable version of 35 U.S.C. 154(b)(4)(A) applied to the patent-term-adjustment calculation. Pet. App. 28a-32a. It further held that petitioner was not entitled to equitable tolling because it had not shown extraordinary circumstances and had not diligently asserted its rights. *Id.* at 40a-43a. The district court explained that petitioner had “possessed all the facts necessary to challenge the USPTO’s [patent-term-adjustment] determinations before” the district court in *Wyeth* rendered its decision, and that petitioner “was free to raise the issues that *Wyeth* \* \* \* raised in [its] lawsuit[] within the 180 days after [its] patents were granted.” *Id.* at 40a (quoting *Novartis AG v. Kappos*, 904 F. Supp. 2d 58, 68 (D.D.C. 2012)) (alterations in original).

5. The court of appeals affirmed. Pet. App. 1a-19a. The court held that the PTO had not abused its discretion in denying petitioner’s requests for reconsideration. *Id.* at 14a. The court explained that the agency was charged with determining the procedures under which such requests would be addressed. *Ibid.* (citing 35 U.S.C. 154(b)(3)). The court held that the PTO’s decisions “provide ample reasoning” for its interpretation of the statute. *Id.* at 14a-15a. It accepted the PTO’s explanation that the statute provides only a short time period for seeking judicial review, indicating Congress’s intent to resolve patent-term issues expeditiously, and that Congress did not likely intend to provide administrative review beyond the 180-day

period for judicial review under this particular statutory scheme. *Id.* at 15a.

The court of appeals rejected petitioner’s contention that the agency was treating similarly-situated patent holders differently. Pet. App. 16a. The court explained that petitioner “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,” *id.* at 17a, since the PTO had denied all such untimely requests, *id.* at 16a. The court further explained that the PTO’s selection of “an administrative filing deadline that mirrors the judicial filing deadline, especially when it lengthens that deadline for some patentees, is neither arbitrary nor capricious.” *Id.* at 18a.

Relying on circuit precedent, the court of appeals also rejected petitioner’s argument that the APA’s six-year statute of limitations applies to patent-term-adjustment challenges. Pet. App. 18a; see *Novartis AG v. Lee*, 740 F.3d 593 (Fed. Cir. 2014).

#### ARGUMENT

The Federal Circuit’s decision is correct and does not conflict with any decision of this Court or another court of appeals. The issues raised here have no prospective importance, moreover, because Congress has since amended the statutory language at issue. Further review is not warranted.

1. Once a legal claim has been finally extinguished, it cannot be revived by a change in law. “New legal principles, even when applied retroactively, do not apply to cases already closed.” *Reynoldsville Casket Co. v. Hyde*, 514 U.S. 749, 758 (1995). On the contrary, “retroactivity in civil cases must be limited by the

need for finality.” *James B. Beam Distilling Co. v. Georgia*, 501 U.S. 529, 541 (1991). “[O]nce suit is barred by res judicata or by statutes of limitation or repose, a new rule cannot reopen the door already closed.” *Ibid.*

A contrary rule would be unmanageable, as court judgments and administrative determinations could be continually reconsidered with every fluctuation in the law. Thus, “the rights of the parties should be considered frozen \* \* \* when the transaction is beyond challenge either because the statute of limitations has run or the rights of the parties have been fixed by litigation and have become *res judicata*.” *United States v. Estate of Donnelly*, 397 U.S. 286, 296 (1970) (Harlan, J., concurring).

After the Federal Circuit issued its decision in *Wyeth*, the PTO created a process for recalculating patent terms that had not yet become final. Petitioner allowed its patent-term determination to become final, however, and therefore could not benefit from this rule. As the district court explained, nothing prevented petitioner from filing a timely petition for judicial review, just as the plaintiff in *Wyeth* did. Pet. App. 40a. Indeed, as to one of the patents at issue in this case, petitioner could still have filed a timely petition even after the district court’s decision in *Wyeth*.

Petitioner does not dispute the existence of a general rule against reopening administrative determinations that have already become final. Nor does petitioner identify any statute or rule that required the PTO to grant an untimely motion for reconsideration under these circumstances. Petitioner instead asserts (Pet. 11-14) that, although the PTO was not required to reconsider its patent term, the agency erroneously

concluded that it lacked the discretion to do so. But the PTO regulation on which petitioner relies provides for reopening only “in an extraordinary situation.” 37 C.F.R. 1.183 (2010). In reviewing petitioner’s initial requests for reconsideration, the PTO properly concluded that petitioner’s case did not present an extraordinary situation because nothing had prevented petitioner from filing a timely request as the petitioner in *Wyeth* had done. Pet. App. 48a-50a.

As the Federal Circuit correctly held, moreover, the PTO reasonably interpreted the patent-term statute to render administrative review unavailable after the six-month window for judicial review had expired. See Pet. App. 14a-15a, 70a-71a. The statute provided that applicants had “180 days after the grant of the patent” to seek judicial review. 35 U.S.C. 154(b)(4)(A) (2010). It also authorized the PTO to “prescribe regulations establishing procedures for the application for and determination of patent term adjustments,” so as to provide “one opportunity to request reconsideration of any patent term adjustment determination made by the Director.” 35 U.S.C. 154(b)(3)(A) and (B)(ii) (2010). In implementing that provision, the PTO reasonably required that, absent another statutory exception, requests for reconsideration must be filed before the time for seeking judicial review expired. The agency viewed Congress’s adoption of a short (180-day) time limit for seeking judicial review in the context of this statutory scheme as indicating an intent that patent-term-calculation issues be resolved expeditiously. See Pet. App. 70a-71a.

Petitioner’s reliance (Pet. 12-13) on *BP America Production Co. v. Burton*, 549 U.S. 84 (2006), is misplaced. In *BP America*, this Court held that a statute

of limitations applicable when the “Government commences any ‘action for money damages’ by filing a ‘complaint’ to enforce a contract” did not bar an administrative order to collect unpaid royalties on a gas lease. *Id.* at 91. Like the Federal Circuit’s decision here, the Court’s decision in *BP America* was based on the language of the particular statute at issue. *Id.* at 91-92 (discussing the meaning of “action” and “complaint”). *BP America* does not suggest that time limits for seeking judicial review can never be relevant to the time limits for seeking administrative review.

Petitioner also argues (Pet. 14) that the PTO has statutory authority to issue a certificate of correction “[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.” 35 U.S.C. 254. Petitioner did not invoke that provision before the PTO, however, so the agency had no occasion to consider whether the statute applied in these circumstances.

Petitioner contends (Pet. 16-18) that the PTO, in concluding that no extraordinary circumstances applied in its case, treated petitioner differently from other similarly-situated patentees. But petitioner “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”: The USPTO denied all such untimely requests. Pet. App. 17a; see *id.* at 16a. Petitioner is not similarly situated to patent holders who were eligible to access the Interim Procedure because their patent terms had not become final. Petitioner’s challenge to the PTO’s calculation

of overlap under 35 U.S.C. 154(b)(2)(A) could have been raised in an application for patent-term adjustment. 37 C.F.R. 1.705(d) (2004). As the PTO explained, there is nothing anomalous about the fact that patentees (like Wyeth) who timely pursued available remedies obtained relief that was not awarded to patentees (like petitioner) who could have pursued such remedies but did not.<sup>2</sup> Pet. App. 49a. As the district court correctly observed in rejecting petitioner’s equitable-tolling argument, the existence of such disparities does not indicate “that extraordinary circumstances exist.” *Id.* at 40a-41a.

Petitioner further asserts (Pet. 14-16) that the Federal Circuit adopted a post hoc rationalization by accepting the PTO’s explanation that it had designed the Interim Procedure to avoid wasteful lawsuits in cases where judicial review was still available. But this design is apparent from the structure of the Interim Procedure itself. The relevant Federal Register notice explained the agency’s intent to create an optional interim procedure whereby patentees were required only to state that reconsideration was re-

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<sup>2</sup> Amicus Nippon Shinyaku Co. points (Br. 8-10) to a small set of patent terms that became final after the Federal Circuit’s *Wyeth* decision but before the PTO issued its interim guidance a few weeks later. No such patent is at issue in this suit, and petitioner seeks a retroactive remedy that would extend to a much broader range of patent holders. In any event, when the PTO announced that the government would not seek further review of the Federal Circuit’s decision in *Wyeth*, the agency stated that it would issue guidance as soon as possible but “reminded” applicants “of the requirement to seek review of [any patent-term] determination within 180 days of patent issuance.” *The USPTO and DOJ Will Not Seek Review of Wyeth v. Kappos* (Jan. 20, 2010), [http://www.uspto.gov/patents/announce/wyeth\\_v\\_kappos.jsp](http://www.uspto.gov/patents/announce/wyeth_v_kappos.jsp).

quested in light of *Wyeth*. Pet. App. 94a. The same Federal Register notice repeatedly linked the time limit for accessing that procedure to the deadline for seeking judicial review. See *id.* at 88a, 89a, 92a, 93a, 95a.

In any event, petitioner does not ask the Court to strike down the Interim Procedure. The Federal Circuit upheld the Interim Procedure on the ground that it “simply provided an alternative, and more cost-effective mechanism” than a petition for judicial review. Pet. App. 18a. But the Federal Circuit separately concluded that patent-term calculations that were allowed to become final were not similarly situated to those for which the time for seeking judicial review had not run. *Id.* at 16a.

2. The Federal Circuit correctly rejected petitioner’s argument (Pet. 18-22) that the APA’s six-year statute of limitations applies to patent-term challenges. Petitioner does not dispute that a specific statute setting out a limitations period for a particular challenge overrides the APA’s general statute of limitations. The Federal Circuit did not err in applying this well-established principle to the statute at issue here.

The statute that was in effect when petitioner sought PTO reconsideration and filed his district-court complaint provided that “[a]n applicant dissatisfied with a determination made by the Director under paragraph (3) shall have remedy by a civil action against the Director filed \* \* \* within 180 days after the grant of the patent.” 35 U.S.C. 154(b)(4)(A) (2010). Paragraph (3) sets out the “[p]rocedures for patent term adjustment determination.” 35 U.S.C. 154(b)(3) (2010).

Petitioner quotes the language of one subsection of paragraph (3) to assert that the paragraph applies only to preliminary calculations of patent term, rather than to final determinations. Pet. 20-21. But the “inference [petitioner] draws is not a reasonable one given the rest of paragraph (b)(3).” *Novartis AG v. Lee*, 740 F.3d 593, 599 (Fed. Cir. 2014). “The applicable version of paragraph (b)(3)—the whole of which subparagraph (b)(4)(A) refers to—addresses all patent term adjustment determinations, not just some.” *Ibid.*

For example, “[s]ubparagraph (b)(3)(A) broadly declares that [t]he Director shall prescribe regulations establishing procedures for the application for and determination of patent term adjustments.” *Novartis*, 740 F.3d at 599 (quoting 35 U.S.C. 154(b)(3)(A) (2010)) (brackets in *Novartis*). And subparagraph (b)(3)(D) “plainly cover[s] the final adjustment announced at issuance, not just a provisional adjustment announced at allowance.” *Ibid.*; see 35 U.S.C. 154(b)(3)(D) (2010) (discussing “*completion* of the Director’s determination of a patent term adjustment”) (emphasis added).<sup>3</sup> Petitioner’s reading would

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<sup>3</sup> Former Section 154(b)(3)(C)(i) (2010) required the PTO to send a patent-term-allowance calculation with the notice of allowance of the patent. When it issues the notice of allowance, however, the PTO does not yet know the patent issue date because that date depends on when the applicant pays the issue fee. Because the PTO cannot calculate the final patent-term adjustment at that time, the agency’s former practice was to send a preliminary calculation of patent-term adjustment with the notice of allowance and a final calculation shortly before the patent issued. Congress has since “correct[ed]” this provision to clarify that the PTO need not send a patent-term-adjustment calculation until the patent issues. Leahy-Smith America Invents Technical Corrections, Pub.

also “produce the senseless result” that the entire judicial-review provision of Section 154(b)(4)—including not only its 180-day limitations period but also “its confinement of venue to one district court—would apply to review only of provisional, but not final, adjustment determinations.” *Novartis*, 740 F.3d at 599-600. The 180-day limitations period is much more naturally understood to govern all “appeals of term adjustment determinations made by the Director” and to “require[] a dissatisfied applicant” to file suit “within 180 days after the grant of the patent.” H.R. Rep. No. 287, 106th Cong., 1st Sess. 52 (1999); see S. Rep. No. 42, 105th Cong., 1st Sess. 103 (1997) (provision “requires that any appeal of the Commissioner’s decision on the patent term be filed \* \* \* within 180 days”).

3. Congress has amended the governing statute to resolve the questions presented here, leaving no issue of continuing importance for this Court to decide.

Under the revised statute, patentees must seek administrative review before seeking judicial review. 35 U.S.C. 154(b)(4)(A). The 180-day time limit for filing suit runs from the conclusion of the administrative-review process, rather than from the date that the patent issues. *Ibid.* The PTO has the authority to design the administrative-review process. 35 U.S.C. 154(b)(3)(A) and (B)(ii). The amendments thus eliminate the prior requirement to begin administrative review within 180 days after the patent issues.

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L. No. 112-274, § 1(h)(3), 126 Stat. 2457. The current statute retains the 180-day limitations period for seeking judicial review of the patent-term-adjustment calculation. 35 U.S.C. 154(b)(3)(B)(i) and (4)(A).

The amendments further clarify that the APA’s six-year statute of limitations does not apply to patent-term-adjustment calculations. Unlike the prior statute of limitations, which referenced 35 U.S.C. 154(b)(3) as a whole, the revised statute specifically references the administrative-review provision. 35 U.S.C. 154(b)(3)(B)(ii) and (4)(A). The administrative-review provision applies to “any patent term adjustment determination made by the Director.” 35 U.S.C. 154(b)(3)(B)(ii). That modification eliminates any basis for arguing that the 180-day limitations period applies only to some patent-term-adjustment calculations. And the title of this modification—both the Act and the section are labelled “technical corrections”—belies petitioner’s view that the amendments dramatically shortened the limitations period from six years to six months. Leahy-Smith America Invents Technical Corrections, Pub. L. No. 112-274, § 1(h)(3), 126 Stat. 2457.

#### CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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