

**IN THE
Supreme Court of the United States**

DAIICHI SANKYO COMPANY, LTD.,
Petitioner,

v.

MICHELLE K. LEE, UNDER SECRETARY OF COMMERCE
FOR INTELLECTUAL PROPERTY AND DIRECTOR, PATENT
AND TRADEMARK OFFICE,
Respondent.

**On Petition for a Writ of Certiorari to the
United States Court of Appeals
for the Federal Circuit**

**BRIEF OF *AMICUS CURIAE*
NEW YORK INTELLECTUAL
PROPERTY LAW ASSOCIATION
IN SUPPORT OF PETITIONER**

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INTEREST OF *AMICUS CURIAE*¹

The New York Intellectual Property Law Association (“NYIPLA”) is a bar association of more than 1,300 attorneys who practice in the area of patent, copyright, trademark and other intellectual property (“IP”) law.² It is one of the largest regional IP bar associations in the United States. Its members include in-house counsel for businesses and other organizations, as well as attorneys in private practice who represent both IP owners and their adversaries (many of whom are also IP owners). Its members represent inventors, entrepreneurs, businesses, universities, and industry and trade associations.

Directly relevant to the issues here, the NYIPLA’s members and their clients regularly participate in proceedings before the United States Patent and Trademark Office (“PTO”), including proceedings to restore patent term lost due to PTO delays in issuing patents, and in judicial review of adverse decisions of the PTO. The NYIPLA thus brings an informed perspective to the issues presented.

Because the PTO procedures at issue in this case resulted in loss of patent term guaranteed by

¹ Pursuant to Sup. Ct. R. 37.6, the NYIPLA and its counsel represent that they have authored the entirety of this brief, and that no person other than the *amicus curiae* or its counsel has made a monetary contribution to the preparation or submission of this brief.

² Pursuant to Sup. Ct. R. 37.2(a), Petitioner’s and Respondent’s written consents to this filing are submitted herewith.

Congress on a massive scale and given the importance of full patent term to future innovation, the NYIPLA's members and their clients have a strong interest in this Court granting the petition for a writ of certiorari.³

INTRODUCTION

This case concerns denial of patent term guaranteed by Congress. It impacts tens of thousands of patents across industries.

In 1994, Congress replaced a patent regime which provided a patent term of seventeen years from grant with one that is twenty years from filing. *See* 35 U.S.C. § 154 (a). Because the twenty-year term began before the patent issued, it became necessary to compensate applicants for delays in processing the patent application at the PTO. Term adjustment was not necessary when the term began at patent grant because the PTO delays occurred prior to the issuance of the patent and had no impact

³ The arguments made in this brief were approved by an absolute majority of NYIPLA's officers and members of its Board of Directors, but do not necessarily reflect the views of a majority of the members of the Association, or of the law or corporate firms with which those members are associated. After reasonable investigation, the NYIPLA believes that no officer or director or member of the Amicus Briefs Committee who voted in favor of filing this brief, nor any attorney associated with any such officer, director or committee member in any law or corporate firm, represents a party to this litigation. Some officers, directors, committee members or associated attorneys may represent entities, including other *amici curiae*, which have an interest in other matters that may be affected by the outcome of this litigation.

on patent term. “Under the twenty-year term, however, those delays consumed the effective term of a patent.” *Wyeth v. Kappos*, 591 F.3d 1364, 1366 (Fed. Cir. 2010).

In 1999, Congress passed the Patent Term Guarantee Act as part of the American Inventors Protection Act, Pub. L. 106-113 (1999). “This new Act promised patent applicants a full patent term adjustment for any delay during prosecution caused by the PTO.” *Wyeth*, 591 F.3d at 1366. Congress provided patent applicants three specific guarantees: “(A) Guarantee of prompt patent and trademark office responses,” “(B) Guarantee of no more than 3-year application pendency,” and “(C) Guarantee of adjustments for delays due to interferences, secrecy orders, and appeals.” *See App.*, 74a-76a⁴ (35 U.S.C. § 154(b)(1) (2010)). Delays relating to these guarantees are referred to as A, B and C delays respectively.

Each guarantee is achieved by requiring the PTO to fully extend the term of the patent if the PTO “fail[s]” to meet the deadlines in the statute. *Id.*, at 74a. This is also referred to as patent term adjustment (“PTA”). With the new Act, Congress “guarantee[d] diligent applicants at least a 17-year term” as provided under the pre-1994 regime. *See H.R. Rep. No. 106-464*, at 125 (1999).

To reinforce its patent term guarantee, Congress also provided for administrative and

⁴ App. refers to the Appendix to the Petition for Writ of Certiorari.

judicial review of the PTO's PTA determinations. *See App.*, 77a-79a (35 U.S.C. § 154(b)(3)-(4) (2010)). As to administrative review, the statute provides an opportunity to request reconsideration of any PTA determination made by the PTO; it does not set any time limit for that request. *See App.*, 78a. The PTO, by rule, generally requires patentees to seek reconsideration within two months of the patent issuing. *See App.*, 85a-87a (37 C.F.R. § 1.705(d) (2010)). As to judicial review, the statute provides for a remedy by civil action for applicants dissatisfied with the PTA determination made by the PTO. Unlike the provisions relating to administrative review of PTA where Congress did not set forth any time limit, the statute requires applicants to seek judicial review within 180 days of the patent issuing. *See App.*, 78a-79a.

For nearly a decade after the amendment of 35 U.S.C. § 154 to set forth Congress's patent term guarantees, the PTO incorrectly adjusted terms for patents that suffered both A and B delays. Based on an erroneous interpretation of the guarantees, the PTO "use[d] either the greater of the A delay or B delay to determine the appropriate adjustment but never combine[d] the two." *Wyeth*, 591 F.3d at 1368. In 2010, the Federal Circuit held that the statutory "language is clear, unambiguous, and intolerant of the PTO's suggested interpretation." *Id.* at 1372.

The PTO responded to the Federal Circuit's decision in *Wyeth* with an "Interim Procedure for Patentees to Request a Recalculation of the Patent Term Adjustment to Comply With the Federal Circuit Decision in *Wyeth v. Kappos* Regarding the

Overlapping Delay Provision of 35 U.S.C. 154(b)(2)(A)” (the “Interim Procedure”) to address its *Wyeth* errors. *See* App., 88a-97a (75 Fed. Reg. 5043 (Feb. 1, 2010)).

In the Interim Procedure, the PTO waived *sua sponte* its two-month deadline for seeking administrative review of PTA determinations. It did so by invoking 37 C.F.R. § 1.183. *See* App., 95(a). 37 C.F.R. § 1.183 allows the agency to waive any rule which is not a requirement of the statute in “an extraordinary situation, when justice requires.” App., 84a. The two-month deadline is not a requirement of the statute since 35 U.S.C. § 154(b) does not limit the period for administrative review.

The PTO waived its two-month deadline only for patents issued within 180 days of February 1, 2010, the publication date of its Interim Procedure. Many of those patents would not have been otherwise eligible for administrative review and correction of the PTO’s errors. But patents issued prior to August 5, 2009 (180 days before the February 1 publication date of the Interim Procedure) with the same errors were not eligible for correction under the PTO’s Interim Procedure. In effect, although the PTO recognized that its errors were systemic and had an extraordinary impact on patent term guaranteed by Congress, it waived its two-month deadline only for a subset of affected patents, leaving its errors uncorrected and uncorrectable for thousands of others.

PROCEDURAL HISTORY

Shortly after the district court's decision in *Wyeth*, but before issuance of the Interim Procedure, Daiichi petitioned the PTO to waive its two-month deadline for seeking administrative review of PTA determinations in view of the extraordinary situation presented by *Wyeth*. The PTO denied the petitions stating that “[p]atentees cannot rely on . . . the *Wyeth* decision to establish that their situation was extraordinary.” App., 50a.

After the Federal Circuit's decision in *Wyeth* and issuance of the Interim Procedure, Daiichi again sought reconsideration of the PTA determinations and waiver of the two-month deadline for seeking administrative review due to the extraordinary situation presented by *Wyeth*. The PTO again denied review but for a different reason. Consistent with the Interim Procedure, the PTO did not deny that *Wyeth* established an extraordinary situation. Instead, the PTO pointed to the fact that its Interim Procedure only provided a “limited waiver” of the two-month deadline. App., 70a.

The PTO waived the deadline for patents that issued within 180 days of the publication of the Interim Procedure but “determined not to accept any requests for PTA recalculation initially filed more than 180 days after patent grant.” *Id.* The PTO reasoned that the 180-day period for seeking judicial review “represent[ed] the outer limit on the USPTO's ability to conclude its PTA determinations.” App., 70a-71a. The PTO said that “particularly in view of the six-year statute of limitations that otherwise is applicable for actions under the Administrative

Procedure Act” the 180-day period for judicial review indicates that Congress did not intend for administrative review to be available when judicial review is not. *Id.*

Daiichi then sought review of these denials in the District Court for the District of Columbia. Before the court, the PTO defended its action on the reasons stated in its denials but also on a new ground. It asserted that it reasonably chose to limit the time for seeking administrative review by the 180-day period for seeking judicial review in order to provide a more cost-effective mechanism for attaining the same result that could be achieved in district court. The district court granted summary judgment in the PTO’s favor. On appeal, the PTO abandoned its “outer limit” rationale for denying administrative review and relied on its new ground. The Federal Circuit affirmed, accepting both the PTO’s stated and new rationales for denying review.

SUMMARY OF THE ARGUMENT

This petition presents an issue of exceptional importance to patent owners across industries and to the fair administration of the patent laws.

In upholding the PTO’s denial of administrative review to correct patent term lost due to its own errors, the Federal Circuit allowed fundamental administrative law principles to be turned on their head.

The PTO and Federal Circuit misinterpreted Congress’s patent term guarantee and conflated judicial and administrative review contrary to the

plain language of the statute, the PTO's own practice and this Court's precedent distinguishing the time limits for judicial and administrative review.

The Federal Circuit also accepted the PTO's *post hoc* rationalization for its action although this Court's precedent establishes that agency action cannot be sustained on that basis. It further contravened bedrock administrative law principles by allowing the PTO to treat patents with the same PTO errors differently. As a result, thousands of patents were denied review to correct the PTO's errors.

This Court's consideration of the issues presented in the petition is crucial at this juncture to ensure that PTO procedures do not present arbitrary hurdles in this and future proceedings. Congress provided its patent term guarantee to fuel innovation. Without this Court's review, the PTO's systemic errors will not be corrected and the patent terms guaranteed by Congress will not be restored.

In addition, there is no reason to wait for further decisions to develop since the PTO's procedure precludes review of all similarly situated patents. The far-reaching consequences of this case also add to the reasons for immediate review. The PTO's procedure impacts patents on a massive scale and has caused great harm. Tens of thousands of patents across industries have been denied statutorily-guaranteed patent term due to the PTO's failure to adhere to administrative law principles and its mandate.

ARGUMENT

I. The Federal Circuit’s Decision Upholding the PTO’s Denial of Administrative Review Contravenes Administrative Law Principles and Deprives Thousands of Patents of Term Guaranteed by Congress

This Court should grant the petition for a writ of certiorari. This case presents a cascade of administrative law errors that contravene fundamental administrative law principles and deprive thousands of patents across industries of patent term that Congress guaranteed.

In upholding the PTO’s denial of administrative review to patents that issued before August 5, 2009, the Federal Circuit conflated judicial and administrative review, accepted a *post hoc* rationalization, and allowed the PTO to treat patents with the same PTO errors differently. In doing so, it cemented the PTO’s systemic errors and deprived patent applicants of valuable patent term, the quid pro quo for public disclosure of the underlying innovation, on a massive scale.

A. The PTO and Federal Circuit Improperly Conflated Judicial and Administrative Review

The PTO determined not to correct its *Wyeth* errors for patents issued more than 180 days before the publication of the Interim Procedure “in view of the statutory judicial-review provisions of 35 U.S.C. § 154(b)(4), which require that any civil action to challenge the USPTO’s PTA determination be

brought within 180 days of patent grant.” App., 70a. The PTO reasoned that “the 180-day period in 35 U.S.C. § 154(b)(4) represents the outer limit on the USPTO’s ability to conclude its PTA determination.” App., 70a-71a. Although the PTO’s reasoning is directly contrary to the plain language of 35 U.S.C. § 154(b), the PTO’s own practice and this Court’s precedent, the Federal Circuit agreed with the PTO.

The PTO and Federal Circuit misinterpreted 35 U.S.C. § 154(b) and improperly conflated its administrative and judicial review provisions. The “starting point in every case involving construction of a statute is the language itself.” *United States v. Hohri*, 482 U.S. 64, 68 (1987) (citations omitted). “[W]hen the statute’s language is plain, the sole function of the courts—at least where the disposition required by the text is not absurd—is to enforce it according to its terms.” *Dodd v. United States*, 545 U.S. 353, 359-360 (2005) (quoting *Hartford Underwriters Ins. Co. v. Union Planters Bank, N. A.*, 530 U.S. 1, 6 (2000)).

35 U.S.C. § 154(b) identifies both administrative and judicial review as different means to challenge the PTO’s PTA determination. It provides an opportunity for administrative review of PTO’s PTA determination under 35 U.S.C. § 154(b)(3)(B)(ii) and for judicial review under 35 U.S.C. § 154(b)(4)(A). *See* App., 77a-78a. The statute does not set any time limit for seeking administrative review. *Id.* By contrast, it limits the period for seeking judicial review to 180 days from the grant of the patent. *Id.*

Congress simply set up two paths for challenging the PTA determination. Both types of review could proceed simultaneously. One did not require or preclude the other and patent applicants frequently pursue both at the same time. Indeed, consistent with the plain language of the statute, Wyeth had challenged the PTO's PTA calculation both before the court and the PTO simultaneously. The PTO's own practice shows that judicial review did not limit or require the completion of administrative review.

This Court's precedents also distinguish the time limits for judicial and administrative review. *See e.g. BP Am. Prod. Co. v. Burton*, 549 U.S. 84 (2006); *Sebelius v. Auburn Reg'l Med. Ctr.*, 133 S. Ct. 817, 821 (2013). For example, in *BP* the Court held that the statute of limitations for judicial review under 28 U.S.C. § 2415(a) did not apply to administrative proceedings provided by the same statute; an administrative order was therefore timely although the time for judicial review had run. Relying on the plain language of the statute, this Court explained that the fact that § 2415(a) "distinguishes between judicial and administrative proceedings" shows that Congress "manifestly had two separate concepts in mind when it enacted [the statute]." *BP*, 549 U.S. at 92.

Here too the limitation on judicial review does not apply to administrative proceedings. On the contrary, the fact that 35 U.S.C. § 154(b) "distinguishes between judicial and administrative review" and includes the 180-day limitation only in the statute's provision for judicial review shows that

it does not limit administrative review. *BP*, 549 U.S. at 92.

The PTO also argued and the Federal Circuit agreed that the 180-day limitation for judicial review signaled that PTA should be decided quickly and that “extension of the period for administrative review beyond 180 days would be contrary to the statute.” App., 13a. This argument ignores the plain language and structure of the statute. The statute guarantees restoration of patent term caused by the PTO’s delays and provides for administrative and judicial review to challenge the PTO’s PTA determination. It does not guarantee that review of this critical determination in either forum will proceed quickly. Indeed, it sets no timeline for the completion of either administrative or judicial review. By improperly conflating administrative and judicial review the PTO denied patent term contrary to the statute.

B. A *Post Hoc* Rationalization Cannot Sustain PTO’s Action

The PTO’s *post hoc* rationalization for denying administrative review cannot sustain its action.

It is well-settled under this Court’s precedent that “[a]n administrative order cannot be upheld unless the grounds upon which the agency acted in exercising its powers were those upon which it can be sustained.” *SEC v. Chenery Corp.*, 318 U.S. 80, 95 (1943). The *Chenery* doctrine is a fundamental principle of administrative law. *See SEC v. Chenery Corp.*, 332 U.S. 194, 196 (1947). It encourages “agency accountability” in exercising its powers by

precluding an agency from defending an administrative decision on grounds not set forth by the agency in its original decision. *Bowen v. Am. Hosp. Ass'n*, 476 U.S. 610, 643 (1986).

Here, it is indisputable that the PTO promulgated its Interim Procedure and denied Daiichi's reconsideration applications on grounds upon which its action cannot be sustained. The period for seeking judicial review does not set the "outer limit" for seeking administrative review.

Before the court, the agency attempted to defend its action on new grounds. The Federal Circuit accepted "counsel's *post hoc* rationalizations for agency action" contrary to the *Chenery* doctrine. *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 168 (1962). It upheld the PTO's denial of Daiichi's reconsideration applications based on the argument that the PTO's Interim Procedure "simply provided an alternative, and more cost-effective, mechanism at the agency for attaining the same result" that could be achieved in district court. *See App.*, 18a. The PTO's use of a *post hoc* rationalization to defend its action and the Federal Circuit's acceptance of that rationalization are clear error under this Court's precedents.

**C. It Is Improper to Deny
Administrative Review to Patents
that Issued More than 180 Days
Before the Publication of the Interim
Procedure**

The Federal Circuit allowed the PTO to treat patents differently depending on whether they issued

more than 180 days before the publication of the Interim Procedure on February 1, 2010, *i.e.*, August 5, 2009, or not. The August 5, 2009 dividing line between patents that can recover term that they erroneously lost due to the PTO's *Wyeth* errors and those that cannot is arbitrary and capricious. There is no reasoned basis for that divide.

The PTO waived its two-month deadline for seeking administrative review because *Wyeth* was extraordinary and had an extraordinary impact on patent term. There is no meaningful difference between patents with *Wyeth* errors that issued before or in the 180 days after the publication of the Interim Procedure other than that most patents will not receive administrative review. Both sets of patents, the much larger group that issued before August 5, 2009 and the much smaller group that issued within 180 days of August 5, 2009, lost term guaranteed by Congress due to errors made by the PTO for nearly a decade.

The PTO could have corrected all of its *Wyeth* errors but it chose to provide administrative review for only those patents that issued within 180 days of the publication of the Interim Procedure. That is arbitrary since the 180-day period for seeking judicial review is not an "outer limit" for seeking administrative review. *See Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 48-49 (1983) ("an agency must cogently explain why it has exercised its discretion in a given manner.").

Instead of a reasoned basis, the subset of patents eligible for administrative review is created by the publication date of the Interim Procedure, a

random event. Depending on the day, week, or month that the Interim Procedure was issued, the group of patents eligible for correction of the PTO's *Wyeth* errors would change. That is arbitrary and capricious as a matter of law.

The Federal Circuit held that the PTO's Interim Procedure did not treat patents differently because the PTO refused administrative review of all patents that issued before August 5, 2009. *See* App., 16a. That misses the point. The August 5, 2009 dividing line itself is arbitrary. The fact that the PTO treated tens of thousands of patents in an arbitrary manner only magnifies the consequences of its disparate treatment of these patents from those that fell within the 180-day orbit of the publication of the Interim Procedure.

II. This Case is an Ideal Vehicle for the Court to Bring PTO Procedures and Judicial Review of those Procedures in Line with Bedrock Administrative Law Principles

The issues presented in this petition are critically important to patent owners across industries and the pharmaceutical industry in particular. The PTO procedures at issue in this case arbitrarily denied patent term to tens of thousands of patents with uncorrected *Wyeth* errors. Without this Court's review, the PTO's systemic errors will not be corrected and the patent terms guaranteed by Congress will not be restored.

Patent rules that comply with administrative law principles are essential for fair administration of

the patent laws. It is critical for this Court to provide guidance at this juncture to ensure that PTO procedures do not present arbitrary procedural hurdles in future proceedings.

This Court has stepped in before when patent special rules have strayed from general legal principles. This case presents a cascade of fundamental administrative law errors that have been fully elaborated through extensive proceedings and briefing by the parties and *amici*. This Court's review is sorely needed to bring PTO procedures and judicial review of those procedures in line with fundamental administrative law principles.

CONCLUSION

This Court should grant the petition for a writ of certiorari.

Respectfully submitted,

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