

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLUMBIA**

NIPPON SHINYAKU COMPANY, LIMITED,	)	
	)	
Plaintiff,	)	
	)	
v.	)	
	)	Civil Action No. 10-1142
	)	
ANDREI IANCU, <sup>1</sup> Under Secretary of	)	
Commerce for Intellectual Property	)	
and Director of the United States	)	
Patent and Trademark Office,	)	
	)	
Defendant.	)	

**MEMORANDUM OPINION**

**I. Introduction**

Nippon Shinyaku Company, Limited ("Nippon") owns United States Patent Nos. 7,205,302 and 7,494,997 (respectively, " '302 patent" and " '997 patent"). The United States Patent and Trademark Office ("USPTO") issued the '302 patent in 2007 with a patent term adjustment ("PTA") of 344 days, and the '997 patent in 2009 with a PTA of ninety-nine days. In 2010, the USPTO adopted new methods for calculating PTAs necessitated by the United States Court of Appeals for the Federal Circuit's ("Federal Circuit") decision in *Wyeth v. Kappos*, 591 F.3d 1364 (Fed. Cir. 2010). Prior to adopting the final procedure for such calculations, the USPTO established an Interim Procedure for

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<sup>1</sup> Andrei Iancu has been automatically substituted as the defendant in this case. See Fed. R. Civ. P. 25(d).

patentees seeking a recalculation of their PTAs subject to certain time restrictions. Given its untimely requests, however, Nippon was ineligible for a recalculation. Nippon brings this action under the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 701 *et seq.*, against the Under Secretary of Commerce for Intellectual Property and Director of the USPTO. Nippon challenges the USPTO's Interim Procedure, alleging that the Interim Procedure arbitrarily ensures disparate treatment of two categories of patents and leaves it without a remedy to correct the improper calculations of the PTAs for the patents at issue.

Pending before the Court are the parties' cross-motions for summary judgment. Having carefully reviewed the motions, oppositions and replies, and the entire record herein, the Court concludes that the USPTO's Interim Procedure was not arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. Therefore, the Court **DENIES** Nippon's motion for summary judgment and **GRANTS** the USPTO's cross-motion for summary judgment.

## **II. Background**

### **A. Statutory and Regulatory Framework**

A patent term begins "on the date on which the patent issues" and "end[s] 20 years from the date on which the application for the patent was filed in the United States[.]"

35 U.S.C. § 154(a)(2).<sup>2</sup> Many patent terms became far shorter than Congress intended, however, due to the USPTO's lengthy delays in examining patent applications and issuing patents. See *Novartis AG v. Kappos* ("Novartis I"), 904 F. Supp. 2d 58, 61 (D.D.C. 2012), *aff'd in part, rev'd in part sub nom. Novartis AG v. Lee* ("Novartis II"), 740 F.3d 593 (Fed. Cir. 2014). To address this problem, Congress enacted the Patent Term Guarantee Act of 1999 ("Act"), which provides a guarantee of prompt USPTO responses. See Pub. L. No. 106-113, §§ 4401-02, 113 Stat. 1501, 1501A-557 (1999) (codified as amended at 35 U.S.C. § 154(b)); see also 35 U.S.C. § 154(b)(1)(A). Section 154(b)(1) also provides a "[g]uarantee of no more than 3-year application pendency," see 35 U.S.C. § 154(b)(1)(B), and a guarantee of "1 day for each day of the pendency" of "deprivation proceedings, secrecy orders, and appeals." See *id.* § 154(b)(1)(C).

Since the prosecution of a patent application may take more than three years, and to give each patent a term of at least seventeen years, the Act allows the USPTO to adjust the terms of a patent for certain delays during the examination process. See

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<sup>2</sup> In 1994, Congress replaced the seventeen-year patent term with a term ending twenty years after the filing of a patent application. See *Wyeth*, 591 F.3d at 1366 (citing Uruguay Round Agreements Act, Pub. L. No. 103-465, § 532, 108 Stat. 4809 (1994) (codified as amended at 35 U.S.C. § 154)). A patent application filed on or after June 8, 1995 has a term of twenty years from the date the application was filed. *Merck & Co. v. Kessler*, 80 F.3d 1543, 1547-48 (Fed. Cir. 1996).

*Daiichi Sankyo Co., Ltd. v. Rea* ("Daiichi I"), 12 F. Supp. 3d 8, 11-12 (D.D.C. 2013) (citations omitted), *aff'd sub nom. Daiichi Sankyo Co. v. Lee* ("Daiichi II"), 791 F.3d 1373 (Fed. Cir. 2015), *cert. denied*, 136 S. Ct. 1491 (2016). The statute provides for the adjustment and calculation of patent terms caused by different categories of delay. *Bristol-Myers Squibb Co. v. Kappos*, 891 F. Supp. 2d 135, 137 (D.D.C. 2012).

Nippon's PTAs resulted from two of those categories:

(1) "A Delay" and (2) "B Delay." See generally Pl.'s Mot. for Summ. J. ("MSJ"), ECF No. 46; Def.'s Mot. for Summ. J. ("MSJ") & Opp'n, ECF No. 48.<sup>3</sup> The A Delay "is excluded from the calculation of the patent term" and "extend[s] the term of the patent one day for each day the [US]PTO does not meet certain examination deadlines[.]" *Daiichi I*, 12 F. Supp. 3d at 12 (citation omitted). The B Delay "extends the term of the patent one day for each day issuance is delayed due to the [US]PTO's failure 'to issue a patent within 3 years after the actual filing date of the application in the United States.'" *Wyeth*, 591 F.3d at 1367 (quoting 35 U.S.C. § 154(b)(1)(B)).

### **1. The *Wyeth* Decision and its Implementation**

On April 22, 2004, the USPTO promulgated regulations

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<sup>3</sup> When citing electronic filings throughout this Opinion, the Court cites to the ECF page number, not the page number of the filed document.

explaining the methodology for calculating the "A/B Overlap." See *Daiichi I*, 12 F. Supp. 3d at 12 (citing Revision of Patent Term Extension and PTA Provisions, 69 Fed. Reg. 21704-01 (Apr. 22, 2004)). Interpreting 35 U.S.C. § 154(b), the USPTO used the greater of the A Delay or B Delay to determine the proper PTA rather than combining the two delays. See *Wyeth v. Dudas*, 580 F. Supp. 2d 138, 140 (D.D.C. 2008), *aff'd sub nom. Wyeth*, 591 F.3d at 1368. In *Wyeth*, the district court rejected this interpretation because the USPTO's "construction [could not] be squared with the language of § 154(b)(1)(B), which applies 'if the issue of an original patent is *delayed* due to the failure of the [USPTO] to issue a patent within 3 years.'" 580 F. Supp. 2d at 142 (emphasis in original) (quoting 35 U.S.C. § 154(b)(1)(B)). The court explained that B Delay "begins when the [US]PTO has failed to issue a patent within three years, *not before*." *Id.* (emphasis added). The Federal Circuit upheld the district court's determination that the USPTO's methodology in calculating the A and B Delay overlap was contrary to the plain language in Section 154(b) because "it effectively counts B delay before it occurs." *Wyeth*, 591 F.3d at 1375.

Consistent with the *Wyeth* decision, after the USPTO decides that a patent application will be granted, it issues a written notice of allowance of the application. See 35 U.S.C. § 151(a). This notice includes the USPTO's initial determination of the

PTA, if applicable. 35 U.S.C. § 154(b)(3)(B)(i) (requiring the USPTO to “make a determination of the period of any [PTA]” and “transmit a notice of that determination no later than the date of issuance of the patent[.]”). The PTA reflected in the notice of allowance does not include the B Delay. See *Bristol-Myers Squibb Co.*, 891 F. Supp. 2d at 137.

The USPTO determines the proper amount of the A Delay when it issues notice to the patent applicant and before the patent is granted. *Daiichi I*, 12 F. Supp. 3d at 12. The USPTO does not determine the proper amount of the B Delay until the patent is granted because the B Delay continues to accrue until the patent is granted. *Id.* After determining the proper amounts for the A Delay and the B Delay, the USPTO determines “the extent of any overlap between the two types of delay.” *Id.* (citation omitted). “To the extent that periods of [A Delay and B Delay] overlap, any [PTA] shall not exceed the actual number of days the issuance of the patent was delayed.” *Id.* (quoting 35 U.S.C. § 154(b)(2)(A)). “Because the overlap determination depends on the amount of B Delay, it is also done at the time the patent is granted.” *Id.* (citation omitted). “The final determination of PTA—which factors in A Delay, B Delay, and A/B Overlap—is done at the time the patent is granted.” *Id.* (citation omitted).

## **2. Administrative and Judicial Review of PTAs**

A patent applicant dissatisfied with PTA determinations may

seek administrative and judicial review. *Id.* at 12-13. The patent applicant may "request reconsideration of any [PTA] determination made by the Director," 35 U.S.C. § 154(b)(3)(B)(ii), "within two months of the date the patent issued," 37 C.F.R. § 1.705(d) (2012) ("Rule 1.705(d)"). *Daiichi I*, 12 F. Supp. 3d at 13. A patentee dissatisfied with the USPTO's response to the request for reconsideration may seek further administrative review of the USPTO's decision under Rule 1.705(d) by submitting a petition under 37 C.F.R. § 1.181(f) ("Rule 1.181(f)") "within two months of the mailing date of the action or notice from which relief is requested[.]" 37 C.F.R. § 1.181(f) (2012). "[O]n petition of the interested party," the two-month limitation "may be suspended or waived by the Director or the Director's designee" in "an extraordinary situation, when justice requires[.]" 37 C.F.R. § 1.183 (2013).

Finally, the patent applicant may seek judicial review in federal district court. 35 U.S.C. § 154(b)(4)(A). At the time that Nippon's patents were issued, a civil action for judicial review of a PTA determination had to be "filed in the United States District Court for the District of Columbia within 180 days after the grant of the patent." *Id.*<sup>4</sup>

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<sup>4</sup> In 2011, Congress amended the venue provisions in certain patent statutes, including Section 154, such that suits under Section 154(b) must be filed in the United States District Court for the Eastern District of Virginia within 180 days after the

### 3. The Interim Procedure

Following the *Wyeth* decision, on February 1, 2010, the USPTO published notice of an Interim Procedure to “provid[e] patentees with the ability to request a recalculation of their [PTA] [consistent with the *Wyeth* decision] without a fee as an alternative to the petition and fee required by 37 CFR 1.705(d).” Interim Procedure for Patentees To Request a Recalculation of the PTA 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) (“Interim Procedure” or “procedure”), 75 Fed. Reg. 5043-01, 5043 (Feb. 1, 2010). According to the USPTO, this procedure would be in effect until March 2, 2010, at which time the modifications to the computer program used to calculate PTAs necessitated by the *Wyeth* decision would be complete. *Id.* at 5043. This procedure was available for only two types of PTA requests for reconsideration based on the *Wyeth* decision: (1) requests that could have been timely made within 180 days of the patent decision as set forth in 35 U.S.C. § 154(b)(4); or (2) requests that could have been timely made within the two-month time period set forth in Rule

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date of the Director’s decision on the applicant’s request for reconsideration. See *Hyatt v. Iancu*, 332 F. Supp. 3d 83, 89 n.4 (D.D.C. 2018) (citing Leahy-Smith America Invents Act, Pub. L. 112-29, § 9 (Sept. 16, 2011)); see also Def.’s MSJ, ECF No. 48 at 4 n.1.



1.181(f). *Id.* at 5043-44. The USPTO explained that the statutory and regulatory framework provides that requests for reconsideration by the USPTO of the PTA must be filed within two months of the date the patent was issued pursuant to Rule 1.705(d), and that applicants dissatisfied with a determination made by the Director of the USPTO could file a civil action within 180 days after the grant of the patent pursuant to 35 U.S.C. § 154(b)(4). *Id.* The USPTO also cited the two-month deadline for reconsideration of a Rule 1.705(d) decision pursuant to Rule 1.181(f). *Id.* at 5044. The Interim Procedure therefore provided patentees who could timely challenge the pre-*Wyeth* PTA determinations to the USPTO pursuant to Rule 1.181(f) or the district court pursuant to 35 U.S.C. § 154(b) with the opportunity to request reconsideration from the USPTO. *Id.* As a practical matter, the Interim Procedure was available for patents that had been issued between August 5, 2009 and March 1, 2010 and for patentees who received the USPTO's decision on a Rule 1.705(d) request for reconsideration on December 1, 2009 or later. *See Daiichi II*, 791 F.3d at 1375-76. Any petitions filed outside of these windows would be denied as untimely by the USPTO. 75 Fed. Reg. at 5043-44.

### **B. Factual and Procedural Background**

The material facts in this case are undisputed. *See* Pl.'s MSJ, ECF No. 46 at 16-18, 20; *see also* Def.'s MSJ, ECF No. 48 at

1, 10-11. Nippon is a foreign corporation with its principal place of business in Kyoto, Japan. Second Am. Compl., ECF No. 24 ¶ 4. Nippon is the owner of the '302 patent, entitled "Heterocyclic Compound Derivatives and Medicines," and the '997 patent, entitled "Amide Derivative." Pl.'s MSJ, ECF No. 46 at 16. The '302 patent was issued on April 17, 2007 with a notice that its term would be extended or adjusted by 344 days under 35 U.S.C. § 154(b). Administrative Record ("A.R."), ECF No. 45-3 at 90. The '997 patent was issued on February 24, 2009 with a notice that its term would be extended or adjusted by ninety-nine days under 35 U.S.C. § 154(b). *Id.* at 3.

On July 6, 2010, before seeking administrative relief, Nippon filed the initial complaint in this Court, alleging, *inter alia*, that the USPTO's pre-*Wyeth* determinations and calculations "of the [PTAs] for the '302 and '997 patents were arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law under 5 U.S.C. § 706(2)(A)." Compl., ECF No. 1 ¶ 18. Nippon filed this civil action more than three years (1,176 days) after the issuance of the '302 patent and more than a year (497 days) after the issuance of the '997 patent. See, e.g., *id.* ¶ 7; Def.'s MSJ, ECF No. 48 at 10.

Beginning in August 2010, Nippon also sought administrative review of the USPTO's PTA determinations in light of the *Wyeth* decision. See A.R., ECF No. 45-3 at 142-43. On October 12, 2010,

the USPTO denied Nippon's August 30, 2010 request for the '302 patent, treating it as a "request for reconsideration of [PTA]" under Rule 1.705(d). *Id.* at 151. Because this request was submitted outside of the "two months after the date of issuance of the ['302] patent," the USPTO dismissed it as untimely under Rule 1.705(d). *Id.* The record does not include the USPTO's decision for Nippon's second request, dated September 10, 2010, for the '302 patent. *See generally* A.R., ECF No. 45-3.

On June 10, 2016, the USPTO mailed its decision on Nippon's request as to the '997 patent, stating that it considered the request "for the issuance of a Certificate of Correction under the provisions of 37 CFR 1.322 and/or 37 CFR 1.323." *Id.* at 86 (styled "Response to the Request for Certificate of Correction").<sup>5</sup> The USPTO denied the request because it was "improper" and "[t]he patent was printed in accordance with the information set forth on the Issue Notification dated [February 24, 2009] which indicated the [PTA] is 99 day(s)." *Id.* The USPTO stated that "[a] petition to Recalculate the [PTA] is required

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<sup>5</sup> Pursuant to 37 C.F.R. § 1.322, "[t]he Director may issue a certificate of correction pursuant to 35 U.S.C. 254 to correct a mistake in a patent, incurred through the fault of the Office, which mistake is clearly disclosed in the records of the Office" under certain conditions. 37 C.F.R. § 1.322(a)(1). Under 37 C.F.R. § 1.323, "[t]he Office may issue a certificate of correction under the conditions specified in 35 U.S.C. 255 at the request of the patentee or the patentee's assignee, upon payment of the fee set forth in § 1.20(a)." 37 C.F.R. § 1.323.

to be granted in order for a certificate of correction to be issued.” *Id.*

Between 2011 and 2014, the Court issued a series of stays, at the parties’ requests, because several cases challenging the USPTO’s pre-*Wyeth* PTA calculations closely resembled the issues in this action. *See generally* docket for Civil Action No. 10-1142. In 2015, Nippon filed a second amended complaint, bringing a single facial challenge to the Interim Procedure, and seeking declaratory relief pursuant to 28 U.S.C. § 2201 in the form of a declaratory judgment stating that the Interim Procedure is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the APA, and requesting that the Court enter an injunction requiring the USPTO to rescind the procedure and correct patent terms. *See* Second Am. Compl., ECF No. 24 at 6-8; *see also* Pl.’s MSJ, ECF No. 46 at 8, 30. Thereafter, the parties filed cross-motions for summary judgment. Those motions are ripe and ready for adjudication.

### **III. Legal Standard**

#### **A. Motion for Summary Judgment**

Under Federal Rule of Civil Procedure 56, “[t]he court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a).

In a case involving review of a final agency action under the APA, ... [the court has a] limited role of ... reviewing the administrative record. The function of the district court is to determine whether or not as a matter of law the evidence in the administrative record permitted the agency to make the decision it did. Summary judgment thus serves as the mechanism for deciding, as a matter of law, whether the agency action is supported by the administrative record and otherwise consistent with the APA standard of review.

*Daiichi I*, 12 F. Supp. 3d at 14 (quoting *Nat'l Parks Conservation Ass'n v. Jewell*, 965 F. Supp. 2d 67, 73 (D.D.C. 2013) (alterations, internal quotation marks, and citations omitted)).

#### **B. Standard of Review**

Under the APA, the Court shall "hold unlawful and set aside" the agency's decision if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2) (A). "[A]n 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) (citation and internal quotation marks omitted). The scope of review under this standard is narrow.

*Id.*; see also *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State*

*Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (reviewing court may not “substitute its judgment for that of the agency.”).

In determining whether the Interim Procedure comports with law, it is necessary to determine the level of deference the USPTO is entitled to in promulgating that procedure. Guided by the limitations placed on the USPTO’s authority to promulgate regulations under Section 154(b), the Federal Circuit and courts in this Circuit have held that the USPTO’s PTA determinations are not owed deference under *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). See, e.g., *Merck*, 80 F.3d at 1550; *Wyeth*, 580 F. Supp. 2d at 141 (noting that the USPTO is not afforded *Chevron* deference because it only has the authority to issue “procedural regulations regarding the conduct of proceedings before the agency.”). Section 154(b) limits the USPTO’s authority to “prescrib[ing] regulations establishing procedures for the application for and determination of [PTAs] [.]” 35 U.S.C. § 154(b)(3)(A). The USPTO is, however, entitled to deference pursuant to *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944) based on “the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control.” *Id.* at 140; see also *Novartis I*, 904 F. Supp. 2d at

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The parties disagree as to whether the USPTO is entitled to deference of its interpretation of its regulations. *Compare* Def.'s MSJ, ECF No. 48 at 12 ("The USPTO's interpretation of its own regulations is also entitled to substantial deference."), *with* Pl.'s Reply, ECF No. 50 at 8 ("The USPTO is not entitled to deference" because Nippon "is not challenging the USPTO's 'interpretation of its own regulations.'"). The Court is not persuaded by Nippon's argument because Nippon expressly challenges the USPTO's implementation of the Interim Procedure that was based on the USPTO's interpretation of 35 U.S.C. § 154(b) and its own regulations. See Pl.'s MSJ, ECF No. 46 at 15, 21; *see also* Second Am. Compl., ECF No. 24 ¶ 15-32.

#### **IV. Analysis**

It is undisputed that the PTAs for Nippon's patents were determined using the pre-*Wyeth* method of calculating A and B Delay overlap. See Second Am. Compl., ECF No. 24 at ¶ 8. It is also undisputed that Nippon's patents were issued before August 5, 2009; Nippon did not request reconsideration of the PTAs within two months of the patents' issuance dates; and Nippon did not file a claim for judicial relief within the 180-day window. See Pl.'s MSJ, ECF No. 46 at 14, 16-17; *see also* Def.'s MSJ, ECF No. 48 at 10-11. Nor does Nippon contend that it was entitled to reconsideration of the PTAs under the Interim Procedure. See

Pl.'s MSJ, ECF No. 46 at 16. Nippon also acknowledges that it was ineligible for relief under the Interim Procedure. See Pl.'s MSJ, ECF No. 46 at 17; see also Second Am. Compl., ECF No. 24 ¶¶ 22, 24. Undeterred, Nippon seeks judicial review of the Interim Procedure. See generally Second Am. Compl., ECF No. 24.

Nippon seeks a recalculation of the PTAs by the USPTO based on the post-*Wyeth* methodology, alleging that the Interim Procedure violated the APA. Pl.'s MSJ, ECF No. 46 at 8. According to Nippon, the "sole issue" is "whether the [temporal] limitations for recalculation of [PTAs] post-*Wyeth*, set by the USPTO in the Interim Procedure, were a valid exercise of agency discretion." *Id.* at 19-20.

**A. Federal Circuit precedent does not foreclose Nippon's arguments**

As an initial matter, the parties dispute whether the doctrine of *stare decisis* determines the outcome of this case. Nippon argues that Federal Circuit precedent does not determine the outcome of this case on *stare decisis* grounds,<sup>6</sup> Pl.'s Reply,

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<sup>6</sup> Nippon also argues that *res judicata* and collateral estoppel do not apply here, see Pl.'s MSJ, ECF No. 46 at 23, a proposition that the USPTO does not dispute, see generally Def.'s MSJ, ECF No. 48; Def.'s Reply, ECF No. 52. Although the USPTO has conceded the argument by not responding, see *Campbell v. Nat'l R.R. Passenger*, 311 F. Supp. 3d 281, 327 n.13 (D.D.C. 2018), the Court agrees that Nippon is not precluded from bringing this case since it was not a litigant in *Daiichi II*. See *Cornish v. United States*, 885 F. Supp. 2d 198, 209 (D.D.C. 2012) (holding that *res judicata* barred a plaintiff's claims where he brought the same claims against the same agency in a prior suit). Courts



ECF No. 50 at 10, because Nippon's arguments here were neither presented to nor considered by the Federal Circuit in two cases dealing with some of the same issues in this case. See *Daiichi II*, 791 F.3d at 1379-80 (holding that the USPTO did not abuse its discretion by only applying the Interim Procedure to patents issued in the 180-day window); see also *Novartis II*, 740 F.3d at 600 (holding that plaintiff did not timely file suit within 180 days of denial of reconsideration pursuant to Section 154(b)(4)).<sup>7</sup> The USPTO responds that the issues raised by Nippon here were decided in the USPTO's favor in that precedent when the Federal Circuit affirmed two lower court decisions, *Daiichi II* and *Actelion Pharmaceuticals Ltd. v. Lee* ("*Actelion II*"), 565 F. App'x 887 (Fed. Cir. 2014), holding that the Interim Procedure did not violate the APA. See Def.'s MSJ, ECF No. 48 at 4-5, 5 n.2, 13-18, 20, 24; see also *Actelion Pharm. Ltd. v.*

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narrowly construe the doctrines of *res judicata* and collateral estoppel to reach the merits. Cf. *Cent. Delta Water Agency v. United States*, 306 F.3d 938, 953 (9th Cir. 2002) ("[W]hen considering whether a prior action involved the same 'nucleus of facts' for preclusion purposes, we must narrowly construe the scope of that earlier action.").

<sup>7</sup> Federal Circuit precedent is binding on this Court because a suit under Section 154(b) may only be appealed to the Federal Circuit. See 28 U.S.C. § 1295(a)(4)(C) (Federal Circuit has "exclusive jurisdiction" over "an appeal from a decision of" a federal "district court to which a case was directed pursuant to section . . . 154(b) of title 35[.]"); cf. *Kline v. Cisneros*, 76 F.3d 1236, 1239 (D.C. Cir. 1996) (holding that the court of appeals had no jurisdiction over an appeal from a district court decision where 28 U.S.C. § 1295(a)(2) gave exclusive jurisdiction to the Federal Circuit over the appeal).

*Kappos* ("Actelion I"), 972 F. Supp. 2d 51, 58 (D.D.C. 2013), *aff'd sub nom. Actelion II*, 565 F. App'x 887. However, the USPTO acknowledges that the doctrine of *stare decisis* may not apply to all of Nippon's arguments. See Def.'s MSJ, ECF No. 48 at 14, 18.

"Stare decisis compels adherence to a prior factually indistinguishable decision of a controlling court." *Brewster v. Comm'r*, 607 F.2d 1369, 1373 (D.C. Cir. 1979).

The rule of stare decisis is never properly invoked unless in the decision put forward as precedent the judicial mind has been applied to and passed upon the precise question. Questions which merely lurk in the record, neither brought to the attention of the court nor ruled upon, are not to be considered as having been so decided as to constitute precedents.

*Nat'l R.R. Passenger v. ExpressTrak, LLC*, Civil Action No. 02-1773, 2006 WL 2947558 at \*6 (D.D.C. Oct. 16, 2006) (citations omitted); see also *Supernus Pharm., Inc. v. Iancu*, 913 F.3d 1351, 1357 (Fed. Cir. 2019) (finding that a prior decision with different facts and a different legal question was not controlling in that action). Here, Nippon has raised arguments in its challenge to the Interim Procedure that were not specifically raised in the prior cases. Therefore, the Court can consider the open question of whether the Interim Procedure violates the APA based on those arguments.

**B. The Interim Procedure does not violate the APA, and is not arbitrary and capricious or otherwise contrary to law**

Nippon contends that the Interim Procedure violates the APA because it treats similarly-situated patentees differently in that it allows some, but not all, patentees to receive post-*Wyeth* PTA recalculations. See Pl.'s MSJ, ECF No. 46 at 1, 9-11, 23-30. The USPTO responds that Nippon's claims must be resolved in its favor based on the Federal Circuit's decisions in *Novartis II*, *Daiichi II*, and the summary affirmance in *Actelion II* because in those decisions, the Federal Circuit concluded that the Interim Procedure is not arbitrary, capricious, or otherwise contrary to law under the APA. See Def.'s MSJ, ECF No. 48 at 13-18. According to the USPTO, Nippon's "challenge is just another collateral attack on the USPTO's decision not to reopen all of the final [PTA] determinations in earlier patents for which the patent owners did not seek timely reconsideration either under 37 C.F.R. § 1.705(d) [2012] or 35 U.S.C. § 154(b) (4) (A)." *Id.* at 19.

**1. Prior challenges to the Interim Procedure**

*Novartis II* involved a challenge to the PTA determinations for certain patents outside of the 180-day limitation period set forth in Section 154(b) (4) rather than, as here, a facial challenge to the Interim Procedure. 740 F.3d at 595, 599-600. There, the plaintiff argued, among other things, that the

limitation period should be equitably tolled because the *Wyeth* decision had not been decided when the patents issued. *Id.* at 600. The Federal Circuit “readily affirm[ed] the district court’s holding that [the plaintiff]’s claims as to fifteen patents were untimely asserted” since the plaintiff did not seek relief within the 180-day period, noting that “nothing stood in the way of Novartis’s timely pressing the very claim *Wyeth* pressed.” *Id.*

The other two cases cited by the USPTO did involve challenges to the Interim Procedure itself. In *Daiichi II*, the Federal Circuit affirmed the district court’s grant of summary judgment in favor of the USPTO where the plaintiff there challenged the USPTO’s use of the 180-day period for administrative review under the APA and the USPTO’s “disparate treatment” of patents issued before August 5, 2009. 791 F.3d at 1379-81. Two of the patents at issue there did not qualify for the USPTO’s Interim Procedure because they were issued before August 5, 2009. *Id.* at 1376. The plaintiff filed Rule 1.705(d) requests for reconsideration of the PTAs outside of the two-month window and petitions under 37 C.F.R. § 1.183 to waive the two-month window in light of the *Wyeth* decision. *Id.* The USPTO denied the plaintiff’s requests and petitions because they were untimely. *Id.* The plaintiff later filed requests for reconsideration of the USPTO’s denials, but the USPTO also

denied those requests because the USPTO's Interim Procedure only allowed requests for recalculation of the PTAs within 180 days after the grant of the patent. *Id.* The USPTO explained, among other things, that the USPTO would not accept any requests for PTA recalculations outside of the 180-day window because "the judicial-review provision of 35 U.S.C. § 154(b)(4) evidenced congressional intent that PTA issues be resolved soon after issuance." *Id.* (citation and internal quotation marks omitted).

Accepting the USPTO's reasoning for only considering requests filed within the 180-day window, the Federal Circuit held that the USPTO "acted within its discretion under the statute to 'prescribe regulations establishing procedures for the . . . determination of [PTAs]' . . . in adopting the 180-day period as part of the Interim Procedure." *Id.* at 1379-80 (quoting 35 U.S.C. § 154(b)(3)). The Federal Circuit also held that "the [US]PTO acted within its discretion in denying Daiichi's requests for reconsideration of the [PTA] determinations." *Id.* at 1380. The Federal Circuit accepted the USPTO's "ample reasoning" that "this brief [180-day] period for judicial review indicates Congress' intent that [the USPTO] resolve [PTA] issues more expeditiously than allowed under the full administrative challenge period." *Id.* In doing so, the Federal Circuit found that the USPTO did not abuse its discretion in fashioning regulations for the procedures of PTA

reconsiderations that rejected petitions for administrative review outside of the 180-day window. *Id.*

The Federal Circuit in *Daiichi II* also rejected the disparate treatment argument the plaintiff made there. *See id.* at 1380-81. The Federal Circuit found that the USPTO's decision to grant extensions of the administrative review period for some patents to match the 180-day judicial review period for all patents was not arbitrary and capricious. *Id.* at 1381. The Federal Circuit determined that the plaintiff "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.* The Federal Circuit made clear that "[c]hoosing 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.*

The USPTO also cites the Federal Circuit's summary affirmance of *Actelion I*, in which the district court held that the Interim Procedure did not violate the APA. *Actelion II*, 565 F. App'x 887 (affirming the district court's decision without an opinion under Federal Circuit Rule 36). However, the grounds upon which the district court relied—that the plaintiff was "foreclosed from using an APA claim to circumvent § 154(b)(4)(A)'s 180-day time limit to attain a PTA

recalculation" because Section 154(b)(4)(A) "expressly waives sovereign immunity for appeals of PTA determinations and makes them reviewable under the APA's judicial review provisions"—is not an argument advanced by the USPTO here. *Id.* at 58 n.9.

## **2. The Rule 1.181(f) Challengers were not treated differently**

Nippon argues that the Interim Procedure violates the APA because it treats two categories<sup>8</sup> of similarly-situated patentees differently without providing a rationale. Pl.'s MSJ, ECF No. 46 at 23. The first category of similarly-situated patentees are

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<sup>8</sup> The USPTO points out that Nippon does not fall into the categories of patents that the USPTO purportedly treated differently under the Interim Procedure because Nippon did not seek judicial relief within the prescribed time limits. See Def.'s MSJ, ECF No. 48 at 19-20. Nippon could not seek administrative relief under the Interim Procedure because it did not file a timely request for reconsideration under Rule 1.705(d), and none of Nippon's patents were issued between July 15, 2009 and August 5, 2009. See *id.* at 19, n.8. In its reply brief, the USPTO states for the first time that the APA's "harmless error" rule weighs against Nippon's APA challenge because "[i]f the agency's mistake did not affect the outcome, if it did not prejudice the petitioner, it would be senseless to vacate and remand for reconsideration." Def.'s Reply, ECF No. 52 at 6 (citation omitted). Although the USPTO pointed out the underlying factual issue in its cross motion, it did not make the legal argument until its reply brief. See generally Def.'s MSJ, ECF No. 48; Def.'s Reply, ECF No. 52. Arguments raised for the first time in a reply brief are waived. *Lindsey v. District of Columbia*, 879 F. Supp. 2d. 87, 95 (D.D.C. 2012). Even if the Court were to consider it, the Court doubts it would be meritorious because the relief Nippon seeks should the Court find the procedure to violate the APA is for the Court to enter an injunction requiring the USPTO to rescind the procedure and correct patent terms affected by the *Wyeth* decision, which would give Nippon the relief it seeks. See Second Am. Compl., ECF No. 24 at 8; see also Pl.'s MSJ, ECF No. 46 at 8, 30.

those who could timely challenge the pre-*Wyeth* determinations to the USPTO pursuant to Rule 1.181(f) ("Rule 1.181(f) Challengers"). *Id.* at 23-24. Nippon argues that the Interim Procedure created an "exception" to allow patentees in this category to seek relief pursuant to the Interim Procedure and that the exception is arbitrary because a patentee's ability to timely seek relief depends upon the date the USPTO's response to the request for reconsideration was mailed pursuant to Rule 1.705(d). *Id.* at 23-25. As a result, two patentees who received a patent on the same day are being treated differently due to the date the USPTO's response was mailed. *Id.* at 25.

Specifically, if one patentee timely requested reconsideration pursuant to Rule 1.705(d) and that request was denied within two months of February 1, 2010, the patentee could seek a post-*Wyeth* adjustment. *Id.* If, however, the patentee's request for reconsideration was denied more than two months prior to February 1, 2010, the patentee could not seek a post-*Wyeth* adjustment. *Id.* Nippon argues that this is arbitrary and capricious because: (1) the two-month window from December 1, 2009 to February 1, 2010 was arbitrary in part because the patentee has no control over the date triggering that window; and (2) no rationale was provided in the Interim Procedure for allowing this category of patentees to challenge the PTA determinations within two months rather than 180 days. *Id.* at



25-28. Nippon concludes that it is illogical to limit the availability of post-*Wyeth* relief for the Rule 1.181(f) Challengers because the reason for implementing the Interim Procedure was to expand administrative relief. *Id.* at 27; see also Pl.'s Reply, ECF No. 50 at 14.

The USPTO responds that this aspect of the procedure is not arbitrary for at least two reasons. First, because the patentees in this category could seek review of the PTAs pursuant to existing regulations, their inclusion in the Interim Procedure was merely a recognition of this fact rather than an "exception" to the procedure. Def.'s MSJ, ECF No. 48 at 20-21. Second, "the Interim Procedure grouped patentees into two categories: those who could still timely challenge their pre-*Wyeth* PTA determination (either administratively or judicially) and those who could not." *Id.* at 21. Patentees in the former category could use the Interim Procedure and those in the latter category could not. *Id.* The USPTO concludes that patentees who could still timely administratively challenge the PTA determination as of the date the Interim Procedure was published were similarly situated with those who could challenge it judicially and were treated alike, so there is no disparate treatment. *Id.* The USPTO also disputes that the two-month window was arbitrary and that no rationale was provided because the two-month window was dictated by existing USPTO regulations and the Interim Procedure

specifically cited 37 C.F.R. § 1.181(f). *Id.* at 22-24.

The Court is not persuaded by Nippon's arguments regarding the Rule 1.181(f) Challengers. Patentees who were able to timely seek post-*Wyeth* relief pursuant to Rule 1.181(f) were able to do so pursuant to long-standing USPTO regulations. See 37 C.F.R. § 1.181(f) (A patentee dissatisfied with the response to the request for reconsideration may seek further administrative review of the USPTO's decision under Rule 1.705(d) by submitting a petition under 37 C.F.R. § 1.181(f) "within two months of the mailing date of the action or notice from which relief is requested."). Although the date of a USPTO decision responding to a Rule 1.705 request for reconsideration is not within the patentee's control, "[f]iling deadlines, like statutes of limitations, necessarily operate harshly and arbitrarily with respect to individuals who fall just on the other side of them, but if the concept of a filing deadline is to have any content, the deadline must be enforced." *United States v. Locke*, 471 U.S. 84, 101 (1985). Moreover, this deadline exists in long-standing USPTO regulations. *Cf. Sec. Univ. v. Acosta*, 317 F. Supp. 3d 343, 348 (D.D.C. 2018) ("Although there is no set timeframe for determining what is or is not arbitrary and capricious, these timeframes are consistent with analogous circumstances."). The Court therefore finds that the two-month window is neither arbitrary nor capricious. See *Daiichi II*, 791 F.3d at 1380-81

(Section 154(b)(3)(A) expressly authorizes the USPTO to make regulations, including administrative filing deadlines, governing the procedures of PTA reconsiderations); *cf. Novartis II*, 740 F.3d at 600 (noting a plaintiff's failure to comply with the USPTO's "reasonable filing deadlines[.]").

Despite Nippon's contention that no rationale was provided for allowing the Rule 1.181(f) challenges, the Interim Procedure itself cited Rule 1.181(f). See 75 Fed. Reg. at 5044. Finally, the Rule 1.181(f) Challengers were treated identically to all other patentees who could still timely challenge their PTA determinations under the Interim Procedure. See *Daiichi II*, 791 F.3d at 1381. And patentees who could not timely challenge their PTA determinations were treated the same since they were excluded from the Interim Procedure. See 75 Fed. Reg. at 5043-44. The USPTO's grouping of challengers into those who could still timely challenge their PTA determinations and those who could not is a reasonable and valid exercise of agency discretion and firmly rooted in long-standing USPTO regulations.

Nippon's remaining arguments are without merit. Nippon argues that the "arbitrary nature of the two-month window for . . . a renewed request for reconsideration as provided in the Interim Procedure is further evidenced by the fact that the concept of the Interim Procedure was . . . to . . . essentially replac[e] the two month deadline with 180 days." Pl.'s MSJ, ECF

No. 46 at 27. But as the USPTO points out, “[t]he Interim Procedure waived the two-month period set forth in Rule 1.705(d) . . . and ‘replaced’ it with the 180-day period set forth in Section 154(b) (4) (A) . . . because such timely judicial challenges would eventually return to the USPTO through remands from the court.” Def.’s MSJ, ECF No. 48 at 26. A similar replacement for the Rule 1.181(f) Challengers did not make sense because they already filed timely requests for reconsideration under Rule 1.705(d).

Nippon also contends that the Interim Procedure was “simply arbitrary and capricious” for “provid[ing] no comment period.” Pl.’s MSJ, ECF No. 46 at 26-27; see also *id.* at 9 (“[T]he USPTO did not provide a period for public comment and articulated no rationale for its position”). The court in *Actelion I* rejected the plaintiff’s argument that the Interim Procedure violated the APA because it “was not promulgated via notice-and-comment rulemaking pursuant to 5 U.S.C. § 553.” 972 F. Supp. 2d at 58 n.9. The court found that the “USPTO was not required to use notice-and-comment rulemaking to devise the Interim Procedure because it is a procedural rule, not a substantive rule.” *Id.* (citing 5 U.S.C. § 553(b) (A); *Chamber of Commerce of U.S. v. U.S. Dep’t of Labor*, 174 F.3d 206, 211 (D.C. Cir. 1999)). For the same reasons, this Court rejects Nippon’s suggestion that a comment period was required prior to the publication of the

Interim Procedure.

### **3. The July patents were not treated differently**

The second category of allegedly similarly-situated patentees who Nippon asserts were treated differently as a result of the Interim Procedure are those whose patents issued between July 15, 2009 and August 5, 2009 (the "July patents"). See Pl.'s MSJ, ECF No. 46 at 28-30; see also Pl.'s Reply, ECF No. 50 at 7, 13, 19. Patents issued during this timeframe "reached 180 days post-issuance between the *Wyeth* decision and the establishment of the Interim Procedure." Pl.'s MSJ, ECF No. 46 at 28. Thus, these patentees could have filed judicial challenges to their PTA calculations in light of the *Wyeth* decision, but no longer could once the Interim Procedure was published. *Id.* Nippon argues that these patentees were treated differently than patentees whose patents had issued more than 180 days prior to the deadline and that they were "misled" by the USPTO's announcements about forthcoming guidance to implement the *Wyeth* decision into thinking that they would have an administrative remedy. *Id.* at 28-30. Nippon maintains that it was "logical" for these patentees not to file a judicial challenge in light of the USPTO's announcements. *Id.* at 28.

The USPTO responds that the Federal Circuit decided this issue in *Daiichi II* when it held that the USPTO "did not abuse its discretion by determining not to accept petitions for

administrative review filed more than 180 days after the patent grant.” Def.’s MSJ, ECF No. 48 at 27 (quoting *Daiichi II*, 791 F.3d at 1380). Even if this decision does not control, the USPTO alternatively maintains that the July patents were treated the same as patents issued before August 5, 2009, and the July patents are actually not a separate category because they belong to the same category of patent holders who fell outside of the 180-day period under the Interim Procedure. See *id.* at 28. The USPTO disputes Nippon’s argument that it was “logical” for this group of patentees not to seek judicial relief because the USPTO’s announcements expressly reminded patentees that they needed to comply with the 180-day period to seek judicial relief. *Id.* at 28-29.

The Court is not persuaded by Nippon’s arguments regarding the July patents. First, as the USPTO points out, it is undisputed that the July patents issued prior to August 5, 2009. See *id.* at 27. In *Daiichi II*, in rejecting the disparate treatment argument advanced there, the Federal Circuit determined that the plaintiff there “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.” 791 F.3d at 1380. In other words, the *Daiichi II* plaintiff was treated identically to all other patentees whose patents issued prior to August 5, 2009.

*See id.*

Nippon maintains that the July patents were treated differently from other patentees whose patents issued prior to August 5, 2009 because they could have sought judicial review of their PTAs after the *Wyeth* decision, but they were “misled” by the USPTO in its announcements. Pl.’s MSJ, ECF No. 46 at 29. Assuming a filing deadline is a proper basis for determining whether parties are similarly-situated, the Court disagrees that the July patents were treated differently because nothing prevented those patentees from filing judicial challenges either pre- or post-*Wyeth*. *See Novartis II*, 740 F.3d at 600 (“At a minimum, nothing stood in the way of Novartis’s timely pressing the very claim *Wyeth* pressed.”).

Finally, the record does not support Nippon’s contention that the July patents were “misled” by the USPTO. Four days after the *Wyeth* decision was issued on January 7, 2010, the USPTO posted a two-paragraph notice stating that pending a determination of whether to seek further review of the decision, “the USPTO is in the process of changing the manner it will calculate [PTAs] under Section 154(b) to conform to the Federal Circuit’s decision.” Pl.’s MSJ, Ex. B, ECF No. 46-3 at 2. The second paragraph reminded interested parties of the deadline for seeking judicial review: “Applicants and Patent Owners dissatisfied with a [PTA] determination by the agency are

reminded of the requirement to seek review of that determination within 180 days of patent issuance and the time periods set in the implementing regulations. See 35 USC 154(b)(4) and 37 CFR 1.705." *Id.* Later, on January 20, 2010, the USPTO issued a two-paragraph announcement stating that it and the Department of Justice would not seek further review of the *Wyeth* decision and that "[t]he USPTO [was] preparing guidance for expediting requests for recalculation of [PTA] by the USPTO in light of the *Wyeth* decision. This guidance will be issued as soon as possible." Pl.'s MSJ, Ex. A, ECF No. 46-2 at 2. The announcement included the exact same reminder of the deadline for seeking judicial review that had been in the January 11, 2010 notice. *Id.* Therefore, rather than it being "reasonable" for the July patents "to believe that the USPTO was going to implement a process to correct its mistake that would not require judicial review" and "[t]here was no reason for these patentees to believe that the USPTO's upcoming guidance would not apply to them[,] " Pl.'s MSJ, ECF No. 46 at 29-30, the USPTO expressly reminded patent applicants and owners of the deadline for seeking judicial review. Since Nippon has failed to show that the Interim Procedure treated similarly-situated patentees - *i.e.*, those whose patents issued prior to August 5, 2009 - differently, and since the record does not support its contention that the July patents were misled by the USPTO, its



APA challenge fails.<sup>9</sup>

## **V. Conclusion**

For the reasons set forth above, and in view of the narrow scope of review and deference appropriately due, the Court finds that the Interim Procedure is not arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. Accordingly, the Court **DENIES** Nippon's motion for summary judgment and **GRANTS** USPTO's cross-motion for summary judgment. A separate Order accompanies this Memorandum Opinion.

## **SO ORDERED**

Signed: Emmet G. Sullivan  
United States District Judge  
February 27, 2019

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<sup>9</sup> Nippon argues that the USPTO treated it disparately when it denied its requests as untimely on different grounds. See Pl.'s MSJ, ECF No. 46 at 25-26. But the USPTO maintains that its denials of Nippon's requests, which were improperly submitted as requests for certificates of correction, did not constitute "impermissible arbitrary and capricious treatment under the APA" because it specifically identified the procedural infirmities in Nippon's requests in different responses—Nippon filed the request for the '302 patent outside of the two-month deadline and Nippon's request for the '997 patent incorrectly used the general provisions of 35 U.S.C. § 254 instead of the regulations promulgated under 35 U.S.C. § 154(b)(4). Def.'s MSJ, ECF No. 48 at 27. The Court agrees.