

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

ACTELION PHARMACEUTICALS, LTD.,
Plaintiff-Appellant

v.

**JOSEPH MATAL, PERFORMING THE FUNCTIONS
AND DUTIES OF THE UNDER SECRETARY OF
COMMERCE FOR INTELLECTUAL PROPERTY
AND DIRECTOR, U.S. PATENT AND TRADEMARK
OFFICE,**
Defendant-Appellee

2017-1238

Appeal from the United States District Court for the Eastern District of Virginia in No. 1:16-cv-00304-LO-TCB, Judge Liam O'Grady.

Decided: February 6, 2018

THOMAS HOXIE, Hoxie & Associates, LLP, Millburn, NJ, argued for plaintiff-appellant.

DANA KAERSVANG, Appellate Staff, Civil Division, United States Department of Justice, Washington, DC, argued for defendant-appellee. Also represented by CHAD A. READLER, DANA J. BOENTE; KIMERE JANE KIMBALL, Office of the United States Attorney for the Eastern

District of Virginia, Alexandria, VA; NATHAN K. KELLEY, BRIAN RACILLA, MOLLY R. SILFEN, Office of the Solicitor, United States Patent and Trademark Office, Alexandria, VA.

Before LOURIE, O'MALLEY, and WALLACH, *Circuit Judges*.

LOURIE, *Circuit Judge*.

Actelion Pharmaceuticals, Ltd. (“Actelion”) appeals from the grant of summary judgment by the United States District Court for the Eastern District of Virginia in favor of the United States Patent and Trademark Office (“PTO”) regarding the length of the patent term adjustment (“PTA”) for U.S. Patent 8,658,675 (“the ’675 patent”), entitled “Pyridin-4-yl Derivatives.” *See Actelion Pharm., Ltd. v. Lee*, 216 F. Supp. 3d 680 (E.D. Va. 2016). For the reasons that follow, we affirm.

BACKGROUND

Congress has established a framework in 35 U.S.C. § 154 (2012) to adjust a patent’s term “[t]o account for any undue delays in patent examination caused by the PTO.” *Pfizer, Inc. v. Lee*, 811 F.3d 466, 468 (Fed. Cir. 2016). One such delay is designated an “A Delay,” which “arises when the PTO fails to meet statutory deadlines for events that occur during prosecution, such as providing notice to the applicant of the rejection of a claim or taking action on an applicant’s reply to such a rejection.” *Daiichi Sankyo Co. v. Lee*, 791 F.3d 1373, 1374 (Fed. Cir. 2015).

The only dispute in the instant case is the A Delay calculation, under 35 U.S.C. § 154(b)(1)(A)(i)(II) in particular, for the ’675 patent granted from U.S. Patent Application 13/383,619 (“the ’619 application”), which was filed as a national stage application pursuant to 35 U.S.C. § 371.

I. Relevant Statutes

On January 14, 2013, Congress enacted the Technical Corrections—Leahy-Smith America Invents Act (“Technical Corrections Act” or “TCA”), Pub. L. No. 112-274, 126 Stat. 2456 (2013). As the name of the Act suggests, the TCA made certain technical corrections to various sections of Title 35 following the enactment of the Leahy-Smith America Invents Act (“AIA”), including amendments to certain provisions of 35 U.S.C. § 154.

The current version of 35 U.S.C. § 154(b)(1)(A), as amended by the TCA, provides in part:

(A) GUARANTEE OF PROMPT PATENT AND TRADEMARK OFFICE RESPONSES.—Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the Patent and Trademark Office to—

(i) provide at least one of the notifications under section 132 or a notice of allowance under section 151 not later than 14 months after—

...

(II) the date of *commencement of the national stage under section 371* in an international application;

...,

the term of the patent shall be extended 1 day for each day after the end of the period specified in clause (i), (ii), (iii), or (iv), as the case may be, until the action described in such clause is taken.

35 U.S.C. § 154(b)(1)(A) (post-TCA) (emphasis added).

Prior to the amendments under the TCA, § 154(b)(1)(A)(i)(II) read:

(II) the date on which an international application *fulfilled the requirements of section 371* of this title;

35 U.S.C. § 154(b)(1)(A)(i)(II) (pre-TCA) (emphasis added).

Subsection 1(n) of the TCA provides that “[e]xcept as otherwise provided in this Act, the amendments made by this Act shall take effect on the date of enactment of this Act, and shall apply to proceedings commenced on or after such date of enactment.” TCA, Pub. L. No. 112-274, § 1(n), 125 Stat. at 2459.

A patent applicant may file an international patent application pursuant to the Patent Cooperation Treaty (“PCT” or “Treaty”), which was implemented in 35 U.S.C. § 351 *et seq.*, and enter a national stage in the PTO by complying with certain filing requirements. *See Exela Pharma Scis., LLC v. Lee*, 781 F.3d 1349, 1350 (Fed. Cir. 2015); *see also* PCT, June 19, 1970, 28 U.S.T. 7645, 1160 U.N.T.S. 231, as amended on Sept. 28, 1979 and modified on Feb. 3, 1984 and Oct. 3, 2001. The commencement of the national stage of an international patent application filed under the PCT is specified in 35 U.S.C. § 371, which provides in part:

(b) *Subject to subsection (f) of this section, the national stage shall commence* with the expiration of the applicable time limit under article 22(1) or (2), or under article 39(1)(a) of the treaty.

(c) The applicant shall file in the Patent and Trademark Office—

(1) the national fee provided in section 41(a);

(2) a copy of the international application, . . . , and a translation into the English

language . . . , if it was filed in another language;

(3) amendments, if any, to the claims in the international application . . . ;

(4) an oath or declaration of the inventor . . . ;

. . . .

(f) *At the express request* of the applicant, the national stage of processing *may be commenced at any time at which the application is in order* for such purpose and the applicable requirements of subsection (c) of this section have been complied with.

35 U.S.C. § 371(b), (c), (f) (emphases added). Section 371 was unchanged by the TCA. *See generally* Pub. L. No. 112-274, 125 Stat. at 2456–59.

Article 22 of the PCT, which is referenced in § 371(b), specifies the national stage filing requirements under the Treaty, including the requirement to file the national stage application “not later than at the expiration of 30 months from the priority date.” PCT art. 22(1); *see* 35 U.S.C. § 371(b).

II. Filing History of the '675 Patent

Actelion filed International Patent Application PCT/IB2009/053089 (“the first PCT application”) on July 16, 2009 (“the priority date”), and International Patent Application PCT/IB2010/053224 (“the second PCT application”) on July 15, 2010, claiming priority from the first PCT application.

On January 12, 2012, four days before January 16, 2012, *i.e.*, 30 months from the priority date (“the 30-month date”), Actelion filed the '619 application as a national stage application of the second PCT application,

claiming priority from the July 16, 2009 priority date. Along with the '619 application, Actelion filed a preliminary amendment with remarks, including one stating that "Applicant earnestly solicits early examination and allowance of these claims," J.A. 162, and submitted a completed PTO Form 1390, which provides checkboxes for the applicant to indicate various information concerning the national stage application. Notably, in its PTO Form 1390, Actelion did not check the box numbered 3 ("box 3") next to the statement reading: "This is an express request to begin national examination procedures (35 U.S.C. [§] 371(f)). . . ." J.A. 151.

It is undisputed that the requirements under 35 U.S.C. § 371(c) were met on January 12, 2012. *See* Appellant's Br. 4; Appellee's Br. 7; J.A. 163. It is also undisputed that the 30-month date, January 16, 2012, fell on a federal holiday, namely, Martin Luther King, Jr. Day. On April 26, 2013, the PTO issued a restriction requirement, which constituted "at least one of the notifications under section 132," 35 U.S.C. § 154(b)(1)(A)(i), undisputedly ending the accrual of A Delay, which started from "14 months after," *id.*, the date specified in § 154(b)(1)(A)(i)(II), the identity of which is at issue in this appeal.

On February 5, 2014, the PTO issued an Issue Notification of the '675 patent, providing a grant of 41 PTA days, encompassing the period from March 16, 2013 to April 26, 2013. The '675 patent thereafter was issued on February 25, 2014, bearing a notice of 41 PTA days. In July 2014, Actelion filed PTO Form 132, entitled "Request for Recalculation of Patent Term Adjustment in View of *AIA Technical Corrections Act*," requesting recalculation of the PTA for the '675 patent. J.A. 178. In September 2014, the PTO did recalculate the PTA for the '675 patent, but reduced it to 40 days, encompassing the period from March 17, 2013 to April 26, 2013.

In November 2014, Actelion filed a petition for reconsideration under 37 C.F.R. § 1.705, contending that the '675 patent is entitled to 45 PTA days, or alternatively, at least 41 PTA days. Actelion argued that the accrual of A Delay for the '675 patent should have been calculated based on the '619 application's filing date, January 12, 2012, or at least based on the 30-month date, January 16, 2012. In September 2015, the PTO denied Actelion's petition. Actelion filed a second petition for reconsideration in November 2015, for which the PTO did not issue a decision in view of the pendency of this suit.

On March 18, 2016, Actelion filed suit against the PTO in the Eastern District of Virginia pursuant to § 154(b)(4). Actelion and the PTO filed, respectively, a motion and a cross-motion for summary judgment in the district court, and the court granted summary judgment in favor of the PTO.¹ *Actelion*, 216 F. Supp. 3d at 688. The district court agreed with the PTO that under either pre- or post-TCA law, the PTA for the '675 patent should be the same because the conditions under 35 U.S.C. § 371(b) and (f) were not met on the day the '619 application was filed. *Id.* at 686. The district court further agreed with the PTO that it properly determined that the national stage did not commence on the 30-month date that fell on a federal holiday. *Id.* at 687–88.

Actelion timely appealed. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(4)(C) (2012).

¹ Although the district court phrased its discussion in terms of “standing,” *Actelion*, 216 F. Supp. 3d at 684–85, the district court's analysis and conclusion actually decided the merits of the PTO's determination of the PTA for Actelion's '675 patent. Because we affirm the district court's merits determination, a remand to correct this error in “label” is unnecessary. *See Morrison v. Nat'l Austl. Bank Ltd.*, 561 U.S. 247, 254 (2010).

DISCUSSION

We review the district court’s grant of summary judgment *de novo*, “applying the same standard as the district court.” *Pfizer*, 811 F.3d at 470 (internal quotation marks and citation omitted). “[W]e review questions of pure statutory interpretation without deference to the district court.” *Mohsenzadeh v. Lee*, 790 F.3d 1377, 1381 (Fed. Cir. 2015) (citation omitted). As Actelion challenges the PTO’s PTA determination that is “governed by those standards employed by the Administrative Procedure Act,” *Pfizer*, 811 F.3d at 470–71 (citing 35 U.S.C. § 154(b)(4)(A)), “we must affirm the PTO’s [PTA] determination unless it is ‘arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law,’” *id.* at 471 (quoting 5 U.S.C. § 706) (citation omitted); *see also Gilead Scis., Inc. v. Lee*, 778 F.3d 1341, 1346 (Fed. Cir. 2015).

On appeal, Actelion makes three arguments in support of its request for additional PTA.² First, Actelion argues that the ’675 patent’s A Delay calculation should be based on the ’619 application’s filing date, January 12, 2012. Actelion contends this is so because, under the pre-TCA version of § 154(b)(1)(A)(i)(II) that Actelion argues should apply here, Actelion “fulfilled the requirements of section 371” by fulfilling all applicant-side requirements of § 371, namely, those set forth in § 371(c), as of that

² Actelion contends that we should reach an argument the district court did not consider: that the PTO’s denial of additional PTA time constituted an unconstitutional taking. Given our conclusion that the district court did not err in affirming the PTO’s PTA calculation, this issue is moot. *See* Oral Argument at 4:28–51, *Actelion Pharm., Ltd. v. Matal*, No. 17-1238 (Fed. Cir. Dec. 8, 2017), <http://oralarguments.cafc.uscourts.gov/default.aspx?fl=2017-1238.mp3>.

date. Second, Actelion argues that regardless whether the pre- or post-TCA version of § 154(b)(1)(A)(i)(II) is applicable, it has made an “express request” under § 371(f) despite its failure to check box 3 because it stated in its preliminary amendment that it “earnestly solicits early examination.” Finally, and alternatively, Actelion argues that the ’675 patent’s A Delay should be based strictly on the 30-month date without regard to the fact that the 30-month date fell on a federal holiday, because § 371(b) requires that the national stage “*shall* commence” on the expiration date specified in PCT Article 22, *i.e.*, “30 months from the priority date.”

A Delay calculation must be based on the date on which the entirety of § 371 has been complied with, including § 371(c) as well as § 371(b) and § 371(f). We conclude that, to commence the national stage early, Actelion was required to make an express request pursuant to § 371(f) regardless whether the pre- or post-TCA version of § 154(b)(1)(A)(i)(II) applies to the ’675 patent. In addition, the district court did not err in affirming the PTO’s finding that Actelion failed to make an express request for early examination on the ’619 application such that national entry could have commenced before January 16, 2012. Nor did it err in affirming the PTO’s A Delay calculation on the ’675 patent, as per the relevant PCT articles and regulations, national stage commencement cannot occur on a federal holiday.

I. Compliance with the Entirety of § 371 Is Necessary
Under § 154(b)(1)(A)(i)(II)

Actelion first argues that the ’675 patent’s A Delay calculation should be based on the ’619 application’s filing date, January 12, 2012. Actelion contends that the pre-TCA version of § 154(b)(1)(A)(i)(II) should apply because the ’619 application was filed before the effective date of the TCA. It asserts that under the pre-TCA version of § 154(b)(1)(A)(i)(II), it has “fulfilled the requirements of

section 371” because it has fulfilled all the applicant’s requirements of § 371(c).

The PTO responds that the pre-TCA “requirements of section 371” include the requirements under § 371(b) and (f), and that, under the PCT, the national stage of an international application cannot commence prior to the expiration of the exclusive 30-month international processing period unless early examination is expressly requested by the applicant pursuant to § 371(f). The PTO argues that, although post-TCA law applies to the PTA for the ’675 patent, whether pre- or post-TCA law applies does not matter because of Actelion’s failure to make an express § 371(f) request under either pre- or post-TCA law.

We agree with the PTO that, under either the pre- or post-TCA version of § 154(b)(1)(A)(i)(II), the A Delay calculation must be based on the date on which the entirety of § 371 is complied with, including § 371(b) and (f). As such, we conclude that under either pre- or post-TCA law, Actelion was required to comply with the “express request” provision of § 371(f) if it wished to commence the national stage before the expiration date provided in § 371(b).

Actelion argues, relying on the pre-TCA statute, that the A Delay calculation should be based on the date that § 371(c) was complied with, regardless of § 371(b) and (f). According to Actelion, on January 12, 2012, *Actelion* “fulfilled” *its* “requirements” by filing all the necessary documents under § 371(c), which is the only subsection of § 371 imposing requirements on an applicant. Actelion further contends that the “requirements” in § 371 refer specifically to *applicant’s* requirements, or § 371(c) requirements, as referenced in § 371(d). Therefore, Actelion argues, the accrual of the ’675 patent’s A Delay should have been based on this “fulfill[ment]” of § 371(c)’s applicant “requirements” under pre-TCA law. Actelion does

not make any corresponding post-TCA statutory arguments.

Actelion's argument for discerning a distinction between the pre- and post-TCA § 154(b)(1)(A)(i)(II) hinges on the alleged distinction between the "commencement of the national stage under" (pre-TCA) and the "fulfilled the requirements of" (post-TCA) language as applied to the filing history of the '675 patent. However, this argument fails for the simple reason that both pre- and post-TCA provisions are followed by reference to "section 371" without reference to any particular subsection of § 371. Congress knew how to specify requirements of particular subsections where it so desired, but did not do so in either the pre- or post-TCA § 154(b)(1)(A)(i)(II). 35 U.S.C. § 371(d) (referring to the "requirements" in specific "subsection[s]"); *id.* § 371(f) (referring to "the applicable requirements of subsection (c)"); *see also Sebelius v. Cloer*, 569 U.S. 369, 378 (2013) ("We have long held that where Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion." (citation and internal quotation marks omitted)).

Aside from urging us to read the PTA statute to compensate an applicant for a time period not attributable to the applicant's inaction, Actelion does not provide a convincing reason why the clear language of "the requirements of section 371" should be limited to the applicant's requirements of § 371(c) under pre-TCA law. Similarly, although not challenged by Actelion on appeal, the post-TCA statute also unambiguously refers to the entirety of "section 371." We therefore decline to read either the pre- or post-TCA § 154(b)(1)(A)(i)(II) in a manner that would disregard compliance with § 371(b) and (f), contrary to the clear language of the statute. *See Simmons v. Himmelreich*, 136 S. Ct. 1843, 1848 (2016) ("Ab-

sent persuasive indications to the contrary, we presume Congress says what it means and means what it says.”).

II. Actelion Failed to Make an Express Request for Early Examination

Having concluded that under either the pre- or post-TCA statute, Actelion was required to make an express request pursuant to § 371(f) if it wished to commence the national stage on January 12, 2012, we next turn to the question whether Actelion actually made such a request.

Actelion argues that even if its statutory argument fails, under either pre- or post-TCA law, it made a § 371(f) express request in its remark that it “earnestly solicits early examination and allowance of these claims.” Appellant’s Br. 28 (citing J.A. 162). Actelion contends that the use of the PTO forms is only optional, as stated in the PTO’s own guidance materials, and that PTO Form 1390 is only one of many ways to make an express § 371(f) request.

The PTO responds that Actelion failed to make an “express request” for early examination under § 371(f) because it did not check box 3, failed to make any mention of § 371(f) in the remarks portion of the preliminary amendment, and, at any rate, the “earnestly solicits early examination” remark was mere boilerplate language it has used in a number of its non-PCT based applications.

Actelion’s argument is unsound. Using the PTO form may be optional, and, as Actelion contends, there may be other ways to communicate to the PTO an “express request” pursuant to § 371(f). However, neither the fact that using the PTO forms may be optional nor the availability of other § 371(f)-compliant means of making an express request excuses an applicant’s failure to make its intention clear. *See Amgen Inc. v. F. Hoffmann-La Roche Ltd*, 580 F.3d 1340, 1354 (Fed. Cir. 2009) (declining to treat the applications at issue as divisional applications

when the applicant indicated that the applications were continuation applications in a PTO form). Even viewed most favorably to Actelion, the casual “solicits early examination” language with no reference to § 371(f), the PCT, or the national stage, when combined with the unchecked box 3 of its completed PTO Form 1390, was, if not an express election not to commence the national stage early, at least an inconsistent or ambivalent request.

We therefore find no error in the PTO’s determination that Actelion’s submission of PTO Form 1390 with box 3 unchecked, and its precatory solicitation remark having no operative consequence, did not amount to an express request pursuant to § 371(f).

III. The PTO Correctly Calculated the A Delay for the '675 Patent

We finally consider whether the PTO properly determined the PTA for the '675 patent. First, we find no error in the PTO’s determination that the A Delay start date calculation for the '675 patent was not based on January 12, 2012, the '619 application’s filing date, because Actelion did not make an express request to commence the national stage on that date under § 371(f).

Actelion alternatively argues that the '675 patent’s A Delay should be based strictly on the 30-month date, January 16, 2012, and should not take into consideration the fact that the 30-month date fell on a federal holiday, because § 371(b) requires that the national stage “*shall* commence” on the expiration date specified in PCT Article 22, *i.e.*, “30 months from the priority date.”

The PTO responds that according to the governing PCT articles and regulations, national stage commencement cannot occur on a federal holiday. Appellee’s Br. 32 (citing PCT Rule 80.5).

We find no error in the PTO's determination that the national stage for the '675 patent commenced on January 17, 2012, the next workday after the 30-month date that fell on a federal holiday. Actelion, again, primarily relies on the fact that it has met all of its filing requirements before the 30-month date. According to Actelion, the PCT Rule 80.5 holiday exception, similar to the federal court rules that govern timeliness of a party's filing, benefits the filer such as Actelion by giving it an option to file on the next workday if a filing date falls on a holiday. Therefore, Actelion argues, if it had not taken advantage of the holiday exception, it should not be "harm[ed]" by it. Appellant's Br. 35. We find this argument unpersuasive.

Actelion's "no holiday exception" argument, similar to its pre-TCA statutory argument, is premised on the assumption that *any* time period of inaction that is not attributable to the applicant should inure to the applicant's benefit. As such, Actelion emphasizes *its* alleged lack of fault during the time periods in question. However, by the same logic, inaction on a holiday is also not attributable to the PTO. Although the PTA statutes do serve a remedial purpose of restoring patent term lost during prosecution of an application, they only restore "undue delays in patent examination *caused by* the PTO" as provided by Congress. *Pfizer*, 811 F.3d at 468 (emphasis added). We find no error in the PTO's determination that the national stage for the '675 patent did not commence until the next workday after the 30-month date that fell on a federal holiday.

We therefore conclude that the PTO did not err in its 40-day determination of the PTA for the '675 patent under § 154(b)(1)(A)(i)(II).

CONCLUSION

For the foregoing reasons, the decision of the district court is affirmed.

AFFIRMED