

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

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**EXELA PHARMA SCIENCES, LLC, EXELA  
PHARMSCI, INC., EXELA HOLDINGS, INC.,**  
*Plaintiffs-Appellants*

**v.**

**MICHELLE K. LEE, Deputy Director,  
U.S. Patent and Trademark Office,**  
*Defendant-Appellee*

**CADENCE PHARMACEUTICALS, INC.,  
SCR PHARMATOP,**  
*Intervenors*

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2013-1206

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Appeal from the United States District Court for the  
Eastern District of Virginia in No. 12-CV-0469, Judge  
Liam O'Grady.

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Decided: March 26, 2015

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MATTHEW JAMES DOWD, Wiley Rein, LLP, Washing-  
ton, DC, argued for plaintiffs-appellants. Also represent-  
ed by CLAIRE JOY EVANS; CLARENCE EDWARD POLK, JR.,  
Exela Pharma Sciences, LLC, Ashburn, VA; ANTHONY H.  
SON, Andrews Kurth, LLP, Washington, DC.

DENNIS C. BARGHAAN, JR., Office of the United States Attorney for the Eastern District of Virginia, Alexandria, VA, argued for defendant-appellee. Also represented by DANA J. BOENTE; NATHAN KELLEY, Office of the Solicitor, United States Patent and Trademark Office, Alexandria, VA.

RICHARD P. BRESS, Latham & Watkins LLP, Washington, DC, argued for intervenors. Intervenor Cadence Pharmaceuticals, Inc., also represented by GABRIEL BELL, Washington, DC; STEPHEN P. SWINTON, San Diego, CA; MARC NATHAN ZUBICK, KENNETH G. SCHULER, Chicago, IL. Intervenor SCR Pharmatop represented by CHARLES A. WEISS, Holland & Knight, LLP, New York, NY.

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Before NEWMAN and DYK, *Circuit Judges*.\*

Concurring opinion filed by *Circuit Judge* NEWMAN

Concurring opinion filed by *Circuit Judge* DYK

PER CURIAM.

This appeal presents the question of whether a third party has the right to challenge, by way of the Administrative Procedure Act (APA), a ruling of the Patent and Trademark Office reviving a patent application that had become abandoned by failure to meet a filing schedule established by the Patent Cooperation Treaty and its implementing statute. The challengers are Exela Pharma Sciences, LLC; Exela Pharmsci, Inc.; and Exela Holdings, Inc. (collectively “Exela”). Exela petitioned the PTO to “reconsider and withdraw” its revival of the national stage

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\* Randall R. Rader, who retired from the position of Circuit Judge on June 30, 2014, did not participate in this decision.

application and to cancel the issued patent. The patent is United States Patent No. 6,992,218 (“the ’218 patent”), assigned to SCR Pharmatop.

The PTO declined to consider Exela’s petition, stating that no law or regulation authorizes non-party challenge to a PTO ruling to accept a tardy filing. Exela then brought suit under the APA in the United States District Court for the Eastern District of Virginia, arguing that the PTO’s action was *ultra vires* and that Exela’s petition should have been considered and favorably decided. The PTO moved to dismiss Exela’s complaint on several grounds.

The district court initially held that Exela was entitled to challenge the PTO’s decision under the APA, but on reconsideration and in view of new Fourth Circuit precedent, the district court dismissed Exela’s complaint for failing to meet the statute of limitations for claims filed against the United States, including APA claims.<sup>1</sup>

We affirm the dismissal, on the ground that PTO revival rulings are not subject to third party collateral challenge, thereby precluding review regardless of whether Exela’s claims were time-barred.

#### BACKGROUND

Patentee SCR Pharmatop filed its initial patent application in France on June 6, 2000 and, in conformity with the Patent Cooperation Treaty (PCT), filed an international patent application identifying the United States, among others, as a designated state on June 6, 2001. The

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<sup>1</sup> *Exela Pharma Sciences, LLC v. Kappos*, No. 1:12-cv-469, 2012 WL 3638552 (E.D. Va. Aug. 22, 2012); *Exela Pharma Sciences, LLC v. Kappos*, No. 1:12-cv-469, 2012 WL 6697068 (E.D. Va. Dec. 21, 2012) (*Reconsideration Decision*).

PCT implementing statute, 35 U.S.C. §351 *et seq.*, requires the applicant to fulfill certain United States documentary and fee requirements within 30 months after the filing of the foreign priority application, here by December 6, 2002. *See* 35 U.S.C. §371(c), (d); PCT art. 22. SCR Pharmatop did not file the required materials by December 6, 2002, and consequently the United States application was deemed abandoned. On January 2, 2003 SCR Pharmatop filed a petition to revive the application, stating that the delay was “unintentional,” using the form provided by the PTO for revival requests. The PTO granted the petition on April 25, 2003. The application was duly examined, and the ’218 patent issued on January 31, 2006.

In August 2011 SCR Pharmatop and exclusive sublicensee Cadence Pharmaceuticals, Inc. (collectively “Pharmatop”) sued Exela in the United States District Court for the District of Delaware for infringement of the ’218 patent. The suit was brought under the Hatch-Waxman Act, 35 U.S.C. §271(e)(2), in response to Exela’s notice and filing of an Abbreviated New Drug Application and Paragraph IV Certification relating to Pharmatop’s injectable acetaminophen-based drug Ofirmev<sup>®</sup>.

On November 30, 2011 Exela filed the subject petition in the PTO, under the APA and 37 C.F.R. §§1.181, 1.182, and 1.183, challenging the PTO’s revival of the patent application that led to the ’218 patent. Exela argued that “unintentional” delay was not an available ground for revival of a U.S. patent application claiming priority under the PCT-implementing statute as then in effect. Exela pointed out that 35 U.S.C. §371(d) limited the revival of such national stage applications to those in which the non-compliance was “unavoidable”:

The requirements with respect to the national fee . . . , the translation . . . , and the oath or declaration . . . shall be complied with by the date of the

commencement of the national stage or by such later time as may be fixed by the Director. . . . Failure to comply with these requirements shall be regarded as abandonment of the application by the parties thereof, unless it be shown to the satisfaction of the Director that such failure to comply was unavoidable. . . .<sup>2</sup>

35 U.S.C. §371(d) (2002). Exela argued that the PTO erred in applying its general revival regulation, 37 C.F.R. §1.137, which provides:

*Revival of abandoned application, terminated reexamination proceeding, or lapsed patent.*

(a) *Unavoidable.* If the delay in reply by applicant or patent owner was unavoidable, a petition may be filed pursuant to this paragraph to revive an abandoned application, a reexamination proceeding . . . , or a lapsed patent. A grantable petition pursuant to this paragraph must be accompanied by: . . .

(b) *Unintentional.* If the delay in reply by applicant or patent owner was unintentional, a petition may be filed pursuant to this paragraph to revive an abandoned application, a reexamination proceeding . . . , or a lapsed patent. A grantable petition pursuant to this paragraph must be accompanied by: . . .

37 C.F.R. §1.137 (2000). Exela asserted that a PTO regulation cannot override a statute, and therefore, the PTO lacked discretion to grant SCR Pharmatop's revival petition for "unintentional" delay.

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<sup>2</sup> The statute was amended, effective December 18, 2013, removing the clause stating the "unavoidable" standard.

The PTO declined to consider Exela's petition, stating that no statute or regulation authorizes third party challenge to a PTO ruling concerning revival of a patent application. See PTO letter to Exela's counsel, February 17, 2012 (returning petition fee).

Following the PTO's rejection of its petition, Exela filed this district court action under the APA, asking the court to compel the PTO to vacate its revival decision. The PTO moved to dismiss Exela's complaint under Federal Rules 12(b)(1) and (6) on several grounds, including that Exela lacks standing to challenge the PTO's revival ruling, that Exela's APA action is time-barred, and that a PTO revival ruling is not subject to judicial review at the request of a third party challenger.

The district court initially denied the PTO's motion to dismiss on all grounds, but while its decision was pending, the Fourth Circuit issued its decision in *Hire Order, Ltd. v. Marianos*, 698 F.3d 136, 170 (4th Cir. 2012), holding that for facial challenges to a federal regulation, the six-year limitations period of 28 U.S.C. §2401(a) starts to accrue when the regulation is adopted. The district court, on reconsideration, observed that the regulation here at issue, 37 C.F.R. §1.137, was adopted in 1982, and that Exela presented a facial challenge to the regulation, for it sought a declaration "regarding which standard to apply across the board." *Reconsideration Dec.* at 4–6. Applying *Hire Order*, the district court held Exela's action time-barred by the six-year period of limitations.

This appeal followed.

#### DISCUSSION

Exela argues that its complaint was improperly dismissed and that it is entitled to proceed, citing the APA's purpose of providing remedy to any "person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a

relevant statute.” 5 U.S.C. §702. Exela stresses that the dominating consideration in APA actions is the “strong presumption that Congress intends judicial review of administrative action,” *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667, 670 (1986). Exela states that the PTO’s action in reviving the Pharmatop application was contrary to the PCT statute, and that unless judicial review is available, an *ultra vires* PTO action will escape correction, thereby enabling enforcement of a patent that should not have issued.

The PTO responds that there is no authority for third parties to collaterally challenge the correctness of PTO revival rulings. Thus the PTO contends that the merits should be decided in its favor, even if dismissal is not appropriate on limitations grounds.

Exela argues that although such third party action is not explicitly authorized by statute or regulation, it is available under the APA. Exela cites the Court’s statement in *Block v. Community Nutrition Institute* that “where substantial doubt about the congressional intent exists, the general presumption favoring judicial review of administrative action is controlling.” 467 U.S. 340, 350–51 (1984).

We conclude that Congress did not intend to permit judicial review for challenges such as the one brought here. Whether the APA confers such a cause of action upon third parties raises a substantial question of patent law, and is reviewable by this court applying Federal Circuit law. See *Helfgott & Karas, P.C. v. Dickinson*, 209 F.3d 1328, 1334 (Fed. Cir. 2000) (holding “[T]he question of whether the Commissioner has violated the APA in applying the PCT rules and regulations, as well as its own regulations, raises a substantial question under the patent laws. . .”).

The question on this appeal is not whether a patent applicant may challenge a PTO revival ruling as to its

application; that question was resolved in the affirmative by this court's decision in *Morganroth v. Quigg*, 885 F.2d 843 (Fed. Cir. 1989). The issue here is whether a third party may collaterally challenge and obtain judicial review of a PTO revival ruling concerning an unrelated patent application. The Patent Act's "intricate scheme for administrative and judicial review of PTO patentability determinations," and "the Patent Act's careful framework for judicial review at the behest of particular persons through particular procedures" demonstrate that third party challenge of PTO revival rulings under the APA is not legislatively intended. *Pregis Corp. v. Kappos*, 700 F.3d 1348, 1357 (Fed. Cir. 2012) ("[A] third party cannot sue the PTO under the APA to challenge a PTO decision to issue a patent.").

We conclude that PTO revival actions are not subject to third party challenge under the APA. On this ground, the dismissal of the Exela complaint is affirmed.

**AFFIRMED**



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NEWMAN, *Circuit Judge*, concurring.

I join the court's decision, for neither the Patent Act  
nor the Administrative Procedure Act provides a cause of  
action in which third persons may challenge the revival  
by the PTO of an application that was deemed abandoned  
for failure to meet a filing date.

I write separately to address the concerns raised in Judge Dyk's concurring opinion, in which he criticizes the court's ruling in *Aristocrat Technologies Australia Pty Ltd. v. International Game Technology*, 543 F.3d 657 (Fed. Cir. 2008). With all respect to my colleague, I do not share the view that *Aristocrat* was wrongly decided.

In *Aristocrat* the defendant in an infringement suit argued that the PTO erroneously revived Aristocrat's Patent Cooperation Treaty application (which was one day late), and sought invalidity on that ground. This court stated that the PTO's revival of an application "is neither a fact or act made a defense by title 35 nor a ground specified in part II of title 35 as a condition for patentability." 543 F.3d at 663. The court explained:

If any prosecution irregularity or procedural lapse, however minor, became grist for a later assertion of invalidity, accused infringers would inundate the courts with arguments relating to every minor transgression they could comb from the file wrapper. This deluge would only detract from the important legal issues to be resolved – primarily, infringement and validity.

*Id.*

The Patent Act is explicit as to the grounds for challenges to issued patents; these grounds do not include challenge to PTO discretionary actions in revival of deemed-abandoned applications. A PTO decision to excuse a tardy filing is not a statutory ground of invalidity or defense to infringement under 35 U.S.C. §282, nor is it a ground on which third persons can initiate and participate in post-issuance disputes, *see* Chapter 30 (prior art citations and requests for reexamination), Chapter 31 (inter partes review), and Chapter 32 (post-grant review). Rather, it is an irregularity in prosecution that "becomes irrelevant after the patent has issued." *Magnivision, Inc. v. Bonneau Co.*, 115 F.3d 956, 960 (Fed. Cir. 1997); *see*

also *Norian Corp. v. Stryker Corp.*, 363 F.3d 1321, 1324 (Fed. Cir. 2004) (“[T]he presumption of validity is not subject to being diluted by ‘procedural lapses’ during prosecution.”). The patent statutes are specific as to legislative intent, and do not extend to “prosecution irregularities and procedural lapses.” *Aristocrat*, 543 F.3d at 663. The Supreme Court in *Block v. Community Nutrition Institute*, 467 U.S. 340 (1984), discussed the principles of challenge to administrative actions, and summarized:

Whether and to what extent a particular statute precludes judicial review is determined not only from its express language, but also from the structure of the statutory scheme, its objectives, its legislative history, and the nature of the administrative action involved.

467 U.S. at 345. The recently enacted America Invents Act (AIA), which provides new mechanisms for third party attacks on issued patents, did not change the principle that internal PTO procedures are not subject to third party collateral attack.

The Court stated in *Block*: “In a complex scheme of this type, the omission of such a provision is sufficient reason to believe that Congress intended to foreclose [the action].” 467 U.S. at 346. The statute concerning filing schedules under the Patent Cooperation Treaty was recently amended to remove the requirement that delay be unavoidable, *see* 35 U.S.C. §371(d) (2013), demonstrating legislative knowledge of the issue decided in *Aristocrat*. However, Congress made no new amendments to the scope of infringement defenses available in the district courts. *Aristocrat* warrants stability, not judicial taint as “problematic.”

Judge Dyk correctly points out that there are areas in which “a non-listed defense has been recognized by courts,” *conc. op.* at 4, citing cases in which antitrust

violation, patent misuse, and shop right have been recognized as defenses to patent infringement. With all respect, my colleague errs in stating that such major substantive issues, each of which is a traditional defense, “cannot be so easily distinguished” from an excuse for a missed filing date. Conc. Op. at 5. If judges cannot easily distinguish the significance of antitrust violation from a missed date, we must try harder.

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DYK, *Circuit Judge*, concurring.

I join the majority opinion holding that the structure  
of the Patent Act bars third party Administrative Proce-  
dure Act (“APA”) challenges to patent validity based on an  
improper revival of an abandoned patent application.

In my view, the Patent Act is structured to channel third party challenges to patent validity to either of two routes: as defenses to infringement actions or as challenges brought at the PTO utilizing statutorily authorized proceedings such as inter partes review, post-grant review, or inter partes reexamination. This statutory scheme is inconsistent with APA review by third parties in the district court. *See Pregis Corp. v. Kappos*, 700 F.3d 1348, 1357 (Fed. Cir. 2012) (“[A] third party cannot sue the PTO under the APA to challenge a PTO decision to issue a patent.”).

The heart of Exela’s argument to the contrary is that it is entitled to proceed under the APA because there is a “strong presumption that Congress intends judicial review of administrative action,” *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667, 670 (1986), and because, since our precedent in *Aristocrat Technologies Australia Pty Ltd. v. International Game Technology*, 543 F.3d 657 (Fed. Cir. 2008), barred review of improper revival as a defense in infringement actions, the only available route to review is under the APA.

In *Aristocrat*, this court held that a defendant in an infringement action could not assert improper revival of an abandoned patent application as a defense in that action. *See* 543 F.3d at 660–61. We need not decide here whether *Aristocrat* was correctly decided. Whether it was or not, the Patent Act is inconsistent with third party APA review. However, I write separately to explain why I think our decision in *Aristocrat* was problematic.

The panel in *Aristocrat* held that improper revival could not be raised as a defense to an infringement action because improper revival was not literally among the catalog of defenses listed in 35 U.S.C. § 282. *See id.* at 663–64. The panel noted that we have held that a “provision of the Patent Act not falling within the literal scope

of section 282 may nevertheless provide a defense of noninfringement or invalidity.” *Id.* at 664 (relying on *Quantum Corp. v. Rodime, PLC*, 65 F.3d 1577, 1584 (Fed. Cir. 1995) (holding that a patentee who improperly enlarged the scope of its claims during reexamination, violating 35 U.S.C. § 305, was subject to a defense of invalidity)). But the panel distinguished *Quantum* on the ground that the concern in *Quantum* that “failure to impose invalidity for violation of the statute would encourage noncompliance” was not present where there is “no legitimate incentive for an applicant to intentionally abandon its application, much less to attempt to persuade the PTO to improperly revive it.” *Id.*

There are four aspects of the *Aristocrat* opinion that in my view warrant its reconsideration.

First, *Aristocrat* did not discuss the presumption of judicial review of agency action. *See Sackett v. Evtl. Prot. Agency*, 132 S. Ct. 1367, 1373 (2012); *Bowen*, 476 U.S. at 670; *Block v. Cmty. Nutrition Inst.*, 467 U.S. 340, 348–49 (1984); *see also* 5 U.S.C. § 702 (conferring a general cause of action upon persons “adversely affected or aggrieved by agency action within the meaning of a relevant statute”). As we hold today, there is no APA review for improper revivals and no alternative mechanism for review, so an invalidity defense would be the only route available for judicial review.

Second, contrary to the suggestion in *Aristocrat* and by my colleague in her concurrence, this is not a case involving a minor procedural error in the PTO process. *See Magnivision, Inc. v. Bonneau Co.*, 115 F.3d 956, 960 (Fed. Cir. 1997) (holding that “[p]rocedural lapses during examination [such as in that case, an examiner’s not recording a phone call] . . . do not provide grounds of invalidity”). Here, Congress thought the issue of timely filing to be sufficiently important that it provided that a

patent would be treated as abandoned for noncompliance, and it allowed the PTO to reinstate the patent only when specific criteria were satisfied. *See* 35 U.S.C. § 371(d) (2002).

Third, in *Morganroth v. Quigg*, 885 F.2d 843, 846 (Fed. Cir. 1989), we held that review of the PTO's refusal to revive a patent application was available under the APA. That case is not cited in *Aristocrat*, and it is indeed difficult to understand why a third party facing liability for infringement of the patent cannot seek judicial review of a revival decision if the patent applicant can do so, even though the patent applicant and accused infringer must pursue different avenues for review (a defense for the accused infringer and review under the APA for the patent applicant).

Fourth, *Aristocrat* failed to recognize that *Quantum* was hardly the only example of situations in which a non-listed defense has been recognized by courts. Obviousness-type double patenting, for example, is a well-established defense that is not specified in the statute. *See, e.g., Gilead Scis., Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208, 1212 (Fed. Cir. 2014). Patent "misuse" is also a defense. *See, e.g., Brulotte v. Thys Co.*, 379 U.S. 29 (1964) (holding that charging royalties beyond life of the patent impermissibly enlarges monopoly of the patent); *Princo Corp. v. Int'l Trade Comm'n*, 616 F.3d 1318, 1326–29 (Fed. Cir. 2010) (describing patent misuse and calling it "mainly a judicially created defense"). The "shop rights" doctrine is also a "judicially created defense to patent infringement" that "applies when an employer is sued for patent infringement by an employee who created the patented invention with the employer's resources while under its employment, even though the employer otherwise has no legal rights to the resultant invention." *Beriont v. GTE Labs, Inc.*, 535 F. App'x 919, 923 (Fed. Cir.



2013). These other cases cannot be so easily distinguished from the situation in *Aristocrat* itself.

In the future, en banc action to reconsider *Aristocrat* may be appropriate.