



**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF VIRGINIA  
Alexandria Division**

EXELA PHARMA SCIENCES, LLC, et al.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Civil Action No.: 1:12-cv-469
	)	
DAVID J. KAPPOS, et al.,	)	
	)	
Defendants.	)	

**MEMORANDUM OPINION**

Before the Court is Defendants’ Motion to Dismiss under 12(b)(1) and (6). Defendants argue that Plaintiffs lack standing, that Plaintiffs’ Complaint is untimely, and that the violation alleged in the Complaint is not subject to review under the Administrative Procedure Act (“APA”). Upon consideration of the parties’ pleadings, in conjunction with the arguments made in open Court, it is hereby ORDERED that Defendants’ Motion is DENIED.

**I. Background**

In 2003, United States Patent and Trademark Office (“PTO”) revived an abandoned international patent application that eventually issued as U.S. Patent No. 6,992,218 (“the ‘218 patent”). Plaintiff challenges the PTO’s revival decision under 35 U.S.C. § 371(d), alleging that the PTO improperly used an “unintentional” rather than an “unavoidable” standard, and that as a result, the PTO erroneously allowed the improperly revived patent to claim priority. Plaintiffs allege they were harmed by this error when the licensee of the ‘218 patent filed an infringement claim against Plaintiffs in Delaware in 2011.

## II. Analysis

### a. Statute of Limitations

Defendants first argue that Plaintiffs' claim is time barred. The parties agree that the six-year statute of limitations in 28 U.S.C. § 2401 governs. *See Jersey Heights Neighborhood Ass'n v. Glendening*, 174 F.3d 180, 186 (4th Cir. 1999). Section 2401 provides that "every civil action commenced against the United States shall be barred unless the complaint is filed within six years after the right of action first accrues." The parties dispute when Plaintiffs' "right of action first accrue[d]." Defendants argue that Plaintiffs' untimely filed their lawsuit nine years after the PTO's 2003 revival decision. However, Plaintiffs could not have filed a lawsuit in federal court until they had suffered an injury in fact. Plaintiffs' alleged injury occurred in 2011, when the PTO's allegedly improper revival decision enabled the '218 licensee to file an infringement action against Plaintiffs.<sup>1</sup> *Id.* (quoting *Franklin v. Massachusetts*, 505 U.S. 788, 797 (1992) ("Conduct becomes reviewable under the APA upon 'final agency action,' 5 U.S.C. § 704, in other words, when 'the agency has completed its decisionmaking process, and [when] the result of that process is one that will directly affect the parties.'") (emphasis added)); *see also Bay Area Laundry and Dry Cleaning Pension Trust Fund v. Ferbar Corp. of Cal., Inc.*, 522 U.S. 192, 201 (1997) ("[T]he limitations period commences when the plaintiff has a complete and present cause of action," and "a cause of action does not become 'complete and present' for limitations purposes until the plaintiff can file suit and obtain relief." (internal quotations omitted)); *Golden and Zimmerman, L.L.C. v. Domenech*, 599 F. Supp. 2d 702, 711 (E.D. Va. 2009) ("In order for

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<sup>1</sup> Plaintiffs claim that the limitations period began in 2012, after they exhausted their administrative remedies by submitting a letter to the PTO challenging the PTO's revival decision. The PTO argues that their response to Plaintiffs' letter did not constitute an agency action because the agency did not deny, but rather refused to consider, Plaintiffs' request. The Court need not decide whether the statute of limitations commenced with the 2011 infringement suit or the 2012 letter to the PTO. The '218 patent licensee filed its infringement action against Plaintiffs in 2011. Plaintiffs filed this lawsuit in 2012—well within the six-years from the date of that action.

an agency action to be deemed final, the agency must have made up its mind, *and its decision must have inflicted an actual, concrete injury upon the party seeking judicial review.*”) (internal quotations omitted) (emphasis added). Plaintiffs could not have challenged the PTO’s revival decision before the decision caused injury to the Plaintiffs in 2011. Plaintiffs’ 2012 challenge is timely.

Defendants also argue that a facial challenge to the relevant statutory provision accrued in 2000, when the PTO promulgated the regulation implementing the challenged “unintentional” standard. *See* 37 C.F.R. 1.137(b). However, the PTO acknowledges that an exception to this accrual date exists when the challenger alleges that the agency applied the statute in a way that exceeds constitutional or statutory authority. *See Wind River Min. Corp. v. United States*, 946 F.2d 710, 715 (9th Cir. 1991). The PTO argues that this exception provides no assistance to the Plaintiffs for two reasons. First, the contested regulation was never applied against the Plaintiffs, and in any event, it was applied over nine years ago when the PTO revived the ‘218 patent in 2003.

*Wind River* makes clear, however, that “[t]he government should not be permitted to avoid all challenges to its actions, even if *ultra vires*, simply because the agency took the action long before anyone discovered the true state of affairs.” *Id.* Indeed, applying *Wind River*, the Ninth Circuit found that plaintiffs were not time barred from bringing a suit fourteen years after the agency’s initial decision applying a regulation when the plaintiffs “could have had no idea” at the time the agency applied the regulation that the agency’s decision would affect them. *See N. Cnty. Cmty. Alliance, Inc. v. Salazar*, 573 F.3d 738, 743 (9th Cir. 2009). Here, the PTO’s revival decision did not affect the Plaintiffs until 2011 when the PTO’s allegedly erroneous decision

permitted the '218 patent licensee to file an infringement action against them. Plaintiffs' challenge is timely.

**b. Standing**

The PTO also argues that Plaintiffs lack standing to bring this cause of action. The Court disagrees. To establish standing, a Plaintiff must allege an injury in fact, caused by the harm complained of, which is redressable by the court. *See McBurney v. Cuccinelli*, 616 F.3d 393, 402 (4th Cir. 2010) (citing *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 102-03 (1998)).<sup>2</sup>

The Court finds that Plaintiffs satisfy each of the standing requirements. There seems to be no dispute that the '218 patent infringement action has caused Plaintiffs injury. Plaintiffs will be required to defend themselves against the allegations made in the underlying lawsuit.

Moreover, the alleged infringement, made possible by the PTO's revival decision, has made it more difficult for Plaintiffs to compete in the market place. *See Canadian Lumber Trade Alliance v. United States*, 517 F.3d 1319, 1332 (Fed. Cir. 2008) (citing *Clinton v. City of New York*, 524 U.S. 417, 433 (1998) ("a plaintiff will likely suffer an injury-in-fact when the government acts in a way that increases competition or aids the plaintiff's competitors.")).

To establish causation, the injury must be "fairly traceable" to the challenged action of the defendant. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992). The PTO argues that the '218 patent licensee caused Plaintiffs' harm by filing the infringement action, not the PTO. However, where "the alleged injury flows not directly from the challenged agency action, but rather from independent actions of third parties," the plaintiff need only show that "the agency action is at least a substantial factor motivating the third parties' actions." *Tozzi v. U.S.*

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<sup>2</sup> To the extent the PTO also challenges Plaintiffs' prudential standing, *see Warth v. Seldin*, 422 U.S. 490, 500-01 (1975), the Court agrees with *Centigram Commc'ns Corp. v. Lehman*, 862 F.Supp. 113, 117 (E.D. Va. 1994). The Plaintiffs, as accused infringers, "clearly fall[] within the 'zone of interests to be protected or regulated by the statute.'" *Id.* at 117 n.9 (quoting *Ass'n of Data Processing Serv. Orgs. v. Camp*, 397 U.S. 150, 153 (1970)).

*Dept. of Health and Human Servs.*, 271 F.3d 301, 308 (2001). When the PTO issues a patent and grants a party the right to exclude others from the market, a likely result is that the patent holder will in fact exercise that right. Here, there could be no infringement action without the PTO's allegedly improper revival decision. *Ass'n For Molecular Pathology v. U.S. Patent and Trademark Office*, 669 F. Supp. 2d 365, 385 (S.D.N.Y. 2009) ("While the USPTO is correct that [the third party's] refusal to license [plaintiffs'] patent broadly contributes to Plaintiffs' alleged injuries, the patents were issued by the USPTO, in accordance with its policies and practices. It is those policies and practices that the Plaintiffs allege are unconstitutional. The injury alleged is therefore 'fairly traceable' to the USPTO.").

The PTO argues that Plaintiffs have not asserted a redressable injury because the underlying infringement action is based on both the '218 patent as well as U.S. Patent No. 6,026,222 ('the '222 patent"). Thus, even if this Court invalidates the '218 patent, unless the '222 patent were also invalidated, this Court could not presently redress Plaintiffs' injury. However, if this Court were to invalidate the '218 patent, it would at least remove any additional costs Plaintiffs' might expend defending against the '218 patent in the underlying litigation. With the '218 patent no longer an issue, Plaintiffs' only barrier would be the '222 patent. *See Larson v. Valente*, 456 U.S. 228, 243 n.15 (1982) ("[A] plaintiff satisfies the redressability requirement when he shows that a favorable decision will relieve a discrete injury to himself. He need not show that a favorable decision will relieve his *every* injury.") (emphasis in original); *see also Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1293 (Fed. Cir. 2008) ("If Caraco obtains a favorable judgment that the drug described in its ANDA does not infringe Forest's '941 patent, then it will only need a judgment of invalidity or noninfringement on Forest's '712 patent in order to activate Ivax's exclusivity period and obtain FDA approval as

swiftly as possible.”). Should this Court invalidate the ‘218 patent, the Plaintiffs will have one less obstacle to surmount before all barriers to marketing their product will be removed.

For these reasons, the Court denies Defendants’ Motion based on the argument that the Plaintiffs lack standing.

**c. Reviewability**

Finally, the PTO contends that a third-party collateral attack of a revival decision is not the sort of agency action that is subject to review under the Administrative Procedure Act (“APA”). However, the presumption is that the APA confers a general cause of action upon all persons adversely affected by an agency action. *See Block v. Cmty. Nutrition Inst.*, 467 U.S. 340, 345 (1984) (quoting 5. U.S.C. § 702). That presumption is overcome when the relevant statute precludes judicial review, which is determined by the statute’s express language, the structure of the statutory scheme, the statute’s objectives, its legislative history, and the nature of the administrative action involved. *Id.*

The PTO cites *Aristocrat Technologies Australia PTY Ltd. v. International Game Technology* as conclusive support for its argument that Congress intended to preclude judicial review of collateral attacks on third-party PTO revival decisions. 543 F.3d 657 (Fed. Cir. 2008). In *Aristocrat*, the Plaintiff (Aristocrat) filed an infringement suit against IGT. IGT moved for summary judgment of invalidity based on the argument that the PTO improperly revived the patent under an “unintentional” rather than an “unavoidable” standard. The Ninth Circuit found that improper revival may not be raised as an invalidity defense in an action involving the infringement or validity of a patent. The court’s conclusion was based on its determination that a revival decision could not be asserted *defensively* in an infringement action.

Here, Plaintiffs challenge the revival decision in a separate cause of action against the PTO, rather than as a defense in the underlying infringement suit. The PTO argues that Plaintiffs' artful pleading should not permit them to escape the Ninth Circuit's holding in *Aristocrat*; however, the Court finds that the procedural posture of the present case is more than a distinction in pleading formalities. In *Aristocrat*, the PTO was not a party to the underlying lawsuit; instead the Ninth Circuit's holding was based on proper defenses to infringement claims. Within that context, the Ninth Circuit noted that prior "procedural irregularities" during prosecution should not provide a basis for invalidity. *Id.* at 663. Instead, the infringement actions should focus on the "metes and bounds of the patentee's right to exclude." *Id.* The fact that Plaintiffs allege this cause of action against the PTO is significant. *Aristocrat* involved an infringement claim. By contrast, Plaintiffs' cause of action asserts a claim under the APA *against the PTO*, alleging error in the agency's decision making process.

Next, the PTO compares the present cause of action to the Supreme Court's decision in *Block v. Community Nutrition Institute*, where the Court found that Congress did not intend to allow consumers to attack marketing orders under the Agricultural Marketing Agreement Act of 1937. 467 U.S. 340 (1984). Notably, the Supreme Court's decision rested in part on the fact that the milk handlers' interests were aligned with the consumer interests. Thus, milk handlers could "be expected to challenge unlawful agency action and to ensure that the statute's objectives would not be frustrated." *Id.* at 352. The Court contrasted its holding in *Block* with its prior holding in *Stark v. Wickard*, 321 U.S. 288 (1944), where it permitted consumers to obtain judicial review of agency decisions. The Court noted that in *Stark*, handlers were precluded from challenging the aspect of the agency's actions in question, and that as a result, consumers had no class to represent their interests. Moreover, if consumers were barred from obtaining judicial

review of the administrative action, there would be no forum to challenge the action. Thus in *Stark*, the Court concluded that judicial review for consumers was necessary.

Likewise, if the Plaintiffs here are prevented from challenging the agency's actions, it is unlikely that any other party would be positioned to do so. The Court finds no support for the PTO's apparent proposition that certain agency actions should remain entirely unchecked. In sum, the presumption in favor of judicial reviewability of agency action has not been overcome by a showing that Congress intended to preclude review in a manner "fairly discernible in the statutory scheme." *Id.* at 351.

**III. Conclusion**

For these reasons, Defendants' Motion to Dismiss (Dkt. No. 7) is DENIED.

An appropriate Order shall issue.

August 22, 2012  
Alexandria, Virginia

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/s/ *leg*  
Liam O'Grady  
United States District Judge