

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

EXELA PHARMA SCIENCES, LLC, et al.,)

Plaintiffs, )

v. )

DAVID J. KAPPOS, et al., )

Defendants. )

Civil Action No.: 1:12-cv-469

**MEMORANDUM OPINION**

Before the Court is Defendants' and Intervenors' Joint Motion for Reconsideration of their earlier Motion to Dismiss under 12(b)(1) and (6). Movants argue that the October 18, 2012 decision by the Fourth Circuit in *Hire Order, Ltd. v. Marianos* alters the controlling law and requires this Court grant the previously denied Motion to Dismiss. 698 F.3d 168 (4th Cir. Oct. 18, 2012).

**I. Background**

In 2003, United States Patent and Trademark Office ("USPTO") revived an abandoned international patent application that eventually issued as U.S. Patent No. 6,992,218 ("the '218 patent"). Plaintiffs challenge the PTO's revival decision under 35 U.S.C. § 371(d), alleging that the USPTO improperly used an "unintentional" rather than an "unavoidable" standard, and that as a result, the USPTO 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.

In August 2011, the Intervenors-Defendants sued Exela for infringement in the District of Delaware. Exela counterclaimed for invalidity and petitioned the USPTO for withdrawal of the

application that eventually became the '218 patent. In February 2012, the USPTO denied Exela's petition and in turn Exela filed this lawsuit, requesting that the Court invalidate the '218 patent. On August 22, 2012, this Court denied Defendants' Motion to Dismiss. In its Order the Court ruled, *inter alia*, that the statute of limitations had not run for this challenge to the relevant USPTO regulation.

Since the time this Court denied Defendants' Motion to Dismiss, the Fourth Circuit has ruled in a case that Defendants' argue affects controlling law in this case. *See Hire Order Ltd. v. Marianos*, 698 F.3d 168 (4th Cir. Oct. 18, 2012). On November 6, 2012, Defendants and Intervenors filed a Joint Motion for Reconsideration of the earlier Defendants' Motion to Dismiss, pursuant to Federal Rule of Civil Procedure 54(b). Dkt. No 48. Plaintiffs opposed the Motion and oral argument was held on November 20, 2012.

## **II. Analysis**

### **A. Statute of Limitations**

Section 2401 of 28 U.S.C. 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 and Intervenors argue that Plaintiffs' filing of its lawsuit came nine years after the PTO's 2003 revival decision, well beyond the six-year statutory period allowed. However, Plaintiffs argue they could not have filed a lawsuit in federal court until they had suffered an injury in fact. That injury, they assert, did not occur until 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

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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

reviewable under the APA upon ‘final agency action,’ 5 U.S.C. § 704, in other words, when ‘the agency has completed its decision-making 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 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). Ultimately, Plaintiffs argue that they could not have challenged the PTO’s revival decision before the decision caused them to suffer an injury.

**B. Reconsideration following *Hire Order, LTD. v. Marianos***

Having previously found that the PTO’s final agency action did not trigger the running of the six-year statute of limitations for this challenge, the Court must now reconsider this decision in light of *Hire Order*. 698 F.3d 168 (4th Cir. Oct. 18, 2012). For in *Hire Order*, the Fourth Circuit affirmed the District Court’s decision to dismiss a lawsuit filed more than six years after the IRS had published a rule change and it had become final. *Id.*

The Court did so despite the fact that the Plaintiffs did not operate as firearms dealers until decades after the IRS promulgated the applicable regulation and would not have suffered an injury to their business until 2008. The Court found that the statute of limitations began to run as soon as the final agency action occurred regardless of when the injury to a particular party

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Plaintiffs’ letter did not constitute an agency action because the agency did not deny, but rather refused to consider, Plaintiffs’ request. The Court agrees with USPTO. *See I.C.C. v. Brotherhood of Locomotive Engineers*, 482 U.S. 270 (1987).

occurred. *Id* at 170 (citing *Dunn-McCampbell Royalty Interest, Inc. v. Nat'l Park Serv.*, 112 F.3d 1283, 1287 (5th Cir. 1997); *see also Wind River Mining Corp. v. United States*, 946 F.2d 710, 715 (9th Cir. 1991)). The Fourth Circuit decision held that in the Administrative Procedures Act (“APA”) setting the need to have a fixed end to potential opposition to regulations trumped the potential perpetual number of years parties might claim injury for its regulations effects. The six-year statute of limitations under 28 U.S.C. § 2401, therefore, begins to run on the day that the final regulation is published in the Federal Registrar. If a party brings a facial challenge against an agency’s regulation under the APA, it must do so within six years of the final agency action.

**B. Count I: Statutory Violations**

The Fourth Circuit’s determination in *Hire Order* only requires that a facial challenge brought more than six years after the publication of the final agency ruling be barred. In Count I of its Complaint, Plaintiffs challenge the USPTO’s interpretation of the governing statute, 35 U.S.C. § 371(d). Plaintiffs claim that despite the express statutory language, the USPTO has promulgated an improper regulation whereby it applies the less stringent “unintentional” standard to the revival of the international patent application, when it should have applied an “unavoidable” standard. This type of challenge to an agency’s decision regarding which standard to apply across the board, rather than a determination regarding *how* to apply a standard, is a facial challenge rather than an as-applied challenge. As such, *Hire Order* controls the Court’s application of the six-year statute of limitations to this case. Plaintiffs’ facial challenge to USPTO’s interpretation of 35 U.S.C. § 371(d) is barred by the six-year statute of limitation.

Defendants’ Motion to Dismiss Count I of Plaintiffs’ Complaint is GRANTED.

**C. Count II: Agency Action Not In Accordance With Regulations**

Count II of Plaintiffs' Complaint claims that Defendant's decision to allow a priority claim from the '218 patent to PCT/FR01/01749 violated its own regulations and was arbitrary, capricious, and an abuse of discretion. While Plaintiffs frame the issue before the Court as a question of the agency's regulations as applied to the claim's priority, their claim is in fact a facial challenge. The original regulation was published in 1982 and amended in 2000 to establish procedures for revival under the "unintentional" delay standard. 37 C.F.R. 1.137(b). Since at least 2000, the USPTO has consistently applied the standard. There is nothing in Plaintiff's Complaint that challenges the particularity of the agency's application that differentiates it from the facial challenge addressed by the Court in *Hire Order*. While the regulation may have been applied to the 2003 Revival Decision, the standard was created and the final agency action was taken years earlier. Plaintiff's challenge to the USPTO's action, therefore, is barred by the six-year statute of limitations.

Defendants' Motion to Dismiss Count II of Plaintiffs' Complaint is GRANTED.

**D. Count III: Constitutional Violation**

Count III of Plaintiffs' Complaint challenges the constitutionality of USPTO's regulation and application of the "unintentional" standard. Plaintiffs claim that by applying the less stringent test to the revival of international patent applications, USPTO ignores the Constitutional mandate requiring the promotion of the progress of science and useful arts. *See Graham v. John Deere*, 383 U.S. 1, 6 (1996). Count III of Plaintiffs' Complaint alleging Constitutional violations undoubtedly challenges USPTO's regulation on its face. In keeping with the decision in *Hire Order*, a constitutional challenge to a federal agency's regulation is,

necessarily, a facial challenge to the agency's interpretation. Count III, therefore, is barred by the six-year statute of limitations, under 28 U.S.C. § 2401.

Defendants' Motion to Dismiss Count III of Plaintiffs' Complaint is GRANTED.

**E. Count IV: Unlawful Rules and Regulations**

Count IV of Plaintiffs' Complaint challenges the rules and regulations promulgated and applied by USPTO to the revival of international patent applications. Again, Plaintiffs assert that the statutory language in 35 U.S.C. § 371 was incorrectly interpreted by USPTO, causing the agency to apply an "unintentional" standard rather than an "unavoidable" standard. Dkt. 1 at 15. According to Plaintiffs, this improper reading of the statute led USPTO to issue rules and regulations that are not in compliance with the authority granted in the express language of the statute. This challenge to the rules and regulations of USPTO is strikingly similar to the challenge brought in *Hire Order*. In that case, the facial challenge brought against the decades-old ruling was barred by the six-year statute of limitations under 28 U.S.C. § 2401. Similarly, Plaintiffs in this case bring a facial challenge to the rules and regulations promulgated by USPTO more than six years prior to the filing of this claim. Plaintiffs' facial challenge to the rules and regulations under 35 U.S.C. § 371, therefore, are barred by the statute of limitations.


Defendants' Motion to Dismiss Count IV of Plaintiffs' Complaint is GRANTED.

**III. Conclusion**

For these reasons, Defendants' Motion for Reconsideration (Dkt. No. 48) is GRANTED and Defendants' Motion to Dismiss (Dkt. No. 7) is GRANTED. This matter is hereby is DISMISSED WITH PREJUDICE.

An appropriate Order shall issue.

December 21, 2012  
Alexandria, Virginia

/s/   
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Liam O'Grady  
United States District Judge

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**ORDER**

This matter comes before the Court on Defendants’ Motion for Reconsideration (Dkt. No. 48) and Defendants’ Motion to Dismiss pursuant to Federal Rules of Civil Procedure 12(b)(1) and (b)(6) (Dkt. No. 7). For the reasons stated in in the accompanying Memorandum Opinion, and for good cause shown, it is hereby

ORDERED that Defendants’ Motion for Reconsideration (Dkt. No. 48) is GRANTED and that Defendants’ Motion to Dismiss (Dkt. No. 7) is GRANTED. This matter is hereby DISMISSED WITH PREJUDICE.

December 19, 2012  
Alexandria, Virginia

*/s/ [Signature]*  
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Liam O’Grady  
United States District Judge