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

EXELA PHARMA SCIENCES, LLC; EXELA PHARMSCI, INC; and EXELA HOLDINGS, INC.	)	
Plaintiffs,	)	
vs.	)	Civil Action No.: 1:12cv469 LO/JFA
HON. DAVID J. KAPPOS, Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office; and	)	
UNITED STATES PATENT AND TRADEMARK OFFICE	)	
Defendants.	)	

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF AND PETITION FOR REVIEW OF RULEMAKING

NATURE OF THE ACTION

1. This is an action for declaratory judgment seeking a reversal of the decision of the United States Patent and Trademark Office ("USPTO") refusing to act on the petition of plaintiffs Exela Pharma Sciences, LLC; Exela PharmSci, Inc. and Exela Holdings, Inc. ("Exela") to vacate the USPTO's order reviving the international application for U.S. Patent No. 6,992,218 ("the '218 patent"). A copy of Exela's petition is attached as Exhibit 1, and the USPTO's order refusing to act on that petition is attached as Exhibit 2. The '218 patent is attached as Exhibit 3.

2. The USPTO's refusal to decide Exela's petition, and its underlying decision to revive and issue the '218 patent, was arbitrary, capricious, an abuse of discretion, not in accordance with the law, unsupported by substantial evidence, and in excess of the USPTO's

statutory authority under 35 U.S.C. § 371(d). As held in *ATA PTY LTD v. Int'l Game Tech.*, 491 F. Supp. 2d 916 (N.D. Cal. 2007),[1] the USPTO's revival of international patent applications under the less-stringent "unintentional" standard, like the international application at issue in this matter (PCT/FR01/01749), is clearly improper, outside of its statutory jurisdiction, and unconstitutional. Specifically, reviving international patent applications under the less-stringent "unintentional" standard violates the express language of 35 U.S.C. § 371(d), and issuing a patent that removes information already in the public domain in a manner contradictory to the Patent Act violates the Constitutional mandate to promote the progress of science and useful arts.

3. Plaintiffs also seek declaratory judgment that the USPTO rules and regulations allowing for revival of abandoned, international patent applications under the "intentional" standard are arbitrary, capricious, an abuse of discretion, not in accordance with the law, unsupported by substantial evidence, in excess of the USPTO's statutory authority, and unconstitutional.

4. Exela further seeks injunctive and other relief as set forth below.

JURISDICTION AND VENUE

5. This action arises under the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 701-706 and 35 U.S.C. § 371.

6. This Court has jurisdiction and is authorized to issue the relief sought under 28 U.S.C. §§ 1331, 1338(a), 1361, 2201-2202, and/or 5 U.S.C. §§ 701-706.

7. Venue is proper in this district under 35 U.S.C. § 1(b) and 28 U.S.C. § 1391(e).

[1] *Reversed on other grounds by Aristocrat Techs. Australia PTY Ltd. v. Int'l Game Tech.*, 543 F.3d 657 (Fed. Cir. 2008).

THE PARTIES

8. Exela Pharma Sciences, LLC is a Delaware corporation with its principal place of business at 1325 William White Place, Lenoir, North Carolina 28645.

9. Exela PharmSci, Inc. is a Virginia corporation that operates primarily through its subsidiary Exela Pharma Sciences, LLC.

10. Exela Holdings is a Delaware corporation, and is the parent of Exela Pharma Sciences, LLC.

11. Defendant the United States Patent and Trademark Office ("USPTO") is a federal agency within the United States Department of Commerce. The USPTO is located at 600 Dulany St., Alexandria, Virginia 22314.

12. Defendant David J. Kappos (the "Director") is the Under Secretary of the United States Department of Commerce and Director of the USPTO. The Director's office is located at 600 Dulany St., Alexandria, Virginia 22314. The Director is sued in his official capacity. References to the Director herein refer both to him and to his official predecessors as the context requires. References to the USPTO herein refer to the defendants collectively.

OWNERSHIP OF THE '218 PATENT

13. Based upon USPTO records, the application that issued as the '218 patent was assigned to SCR Pharmatop by the named inventors Francois Dietlin and Daniele Fredj.

14. Upon information and belief, the '218 patent is still assigned to and owned by SCR Pharmatop.

15. Upon information and belief, the '218 patent is licensed exclusively in the United States to Bristol-Myers Squibb Company, who in turn in-licensed the exclusive United States rights to the '218 patent to Cadence Pharmaceuticals, Inc.

REVIEWABILITY AND EXELA'S STANDING TO CHALLENGE THE USPTO'S ORDERS

16. Agency action is presumptively subject to judicial review under the APA. USPTO rules and orders affecting the revival of patents and issuance of patents in violation of the Constitution have been reviewed in this Court and others. *See, e.g., Centigram Comm'n Corp. v. Lehman*, 862 F. Supp. 113, 117 n. 9 (E.D. Va. 1994) (allowing judicial review of USPTO rules directed to revival of patents expired for unintentional failure to make timely maintenance payments); *see also Ass'n for Melocular Pathology v. USPTO*, 669 F. Supp.2d 365, 381-85 (S.D.N.Y. 2009) ("As discussed supra in Section IV, these cases do not, as the USPTO suggests, establish that the remedial scheme provided by the Patent Act for statutory violations divests the Plaintiffs of standing to assert constitutional claims for which the Patent Act provides no remedy"), *aff'd in part, rev'd in part*, 653 F.3d 1329 (Fed. Cir. 2011); *New York Univ. v. Autodesk, Inc.*, 466 F. Supp. 2d 563, 565 (S.D.N.Y. 2006) (explaining that "it would be illogical to hold that [US]PTO decision granting revival are immune from review, even where they lack any basis in reason or common sense") (internal quotations omitted); *Morganroth v. Quigg*, 885 F.2d 843, 846 (Fed. Cir. 1989) (holding that "denial of a petition to revive a patent application is subject to review").

17. Exela has standing to bring this action at least because it has been sued for alleged infringement of a patent, the '218 patent, that was improperly revived and improperly issued by the USPTO. In particular, on or about August 18, 2011, SCR Pharmatop and Cadence Pharmaceuticals, Inc. ("Cadence"), filed a patent infringement lawsuit in the U.S. District Court for the District of Delaware ("the Delaware Action") against Exela for infringement of, *inter alia*, the '218 patent.

18. The Delaware Action is civil action number 11-733-LPS, and is currently pending before Judge Leonard P. Stark.

19. The plaintiffs in the Delaware Action seek to preclude Exela from entering the United States market with a generic version of a drug called Ofirmev. Ofirmev is a brand drug that allegedly is covered by claims issued by the USPTO in the '218 patent.

20. According to the publication Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book"), the '218 patent is the latest expiring patent allegedly covering Ofirmev.

21. Absent the USPTO's wrongful revival and issuance of the '218 patent, this patent would not be asserted against Exela in the Delaware Action.

22. Absent the USPTO's wrongful revival and issuance of the '218 patent, full generic competition for Ofirmev likely would commence no later than August 5, 2017. Instead, and as a direct result of the USPTO's improper revival and issuance of the '218 patent, patent protection for Ofirmev is not set to expire until June 6, 2021.

23. Accordingly, Exela falls within the "zone of interests" to be protected or regulated by the applicable statutes, *e.g*., 5 U.S.C. § 701 et. seq. and 35 U.S.C. § 371, and otherwise satisfies the constitutional and other prerequisites for standing to challenge the USPTO's decisions. *See, e.g., Centigram Comm'n Corp. v. Lehman*, 862 F.Supp. 113,117 n. 9 (E.D. Va. 1994); *Ass'n for Melocular Pathology v. USPTO*, 653 F.3d 1329 (Fed. Cir. 2011).

24. Significantly, Exela has no other adequate forum in which to raise this issue, as it is foreclosed from asserting the defense of "improper revival" in the pending Delaware Action. *See Aristocrat Techs. Austl. Pty Ltd. v. Int'l Game Tech.*, 543 F.3d 657, 663 (Fed. Cir. 2008)

("[W]e hold that improper revival may not be asserted as a defense in an action involving the validity or infringement of a patent.").

25. Accordingly, the USPTO's improper revival and improper issuance of the '218 patent, its unlawful rules and regulations allowing for revival of the international patent application that led to issuance of the '218 patent, and its subsequent decision refusing to act on Exela's petition each constitute "final agency action for which there is no other adequate remedy in a court" and properly is subject to judicial review under the APA.

26. Further, there is an actual controversy between the parties within the meaning of 28 U.S.C. § 2201.

USPTO'S RULEMAKING AUTHORITY

27. The Patent Act established the USPTO, which is responsible for, *inter alia*, the granting and issuing of patents and for disseminating information to the public with respect to patents. 35 U.S.C. § 2(a)(2). The USPTO Director (*i.e.*, Defendant David J. Kappos) administers the issuance of patents by the USPTO. *Id.* § 2(a)(1).

28. Section 2 of the Patent Act authorizes the Director to establish regulations that facilitate and expedite the processing of patents, but limits the Director's power to enacting regulations that are not inconsistent with the law. *Id.* § 2(b)(2).

29. The USPTO has authority to enact procedural rules and regulations, but has no authority from Congress to make substantive rules and regulations. The USPTO has no authority to make substantive changes to the statutory scheme chosen by Congress for the revival of international patent applications.

TIMELY ENTRY OF NATIONAL STAGE PATENT APPLICATIONS AND REVIVAL OF INTERNATIONAL APPLICATIONS UNDER 35 U.S.C. § 371(D)

30. Section 371 of the Patent Act requires, in relevant part, that a national stage application be filed, including the applicable fees, within 30 months of priority date of the application.

31. On June 6, 2000, SCR Pharmatop filed French patent application FR 00 07231.

32. One year later, on June 6, 2001, SCR Pharmatop filed in the United States, under the Patent Cooperation Treaty, international patent application number PCT/FR01/01749 claiming priority to FR 00 07231. United States patent application number 10/332,060 was the national stage application for PCT/FR01/01749, and it ultimately issued in the United States on January 31, 2006 as the '218 Patent.

33. Based upon the requirements of 35 U.S.C. § 371, the United States national stage patent application, inventor declaration, and filing fees were required to be submitted to the USPTO on or before December 6, 2002, *i.e.*, 30 months from the filing date of French patent application FR 00 07231. The applicant did not meet any of the requirements of 35 U.S.C. § 371(c) by the statutory deadline.

34. As a result of not timely meeting the national stage requirements, PCT/FR01/01749 was abandoned as to the United States under the express terms of 35 U.S.C. § 371(d), which states in relevant part that "[f]ailure 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**." (emphasis added)

35. Once abandoned, any invention disclosed in PCT/FR01/01749 passed into the public domain as to the United States, and became free for anyone to exploit in the United States. *Pennock v. Dialogue*, 27 U.S. 1, 16 (1829); *see also* 37 C.F.R. § 1.495 ("An international

application becomes abandoned as to the United States thirty months from the priority date if the requirements of paragraph (b) of this section have not been complied with within thirty months from the priority date.").

36. On or about December 23, 2002, the assignee of the '218 patent, SCR Pharmatop, entered into a license agreement with Bristol-Myers Squibb (BMS). Section 5.1 of that license agreement required that SCR Pharmatop "use its best efforts to diligently prosecute" certain patent applications.

37. Section 1.16 of the December 23, 2002 license agreement defined the patents that were required to be "diligently" prosecuted by SCR Pharmatop to include "PCT/FR01/01749, filed on 6th June 2001." However, when SCR Pharmatop signed this agreement PCT/FR01/01749 had already gone abandoned under 35 U.S.C. § 371(d) as to any patent rights in the United States.

38. On or about January 2, 2003, shortly after SCR Pharmatop signed the license agreement requiring it to diligently prosecute the national stage application of PCT/FR01/01749, the applicants filed a petition to revive PCT/FR01/01749 as to the United States, declaring to the USPTO that the entire delay in meeting the national stage requirements was "unintentional."

39. On information and belief, the entire delay by the applicants in meeting the national stage filing requirements for PCT/FR01/01749 was neither "unintentional" nor "unavoidable."[2]

40. On April 23, 2003, the PTO granted the petition to revive under 37 C.F.R. § 1.137, despite the clear and unambiguous statutory language requiring that any delay be

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[2] The propriety of claiming un-intentionality and the circumstances under which the abandonment occurred are not currently before this Court.

"unavoidable," not merely "unintentional," before the statutory abandonment can be overcome; and despite the fact that 37 C.F.R. § 1.137 is applicable only where the applicant fails to file a "reply." Not, as the case here, where no "reply" is actually due, but instead the applicant simply fails to submit the application and other required materials by the statutory deadline.

41. Issuance of a patent covering subject matter that has been dedicated to the public is a violation of U.S. Constitution Art 1, § 8, cl. 8. *Graham v. John Deere*, 383 U.S. 1, 6 (1966).

42. Despite this clear statutory and constitutional error, the USPTO subsequently forwarded the national stage application of PCT/FR01/01749 to the National Stage Processing Branch of the PCT Operations for continued processing.

43. U.S. application no. 10/332,060 eventually issued on January 31, 2006 as the '218 Patent.

EXELA'S ANDA AND THE DISTRICT COURT LITIGATION

44. Exela is a small company that began operations in about 2005. Exela researches and develops noninfringing, generic equivalents to brand drug products. According to the Congressional Budget Office, generic drugs save consumers an estimated $8 to $10 billion a year at retail pharmacies. And, according to the FDA, even more billions are saved when hospitals use generic drugs.

45. On or about April 7, 2011, Exela submitted ANDA No. 20-3092 to the Federal Drug Administration for generic Acetaminophen Injection, 10 mg/mL.

46. Exela seeks to market a generic equivalent of a brand drug called Ofirmev, which is basically an injectable form of the drug commonly known as Tylenol. Ofirmev is primarily used in hospitals for post-operative pain management.

47. The Orange Book identifies U.S. Patent Nos. 6,028,222 ("the '222 patent") and 6,992,218 ("the '218 patent") as covering Ofirmev.

48. On information and belief, the '222 patent expires on August 5, 2017 and the '218 patent expires on June 6, 2021.

49. On or about August 18, 2011, SCR Pharmatop and Cadence asserted the '218 patent against Exela in the Delaware Action, alleging that Exela's proposed generic version of Ofirmev infringes the '218 and '222 patents.

50. On or about November 30, 2011, Exela filed a petition with the USPTO, asking that the USPTO withdraw its revival of PCT/FR01/01749 as to the United States because, among other things, the USPTO exceeded its statutory authority in doing so, and reviving PCT/FR01/01749 as to the United States in the manner done by the USPTO was unconstitutional.

51. On or about February 17, 2012, the USPTO refused to act on Exela's petition, asserting that "[a]s a third party to an *ex parte* proceeding, petitioner is not in a position to demand that the USPTO act to vacate a prior decision unless specifically authorized by statute or regulation. In particular, neither the patent statute nor its implementing regulations, confer a right upon a third party to intervene or otherwise challenge the Office's decision to revive the international application ... Accordingly, the USPTO declines to take any action on petitioner's request and the petition fee will be returned."

52. The APA prohibits agency action which is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. 5 U.S.C. § 706(2)(A). Furthermore, the APA prohibits agency action which is "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." *Id.* § (C).

53. APA Section 702 provides a party "suffering legal wrong because of agency action," such as Exela, with the right of judicial review. *Id.* § 702.

COUNT I: STATUTORY VIOLATIONS

54. Exela repeats and incorporates by reference the allegations set forth in paragraphs 1 through 53.

55. When PCT/FR01/01749 went abandoned as to the United States under the express terms of 35 U.S.C. § 371(d), the only means for reviving the application was through a showing by the applicant that the entire delay in meeting the national stage requirements was "unavoidable."

56. Despite the express language of 35 U.S.C. § 371(d), the USPTO revived the subject application under the less stringent "unintentional" standard.

57. Had the USPTO applied the correct "unavoidable" standard for revival of national stage patent applications, the '218 patent would not have issued because the petition to revive filed by the applicants did not meet the stringent "unavoidable" standard.

58. At least one district court has already held that this practice by USPTO of reviving abandoned international patent applications under the less stringent "unintentional" standard violates the express statutory language of 35 U.S.C. § 371(d). *See ATA PTY LTD v. Int'l Game Tech.*, 491 F. Supp. 2d 916 (N.D. Cal. 2007). Despite this holding, and on information and belief, the USPTO continues this *ultra vires* practice, and has denied Exela's petition seeking to have the USPTO comply with the statutory scheme chosen by Congress for revival of international patent applications that have gone abandoned under 35 U.S.C. § 371(d).

59. Accordingly, the USPTO's revival of the international patent application that led to issuance of the '218 patent, in a manner that conflicts with 35 U.S.C. § 371, was arbitrary,

capricious, an abuse of discretion and not in accordance with law; unsupported by substantial evidence, and in excess of the USPTO's statutory authority. 5 U.S.C. §§ 701-706 and 35 U.S.C. § 371.

COUNT II: AGENCY ACTION NOT IN ACCORDANCE WITH REGULATIONS

60. Exela repeats and incorporates by reference the allegations set forth in paragraphs 1 through 59.

61. The '218 patent claims priority to PCT/FR01/01749.

62. The USPTO's regulations on claiming priority to foreign patent applications require "compliance with 35 U.S.C. 371" before a priority claim can be made. 37 C.F.R. § 1.55(a)(1)(ii). Also, a United States national stage patent application can only claim priority to another co-pending patent application. 37 C.F.R. § 1.78(a); *see also* MPEP § 1893.03(c).

63. The '218 patent is not entitled to claim priority to PCT/FR01/01749 at least because PCT/FR01/01749 had already gone abandoned as to the United States, 37 C.F.R. § 1.495, before the applicants filed the national stage application for PCT/FR01/01749 and because PCT/FR01/01749 was never properly revived by the USPTO. Thus, there was no co-pendency between PCT/FR01/01749 and the national stage application for the '218 patent.

64. The '218 patent also was not entitled to claim priority to PCT/FR01/01749 because the applicants did not meet the express requirements of 37 C.F.R. § 1.55(a)(1)(ii), which mandate compliance with 35 U.S.C. 371 before a priority claim can be made. Because applicants never showed that the abandonment of PCT/FR01/01749 was "unavoidable," applicants never complied with 35 U.S.C. 371(d) and, thus, were not entitled to claim priority based upon the express language of 37 C.F.R. § 1.55(a)(1)(ii).

65. The USPTO decision to allow a priority claim from the '218 patent to PCT/FR01/01749 violated the express language of its own regulations and, thus, was arbitrary, capricious, an abuse of discretion and not in accordance with law; unsupported by substantial evidence, and in excess of the USPTO's statutory authority.

COUNT III: CONSTITUTIONAL VIOLATION

66. Exela repeats and incorporates by reference the allegations set forth in paragraphs 1 through 65.

67. When PCT/FR01/01749 went abandoned under the express terms of 35 U.S.C. § 371(d), any invention disclosed in the patent passed into the public domain and became free for all to exploit in the United States.

68. In allowing for revival of abandoned international patent applications, Congress struck a balance between the public's right to exploit inventions in the public domain and the inventor's rights to prosecute their applications, in light of mistakes that occur through no fault of the applicant. Congress struck that balance by only allowing international patent applications commenced in the United States pursuant 35 U.S.C § 371 to be revived under the stringent "unavoidable" standard.

69. With no authority to do so, the USPTO has readjusted this balance, in an unconstitutional manner, through use of the less stringent "unintentional" standard when reviving abandoned applications under section 371(d).

70. The USPTO's use of the lesser "unintentional" standard for revival under section 371(d) exceeds the limited statutory power granted to the USPTO by Congress for revival of international patent applications, and ignores the mandate from the Supreme Court that the patent laws and regulations must be written in a manner that adheres to the Constitutional mandate of

promoting the progress of science and useful arts. *Graham v. John Deere*, 383 U.S. 1, 6 (1966) ("It is the duty of the Commissioner of Patents and of the courts in the administration of the patent system to give effect to the constitutional standard by appropriate application, in each case, of the statutory scheme of the Congress.")

71. The USPTO's actions in allowing for the revival of abandoned national stage patent applications under the lesser "unintentional" standard violates Article I, Section 8, Cl. 8 of the United States Constitution by virtue of the USPTO, upon information and belief, failing to appropriately weigh the effect of its rules and regulations on the promotion of the progress of science and the useful arts, and ignoring the statutory scheme for revival of international patent applications chosen by Congress.

72. Accordingly, the USPTO's revival of PCT/FR01/01749 was arbitrary, capricious, an abuse of discretion and not in accordance with law; unsupported by substantial evidence, and in excess of the USPTO's statutory authority.

COUNT IV: UNLAWFUL RULES AND REGULATIONS

73. Exela repeats and incorporates by reference the allegations set forth in paragraphs 1 through 72.

74. The USPTO has no substantive rule making authority. As such, the USPTO can only enact rules and regulations that are consistent with authority expressly granted to the USPTO by Congress.

75. Congress enacted 35 U.S.C. § 371(d) to give the USPTO Director express authority to revive abandoned international patent applications if the applicant can demonstrate "to the satisfaction of the Director that such failure to comply was ***unavoidable***." (emphasis added).

76. Despite the express statutory language only allowing the USPTO to revive an international patent application as to the United States if the abandonment was "unavoidable," the USPTO has implemented and interpreted its rules and regulations as allowing it to revive international patent applications under the less stringent "unintentional" standard.

77. Accordingly, the USPTO's rules and regulations allowing for revival of abandoned international patent applications under the "unintentional" standard are arbitrary, capricious, an abuse of discretion and not in accordance with law; unsupported by substantial evidence, and in excess of the USPTO's statutory authority.

RELIEF REQUESTED

WHEREFORE, Plaintiffs respectfully request that the Court:

a. Issue a declaratory judgment or other order holding that Exela has standing to challenge the USPTO's revival and issuance of the '218 patent;

b. Issue a declaratory judgment or other order holding that the '218 patent was improperly revived and, thus, is invalid, unenforceable and/or without legal effect;

c. Issue a declaratory judgment or other order holding that the '218 patent is not entitled to claim priority to PCT/FR01/01749;

d. Issue a declaratory judgment or other order holding that any delay in meeting the national stage requirements of 35 U.S.C. § 371 can only be excused under the stringent "unavoidable" standard as expressly required by 35 U.S.C. § 371(d);

e. Issue a declaratory judgment or other order holding that the USPTO rules and regulations allowing for the revival of an international patent application under the "unintentional" standard are unlawful;

f. Issue a declaratory judgment or other order compelling the USPTO to vacate its revival of PCT/FR01/01749 as to the United States or, in the alternative, issue an order compelling the USPTO to comply with the requirements of 35 U.S.C. § 371(d) in reviving PCT/FR01/01749, including but not limited to issuing a show cause order to the applicant requiring it to show that the entire delay in meeting the U.S. national stage requirements for PCT/FR01/01749 was unavoidable and, otherwise, ordering the USPTO to address the merits of Exela's Petition;

g. Award Exela its costs and reasonable attorneys fees; and

h. Grant other or further relief as may be deemed appropriate by the Court.

Dated: April 26, 2012

Respectfully submitted,

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