IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

GENETICS INSTITUTE, LLC,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civ. No. 08-290-SLR
	)	
NOVARTIS VACCINES AND DIAGNOSTICS, INC.,	)	
	)	
	)	
Defendant.	)	

Jack B. Blumenfeld, Esquire, Karon Jacobs Louden, Esquire and James W. Parrett, Esquire of Morris, Nichols, Arsht & Tunnell LLP, Wilmington, Delaware. Counsel for Plaintiff. Of Counsel: Barbara C. McCurdy, Esquire, Steven P. O'Connor, Esquire, and Sanya Sukduang, Esqure of Finnegan, Henderson, Farabow, Garrett & Dunner, LLP, Washington, D.C.

Richard K. Hermann, Esquire, and Mary B. Matterer, Esquire of Morris James LLP, Wilmington, Delaware. Counsel for Defendant. Of Counsel: George A. Riley, Esquire, John C. Kappos, Esquire and George C. Yu, Esquire, of O'Melveny & Myers LLP, San Francisco, California.

**** SECOND AMENDED MEMORANDUM OPINION**

**Dated: May 7, 2009
Wilmington, Delaware

ROBINSON, District Judge

I. INTRODUCTION

Plaintiff Genetics Institute, LLC ("GI, LLC" or "plaintiff") filed its "complaint for the adjudication of priority of invention over defendant's interfering patents under 35 U.S.C. § 291" on May 16, 2008. (D.I. 1) In lieu of an answer, defendant Novartis Vaccines and Diagnostics, Inc. ("Novartis" or "defendant") filed a motion to dismiss for lack of jurisdiction over the subject matter or, in the alternative, for transfer under 28 U.S.C. § 1404, following a stipulation to extend time. (D.I. 8) For the following reasons, the court denies defendant's motion.

II. BACKGROUND

GI, LLC is a Delaware limited liability company with a principal place of business in Cambridge, Massachusetts. (D.I. 1 at ¶ 1) GI, LLC is a wholly owned subsidiary of Wyeth. In its complaint, GI, LLC states that it owns U.S. Patent No. 4,868,112 ("the '112 patent"), entitled "Novel procoagulant proteins." The '112 patent issued September 19, 1989; priority is claimed to an international (PCT) application filed April 11, 1986. John J. Toole Jr. is the named inventor. Mr. Toole assigned all interest in the applications leading to the '112 patent to Genetics Institute, Inc. ("GI, Inc.") in 1985 and 1986. (D.I. 11, exs. 2, 3)

The '112 patent was set to expire September 19, 2006, based on a seventeen-year statutory term. On May 4, 2000, counsel for GI, Inc. filed an application for an extension of patent term under 35 U.S.C. § 156[1] based on the period of time the drug

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[1]"The term of a patent which claims a product, a method of using a product, or a method of manufacturing a product shall be extended in accordance with this section from the original expiration date of the patent, which shall include any patent term adjustment granted under section 154(b), if – . . . (4) the product has been subject to a

ReFacto®[2] was in the regulatory approval process. (D.I. 11, ex. 8) The length of the requested extension was 1475 days, or to October 3, 2010. (*Id.*) The United States Patent and Trademark Office ("PTO") granted an extension through February 28, 2010. (D.I. 10, ex. 8)[3]

Novartis is a Delaware corporation with a principal place of business also in Cambridge, Massachusetts. (*Id.* at ¶ 2) Novartis is the assignee of U.S. Patent Nos. 6,060,447 ("the '447 patent") and 6,228,620 ("the '620 patent"). The '447 and '620 patents are entitled "Protein complexes having Factor VIII:C activity and production thereof." The '447 patent issued May 9, 2000 from U.S. Patent Application No. 08/441,935, filed May 16, 1995. The '620 patent issued May 8, 2001 from U.S. Patent Application No. 08/441,943, also filed May 16, 1995.

The '112 patent was previously involved in PTO Interference No. 103,215 (hereinafter, "the Interference"). The Interference involved a priority determination between the '112 patent and a patent application (no. 07/584,076) assigned to Genentech, Inc. ("Genentech"). (D.I. 10, ex. 1) The '112 patent was awarded priority on both designated counts.

During the Interference, on May 1, 2002, the following disclosure was filed with

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regulatory review period before its commercial marketing or use[.]" 35 U.S.C. § 156(a). Generally, "[t]he term of a patent eligible for extension under subsection (a) shall be extended by the time equal to the regulatory review period for the approved product which period occurs after the date the patent is issued[.]" 35 U.S.C. § 156(c).

[2]"[A]n antihemophilic factor for use in therapy for factor VIII deficiency comprising a purified protein produced by recombinant DNA technology." (D.I. 11, ex. 8 at 2)

[3]An extension of 1258 days was awarded; the parties agree on the applicable expiration date. (D.I. 22; D.I. 23)

the PTO pursuant 37 C.F.R. § 1.602(c)[4] on behalf of Mr. Toole, the designated Senior Party:

> In 1996, GI was purchased by American Home Products ("AHP") but GI still existed as a wholly owned subsidiary of AHP. Later, all of the assets of GI were transferred to AHP, and on March 11, 2002, AHP changed its name to Wyeth. Thus, Wyeth is **[**]now** the real party in interest and owner of all right, title and interest in [the '112 patent].

(D.I. 10, ex. 4) Documentation of record confirms that, in 1992, AHP (Wyeth's predecessor) purchased 60% ownership interest in GI, Inc., and Wyeth purchased the remaining 40% of GI, Inc.'s stock in 1996, whereupon GI, Inc. became Wyeth's wholly-owned subsidiary. (D.I. 11 at ex. 5 at 6, ex. 6 at I-1)

In 2002, GI, Inc. converted to GI, LLC. GI, LLC recorded two documents demonstrating this change in corporate name and status with the PTO – one in March 2002 and again in June 2002[5] – indicating that all of GI, Inc.'s patents are now owned by GI, LLC. (D.I. 11, ex. 4)

On December 23, 2003, Genentech and Bayer Healthcare LLC ("Bayer") filed suit in this district seeking review of the Board Decision on priority issued in the Interference. Civ. No. 03-1160-GMS. Both Wyeth and GI, LLC were named as defendants. (Civ. No. 03-1160, D.I. 10, ex. 1) The complaint explained that GI, LLC was named as a defendant out of caution because "the most recent written assignment recorded with the PTO shows GI, LLC as the assignee"; it was plaintiffs' belief that "at

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[4]"If a change of any right, title, and interest in any application or patent involved or relied upon in the interference occurs after notice is given declaring the interference and before the time expires for seeking judicial review of a final decision of the Board, the parties shall notify the Board of the change within 20 days after the change."

[5]The first version did not include GI, LLC's address.

all times including and since the Board's October 31, 2003 decision complained of herein, all right, title, and interest has resided in Wyeth alone." (*Id.*, ex. 1 at ¶ 8) Defendants Wyeth and GI, LLC answered that "Wyeth is the real party in interest and owner of all right, title and interest in the '112 patent." (*Id.*, ex. 2 at ¶¶ 6, 8) Defendants also acknowledged that the most recent assignment recorded at the PTO records shows GI, LLC as the assignee. (*Id.* at ¶ 8) Civil Action 03-1160 was terminated on October 13, 2005 by stipulation of the parties.

On February 15, 2008, Novartis filed a patent infringement suit in the United States District Court for the Eastern District of Texas against Wyeth asserting infringement of the '447 and '620 patents. E.D. Tex. Civ. No. 08-067 (D.I. 1) (hereinafter, "the Texas litigation"). GI, LLC is not a party to that suit. Wyeth answered the complaint on August 1, 2008. (*Id.*, D.I. 18) Wyeth asserts invalidity defenses; no specific prior art has been named in its pleadings.

GI, LLC filed the complaint at bar on May 16, 2008, seeking adjudication of priority of invention between the '112 patent and the '447 and '620 patents pursuant to 35 U.S.C. § 291.[6] Novartis moves to dismiss on the grounds that Wyeth, not GI, LLC, is the owner of right, title, and interest in the '112 patent or, alternatively, the court cannot adjudicate priority issues because the '112 patent is expired but for its "extension period" pursuant to 35 U.S.C. § 156. If its motion is denied, Novartis seeks

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[6]"The **owner** of an interfering patent may have relief against the owner of another by civil action, and the court may adjudge the question of the validity of any of the interfering patents, in whole or in part. The provisions of the second paragraph of section 146 of this title shall apply to actions brought under this section." (emphasis added)

transfer of this case to the Eastern District of Texas.

III. STANDARD

Not only may the lack of subject matter jurisdiction be raised at any time, it cannot be waived and the court is obliged to address the issue on its own motion. *See Moodie v. Fed. Reserve Bank of NY*, 58 F.3d 879, 882 (2d Cir. 1995). Once jurisdiction is challenged, the party asserting subject matter jurisdiction has the burden of proving its existence. *See Carpet Group Int'l v. Oriental Rug Importers Ass'n, Inc.*, 227 F.3d 62, 69 (3d Cir. 2000).

Under Rule 12(b)(1), the court's jurisdiction may be challenged either facially (based on the legal sufficiency of the claim) or factually (based on the sufficiency of jurisdictional fact). *See* 2 James W. Moore, Moore's Federal Practice § 12.30[4] (3d ed. 1997). Under a facial challenge to jurisdiction, the court must accept as true the allegations contained in the complaint. *See id.* Dismissal for a facial challenge to jurisdiction is "proper only when the claim 'clearly appears to be immaterial and made solely for the purpose of obtaining jurisdiction or . . . is wholly insubstantial and frivolous.'" *Kehr Packages, Inc. v. Fidelcor, Inc.*, 926 F.2d 1406, 1408-09 (3d Cir. 1991) (quoting *Bell v. Hood*, 327 U.S. 678, 682 (1946)).

Under a factual attack, however, the court is not "confine[d] to allegations in the . . . complaint, but [can] consider affidavits, depositions, and testimony to resolve factual issues bearing on jurisdiction." *Gotha v. United States*, 115 F.3d 176, 179 (3d Cir. 1997); *see also Mortensen v. First Fed. Sav. & Loan Ass'n*, 549 F.2d 884, 891-92 (3d Cir. 1977). In such a situation, "no presumptive truthfulness attaches to plaintiff's

allegations, and the existence of disputed material facts will not preclude the trial court from evaluating for itself the merits of jurisdictional claims." *Carpet Group*, 227 F.3d at 69 (quoting *Mortensen*, 549 F.2d at 891). Although the court should determine subject matter jurisdiction at the outset of a case, "the truth of jurisdictional allegations need not always be determined with finality at the threshold of litigation." 2 Moore § 12.30[1]. Rather, a party may first establish jurisdiction "by means of a nonfrivolous assertion of jurisdictional elements and any litigation of a contested subject-matter jurisdictional fact issue occurs in comparatively summary procedure before a judge alone (as distinct from litigation of the same fact issue as an element of the cause of action, if the claim survives the jurisdictional objection)." *Jerome B. Grubart, Inc. v. Great Lakes Dredge & Dock Co.*, 513 U.S. 527, 537-38 (1995) (citations omitted).

IV. DISCUSSION

A. Ownership

In response to defendant's motion, plaintiff asserts that the '112 patent has always been assigned to it. When GI, Inc. became a wholly-owned subsidiary of Wyeth in 1996 (prior to the change to GI, LLC), patents were expressly excluded from the transfer of assets to Wyeth. (D.I. 11 at 5) Plaintiff provides a declaration by its Corporate Counsel stating that he searched Wyeth's legal records and found the following:

> Those files generally include corporate agreements relating to Wyeth and any existing or former subsidiaries of Wyeth (such as Genetics Institute, LLC and Genetics Institute, Inc.) and include agreements involving transfers of assets. Upon a search of those files, I found no transfer of any intellectual property assets from Genetics Institute, Inc. or Genetics Institute, LLC to Wyeth. Based on my search of those files, I conclude that at no time did Genetics Institute, Inc.

> or Genetics Institute, LLC transfer any of its intellectual property assets, which includes [the '112 patent] to Wyeth.
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> The declaration further provides:
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> I have also searched the minutes of the Board of Directors of Genetics Institute, Inc. and Genetics Institute, LLC and I found no authorization for a transfer of U.S. Patent No. 4,868,112 or any patent to Wyeth. The only authorization by the Board of Directors of Genetics Institute, Inc. or Genetics Institute, LLC for a transfer of assets to Wyeth that I found expressly excluded patents.

(D.I. 11, ex. 12)

That authorization is of record, and is entitled "Unanimous Consent of the Board of Directors of Genetics Institute, Inc.," executed on December 27, 2001. (*Id.*, ex. 7) It states "that the proposed transfer and distribution by the Corporation [GI, Inc.] to [AHP] of all assets and properties owned by [GI, Inc.], except for the assets set forth below, be, and it hereby is approved and adopted in all respects, effective as of 11:59 pm on December 31, 2001[.] (*Id.*) "[A]ll patents" are indeed listed as excluded from transfer. (*Id.*)

Plaintiff has adduced uncontraverted documentary evidence indicating, commensurately with the last assignment recorded with the PTO, that GI, LLC (and not Wyeth) retained its rights in the '112 patent. Novartis's motion to dismiss must be denied at this time. Novartis may renew its motion at a later time should discovery illustrate otherwise.[7]

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[7]The court notes at this juncture that it is well aware of the fact that counsel for GI, LLC has taken one position before **[ ] the court in this case[ ] and another before Judge Sleet in prior litigation. Although different local counsel appear to have been involved, plaintiff had the same lead counsel in both cases. Plaintiff characterizes its prior representations as simple misstatements, emphasizing that an August 2005 settlement agreement between GI, LLC, Wyeth, Genentech and Bayer, post-dating the statements at issue, acknowledges that GI, LLC owns the '112 patent. (D.I. 11, ex. 9)

B. 35 U.S.C. § 156

In *Albert v. Kevex Corp.*, 729 F.2d 757, 758 (Fed. Cir. 1984) (hereinafter, "*Albert*"), the Federal Circuit stated that the *sine qua non* of an action under § 291 is the determination of whether an interference in fact exists. 729 F.2d at 760-61 ("Mere citation of that statute or recitation in a pleading as a basis for suit is not enough."). "Absent interference, a court has no power under § 291 to adjudicate the validity of any patent." *Id.*

Defendant does not present arguments regarding the scope of the claims of the '112, '447 and/or '620 patents; it asserts only that there is no interference-in-fact because the claims of the '112 patent have expired. According to defendant, § 156(b)[8]

Should discovery demonstrate that GI, LLC and Wyeth are engaged in a "shell game," as defendant suggests, the court will revisit the issue in the context of a subsequent motion following jurisdictional discovery. For purposes of the record, the court does not find plaintiff's prior statement a "judicial admission," as defendant argues, in view of the fact that it occurred in separate litigation. Plaintiff's motion to file a sur-reply to defendant's motion to address this issue (D.I. 18) is denied.

[8]"(b) Except as provided in subsection (d)(5)(F), the rights derived from any patent the term of which is extended under this section shall during the period during which the term of the patent is extended –

(1) in the case of a patent which claims a product, **be limited to any use approved for the product** –

(A) before the expiration of the term of the patent –

(i) under the provision of law under which the applicable regulatory review occurred, or

(ii) under the provision of law under which any regulatory review described in paragraph (1), (4), or (5) of subsection (g) occurred, and

(B) on or after the expiration of the regulatory review period upon which the extension of the patent was based;

(2) in the case of a patent which claims a method of using a product, **be limited to any use claimed by the patent and approved for the product** –

(A) before the expiration of the term of the patent –

(i) under any provision of law under which an applicable regulatory review occurred, and

"provides exclusivity only for approved uses of a particular product, not for the now-expired *claims* of the '112 patent." (D.I. 9 at 10)

Defendant, however, cites no caselaw that supports its position. *Albert* establishes only that an interference must exist for jurisdiction to lie – validity cannot be adjudicable prior to this deterrnination. 729 F.2d at 760-61. In *Pfizer Inc. v. Dr. Reddy's Laboratories, Ltd.*, 359 F.3d 1361 (Fed. Cir. 2004), another case cited by defendant, the Federal Circuit held that the term of the extension of § 156 is measured by the period of delay for the product for which regulatory approval was sought, in any form, including changes to a salt or ester. This case deals with the amount of time that should be granted, and is inapposite. *See also Merck & Co., Inc. v. Kessler*, 80 F.3d 1543, 1547 (Fed. Cir. 1996) (explaining that the restoration period extends "not to all products protected by the patent but only to the product on which the extension was based") (cited by defendant at D.I. 9 at 7); MPEP § 2750 (same).

The House Report discussing the Hatch-Waxman Act describes several "limits on the period of patent extension," relating to the maximum allowable period of extension, but otherwise does not iterate substantive limits on the rights of the patentee during the extension. H.R. Rep. 98-857(I), 1984 U.S.C.C.A.N. 2647 at *2648, 1984 WL

(ii) under the provision of law under which any regulatory review described in paragraph (1), (4), or (5) of subsection (g) occurred, and
(B) on or after the expiration of the regulatory review period upon which the extension of the patent was based; and
(3) in the case of a patent which claims a method of manufacturing a product, **be limited to the method of manufacturing** as used to make –
(A) the approved product, or
(B) the product if it has been subject to a regulatory review period described in paragraph (1), (4), or (5) of subsection (g)."

37416 at *16 (Leg. Hist. June 21, 1984) (of record at D.I. 11, ex. 10). With respect to section 156(b), specifically the "rights to be extended," the report states that "except for the limitations described below with respect to the scope of the patent claims, all provisions of the patent law apply to the patent during the period of extension." 1984 WL 37416 at *39. The provided limitations concern which products (or methods) may be used to calculate the term. *Id.*

In sum, there is no indication that § 156 confers anything less than the full scope of a patentee's rights during the extension period. Congress could have provided the specific limitations defendant asserts, but did not. The court does not read § 156 narrowly on this record, and declines to find that plaintiff is precluded from bringing its § 291 interference action during the extension period. *Compare Alberta Telecom. Research Centre v. Rambus Inc.*, No. Civ. A. 06-2595, 2006 WL 3041075, *3 (N.D. Cal. Oct. 24, 2006) (holding that the undisputed expiration of the alleged interfering patent mooted the claim of interference). Put another way, the court does not distinguish the period between the patent's original expiration date and February 28, 2010. Defendant's motion is denied on this ground.

C. Transfer

The only similarity between this litigation and the Texas litigation is that the '620 and '447 patents are involved in both. It is not clear from the face of Wyeth's pleading whether the '112 patent will ultimately be asserted as prior art in the Texas litigation (as defendant suggests); it has not been asserted to date. The Texas litigation concerns infringement of the '620 and '447 patents, while plaintiff seeks a determination of

priority vis-a-vis the '112 patent in the case at bar. These issues are distinct and the court disagrees with defendant that its consideration of the latter issue will result in a "substantial duplication of judicial effort" or a "risk of inconsistent judgments." (D.I. 15 at 11) Plaintiff and defendant are Delaware corporate entities. (D.I. 1 at ¶¶ 1, 2) The court, having personal jurisdiction over the parties and no arguments having been presented regarding the factors in 28 U.S.C. § 1404(a),[9] denies defendant's motion to transfer venue.

V. CONCLUSION

For the aforementioned reasons, defendant's motion to dismiss or in the alternative to transfer (D.I. 8) is denied without prejudice. An appropriate order shall issue and shall provide for a Rule 16(a) teleconference in this matter, at which time plaintiff's motion requesting a trial date (D.I. 22) may be addressed.

[9] *See Jumara v. State Farm Ins. Co.*, 55 F.3d 873, 879 (3d Cir. 1995).