

**UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK**

ASSOCIATION FOR MOLECULAR PATHOLOGY;
AMERICAN COLLEGE OF MEDICAL GENETICS;
AMERICAN SOCIETY FOR CLINICAL PATHOLOGY;
COLLEGE OF AMERICAN PATHOLOGISTS; HAIG
KAZAZIAN, MD; ARUPA GANGULY, PhD; WENDY
CHUNG, MD, PhD; HARRY OSTRER, MD; DAVID
LEDBETTER, PhD; STEPHEN WARREN, PhD; ELLEN
MATLOFF, M.S.; ELSA REICH, M.S.; BREAST CANCER
ACTION; BOSTON WOMEN'S HEALTH BOOK
COLLECTIVE; LISBETH CERIANI; RUNI LIMARY;
GENAE GIRARD; PATRICE FORTUNE; VICKY
THOMASON; KATHLEEN RAKER,

Plaintiffs,

-against-

UNITED STATES PATENT AND TRADEMARK OFFICE;
MYRIAD GENETICS; LORRIS BETZ, ROGER BOYER,
JACK BRITTAI, ARNOLD B. COMBE, RAYMOND
GESTELAND, JAMES U. JENSEN, JOHN KENDALL
MORRIS, THOMAS PARKS, DAVID W. PERSHING, and
MICHAEL K. YOUNG, in their official capacity as Directors of
the University of Utah Research Foundation,

Defendants.

No. 09 Civ. 4515 (RWS)

ECF Case

**MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS'
MOTION TO DISMISS**

JONES DAY
222 East 41st Street
New York, NY 10017-6702
Tel: (212) 326-3939
Fax: (212) 755-7306

TABLE OF CONTENTS

	Page
TABLE OF AUTHORITIES	ii
PRELIMINARY STATEMENT	1
STATEMENT OF FACTS	3
The Complaint	3
The Plaintiffs.....	4
The Defendants	5
ARGUMENT	6
I. PLAINTIFFS LACK STANDING TO CHALLENGE THE VALIDITY OF THE DEFENDANTS’ PATENTS	6
A. There Has Been No Action By Any Of The Defendants That Gives Rise To A Case Or Controversy With The Plaintiffs.....	6
1. There has been no relevant affirmative act by the Defendants.....	6
2. The cease-and-desist letter of 1998 is insufficient to create a case or controversy now.....	9
B. Plaintiffs Also Lack Standing Because They Fail To Allege Any Concrete Plans For Potentially Infringing Action.....	11
II. THERE IS NO PERSONAL JURISDICTION OVER THE DIRECTORS OF THE UNIVERSITY OF UTAH RESEARCH FOUNDATION.	13
A. There Is No Personal Jurisdiction Under The New York Long-Arm Statute.....	13
B. There Is No Personal Jurisdiction Under The Federal Due Process Standard.....	14
CONCLUSION.....	15

TABLE OF AUTHORITIES

	Page
<i>Aetna Life Ins. Co. v. Haworth</i> , 300 U.S. 227 (1937).....	6
<i>Animal Legal Defense Fund v. Quigg</i> , 932 F.2d 920 (Fed. Cir. 1991).....	13
<i>Arquest, Inc. v. Kimberly-Clark Worldwide, Inc.</i> , No. 07 Civ. 11202, 2008 WL 2971775 (S.D.N.Y. July 31, 2008)	14, 15
<i>Automated Salvage Transp., Inc. v. Wheelabrator Env'tl. Sys., Inc.</i> , 155 F.3d 59 (2d Cir. 1998).....	3
<i>Avocent Huntsville Corp. v. Aten Intern. Co., Ltd.</i> , 552 F.3d 1324 (Fed. Cir. 2008).....	13, 15
<i>Baker Hughes Oilfield Operations, Inc. v. Reedhycalog UK, Ltd.</i> , No. 2:05-CV-931, 2008 WL 345849 (D. Utah Feb. 6, 2008).....	7, 8
<i>Benitec Australia Ltd. v. Nucleonics, Inc.</i> , 495 F.3d 1340 (Fed. Cir. 2007).....	11, 12
<i>Breckenridge Pharmaceutical, Inc. v. Everett Laboratories, Inc.</i> , No. 09-80015-CIV, 2009 WL 654214 (S.D. Fla. Mar. 11, 2009)	7
<i>Broadcom Corp. v. Qualcomm Inc.</i> , No. 08cv1829, 2009 WL 684835 (S.D. Cal. Mar. 12, 2009).....	7
<i>Burger King v. Rudzewicz</i> , 471 U.S. 462 (1985).....	15
<i>Cat Tech LLC v. TubeMaster, Inc.</i> , 528 F.3d 871 (Fed. Cir. 2008).....	11
<i>Chambers v. Time Warner, Inc.</i> , 282 F.3d 147 (2d Cir. 2002).....	5
<i>Cygnus Therapeutics Systems v. ALZA Corp.</i> , 92 F.3d 1153 (Fed. Cir. 1996).....	10
<i>Davis v. Fed. Election Comm'n.</i> , 128 S. Ct. 2759 (2008).....	6

TABLE OF AUTHORITIES
(continued)

	Page
<i>Document Sec. Systems, Inc. v. Adler Technologies, Inc.</i> , No. 03-CV-6044, 2008 WL 596879 (W.D.N.Y. Feb. 29, 2008)	7
<i>Edmunds Holding Co. v. Autobytel Inc.</i> , 598 F. Supp. 2d 606 (D. Del. 2009).....	9, 10
<i>Geisha, LLC v. Tuccillo</i> , 525 F. Supp. 2d 1002 (N.D. Ill. 2007)	12
<i>Geospan Corp. v. Pictometry Int’l Corp.</i> , 598 F. Supp. 2d 968 (D. Minn. 2008).....	8
<i>Helicopteros Nacionales de Colombia, S. A. v. Hall</i> , 466 U.S. 408 (1984).....	14
<i>Impax Laboratories, Inc. v. Medicis Pharmaceutical Corp.</i> , No. C-08-0253, 2008 WL 1767044 (N.D. Cal. Apr. 16, 2008).....	7
<i>Indigodental GMBH & Co. KG v. Ivoclar Vivadent, Inc.</i> , No. 08 Civ. 7657, 2008 WL 5262694 (S.D.N.Y. Dec. 10, 2008).....	8
<i>Innovative Therapies, Inc. v. Kinetic Concepts, Inc.</i> , No. 07-589-SLR-LPS, 2008 WL 2746960 (D. Del. July 14, 2008)	7
<i>Insured Deposits Conduit, LLC v. SPFI, LLC</i> , No. 07-22735-CIV, 2008 WL 5691350 (S.D. Fla. June 24, 2008).....	11
<i>Jervis B. Webb Co. v. Southern Systems, Inc.</i> , 742 F.2d 1388 (Fed. Cir. 1984).....	12
<i>MedImmune, Inc. v. Genentech, Inc.</i> , 549 U.S. 118 (2007).....	passim
<i>Mega Lift Systems, LLC v. MGM Well Services, Inc.</i> , No. 6:08 CV 420, 2009 WL 1851919 (E.D. Tex. June 29, 2009)	12
<i>Micron Technology, Inc. v. Mosaid Technologies, Inc.</i> , 518 F.3d 897 (Fed. Cir. 2008).....	10
<i>Monsanto Co. v. Syngenta Crop Protection, Inc.</i> , No. 4:07-CV-543, 2008 WL 294291 (E.D. Mo. Jan. 31, 2008)	8

TABLE OF AUTHORITIES
(continued)

	Page
<i>PDK Labs v. Friedlander</i> , 103 F.3d 1105 (2d Cir. 1997).....	14
<i>Prasco, LLC v. Medicis Pharmaceutical Corp.</i> , 537 F.3d 1329 (Fed. Cir. 2008).....	7
<i>San Leandro Emergency Med. Group Profit Sharing Plan v. Philip Morris Cos., Inc.</i> , 75 F.3d 801 (2d Cir. 1996).....	3
<i>SanDisk Corp. v. STMicroelectronics, Inc.</i> , 480 F.3d 1372 (Fed. Cir. 2007).....	7
<i>Shaunnessey v. Monteris Medical, Inc.</i> , 554 F. Supp. 2d 1321 (M.D. Fla. 2008).....	12
<i>Sierra Applied Sciences, Inc. v. Advanced Energy Indus., Inc.</i> , 363 F.3d 1361 (Fed. Cir. 2004).....	9, 10
<i>Sound Around Inc. v. Audiobahn, Inc.</i> , No. 07 CV 773, 2008 WL 5093599 (E.D.N.Y. Nov. 24, 2008)	14
<i>Warrior Sports, Inc. v. STX, L.L.C.</i> , 596 F. Supp. 2d 1070 (E.D. Mich. 2009).....	12
<i>The Wooster Brush Co. v. Bercom Int’l, LLC</i> , No. 5:06CV474, 2008 WL 1744782 (N.D. Ohio Apr. 11, 2008).....	7

STATUTES AND RULES

35 U.S.C. § 101.....	3
FED. R. CIV. P. 12(b)(1)	1, 6
FED. R. CIV. P. 12(b)(2)	1, 13
N.Y. C.P.L.R. § 301.....	13
N.Y. C.P.L.R. § 302.....	14

Defendants Myriad Genetics (“Myriad”) and the ten individuals alleged to be Directors of the University of Utah Research Foundation (the “Directors”) (collectively Myriad and the Directors are referred to as the “Defendants”) submit this memorandum of law and accompanying declarations in support of their motion to dismiss the Complaint pursuant to Rule 12(b)(1) of the Federal Rules of Civil Procedure, or in the alternative to dismiss the Directors pursuant to Rule 12(b)(2) of the Federal Rules of Civil Procedure.

PRELIMINARY STATEMENT

This case is a thinly veiled attempt to challenge the validity of patents where, other than an overall policy disagreement concerning the legitimacy of gene patents, the plaintiffs have no actual dispute with the Defendants over patent infringement. If the plaintiffs in this case have standing, then virtually anyone can challenge any patent at any time.

The plaintiffs seek to challenge the Defendants’ patents concerning the *BRCA1* and *BRCA2* genes, and more generally the idea of the existence of patents with respect to genes. According to the plaintiffs, patenting with respect to genes is a corruption of the patent system that is unlawful and even unconstitutional. However, the patent system has worked exactly as it was designed to do. Myriad Genetics and the other Defendants have spent considerable time, effort, and money, in competition with other researchers, to discover the *BRCA1* and *BRCA2* genes, synthesize DNA corresponding to the genes in test tubes, and identify specific gene mutations that are correlated with breast and ovarian cancer. Using their synthetic tools and discoveries, the inventors engineered diagnostic tests for detecting these mutations in patients. The testing for these mutations has helped thousands of women get information that enabled them to make important choices and take steps to reduce their risk of breast and ovarian cancer. Advances in genetic testing such as these are transforming the way clinical medicine is practiced.

The plaintiffs accept these facts, but they object to the Defendants' exclusive rights covering the diagnostic tests. Of course, such limited terms of exclusivity is exactly how the patent system rewards the Defendants' landmark discoveries, and encourages the life-saving research that the Defendants have performed. Without such efforts incentivized by exclusivity, there would be a much smaller number of women, if any, tested for mutations in the *BRCA1* and *BRCA2* genes. Indeed, but for the prospect of the patent exclusivity, Myriad Genetics would not have been established and funded by investors.

In any event, the plaintiffs' policy disagreement concerning gene patents does not arise from an actual dispute with the Defendants. The Defendants have not had contact with any of the plaintiffs, except for an eleven-year-old letter to one of the plaintiffs that has no relevance today. Without any relevant affirmative act by the Defendants toward the plaintiffs, there is no standing to challenge the patents. Furthermore, none of the plaintiffs has any concrete plan for infringement. The existence of such a plan is a well-established requirement for standing in a declaratory judgment action for patent invalidity. Federal Circuit and district court cases have uniformly dismissed complaints based on the same deficiencies that the plaintiffs have here. As the Supreme Court recognized in *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007), there must be a real controversy, not a mere policy disagreement, to warrant a declaratory judgment. Instead, the plaintiffs here seek nothing more than an advisory opinion in support of an anti-gene patent agenda. Accordingly, the Complaint should be dismissed for lack of subject matter jurisdiction.

In addition, the plaintiffs' claims against the Directors of the University of Utah Research Foundation should be dismissed for lack of personal jurisdiction. The Complaint does not allege that the Directors have had any contact with people or businesses in New York. Moreover, the

declarations of the Directors establish that they have not engaged in continuous and systematic business activities in New York, and have had no contacts in New York concerning the patents at issue in this case. Thus, there is no personal jurisdiction over the Directors in this forum.

STATEMENT OF FACTS¹

The Complaint

The Complaint concerns patents, owned by or licensed to the Defendants, that relate to the *BRCA1* and *BRCA2* genes. *See* Compl. ¶ 2. Many genetic researchers around the world had been looking for genes that correlate with an increased risk of breast and/or ovarian cancer. *Id.* ¶ 41. The inventors of the patents in issue discovered and isolated such genes, which became known as *BRCA1* and *BRCA2*. *Id.* ¶¶ 2, 3, 37. Each of the seven patents in suit include claims based on those genes or specific variants of the genes. *Id.* ¶ 55-67.

According to the Complaint, practicing the claims of the patents in suit has had very significant results. Approximately 5-10% of women who develop breast cancer have a mutation in their *BRCA1* or *BRCA2* genes, *id.* ¶ 38, and women with one of these mutations have a 40-85% lifetime risk of developing breast cancer, *id.* ¶ 39. The detection of a mutation can provide substantial benefits in deciding what preventative care is appropriate. *Id.* ¶ 40.

The plaintiffs claim that the *BRCA1* and *BRCA2* patents are invalid because they concern products of nature, and such products cannot be patented under Article I, section 8, clause 8 of the U.S. Constitution and 35 U.S.C. § 101. *Id.* ¶ 102. The plaintiffs also claim that the patents concern abstract ideas or basic human knowledge, and are accordingly unconstitutional under the

¹ Well-pleaded factual allegations in the Complaint are assumed to be true solely for purposes of this motion. The remaining facts are those that the Court may consider on this motion to dismiss, such as documents incorporated by reference therein, as well as “matters of public record.” *See Automated Salvage Transp., Inc. v. Wheelabrator Env'tl. Sys., Inc.*, 155 F.3d 59, 67 (2d Cir. 1998); *San Leandro Emergency Med. Group Profit Sharing Plan v. Philip Morris Cos., Inc.*, 75 F.3d 801, 808-09 (2d Cir. 1996).

First and Fourteenth Amendments to the U.S. Constitution. *Id.* ¶ 103. For relief, they seek a declaratory judgment declaring the patents invalid.

The Plaintiffs

There are twenty plaintiffs in this case, and all but one of them fall into three basic categories. First, there are groups with members “some of whom are ready, willing, and able to engage in research and clinical practice involving the *BRCA1* and *BRCA2* genes if the patents are invalidated.” Compl. ¶¶ 7-10; *see also id.* ¶ 12. The Complaint does not allege that any of these members are currently infringing the patents, nor does it specify what research or clinical practice they wish to begin. Second, there are individuals who are “ready, willing, and able” to evaluate samples themselves, or find other labs to do so, if the patents are invalidated. *Id.* ¶¶ 13-16. The Complaint does not allege what this evaluation would entail, which (if any) of the patent claims it would infringe, or any plans to actually conduct the evaluation. Third, there are groups and individuals who are not researchers or doctors, but who would be “ready, willing, and able” to use the additional resources that might be developed by others if the patents were invalidated. *Id.* ¶¶ 17-26. The Complaint does not specify what additional resources would be forthcoming, or any plans to develop such resources.

Finally, there is plaintiff Haig Kazazian, M.D., the only plaintiff who is alleged to have had contact with any of the Defendants.² According to the Complaint, Dr. Kazazian received a cease-and-desist letter from Myriad. *See* Compl. ¶ 11. However, this letter was actually sent in 1998, was addressed to Dr. Kazazian in his capacity as Director of the Genetic Diagnostic Laboratory for the University of Pennsylvania, and gave rise to a lawsuit filed against the

² The Complaint identifies one other plaintiff, Dr. Arupa Ganguly, who allegedly is the co-director of the laboratory with Dr. Kazazian. *See* Compl. ¶ 12. However, the Complaint alleges only that Dr. Kazazian, not Dr. Ganguly, received a cease-and-desist letter from the Defendants. Accordingly, Dr. Ganguly is in the same position as the other plaintiffs in the first group described above.

University of Pennsylvania that was dismissed in 1999 for failure to serve process on the named defendant, the University of Pennsylvania. *See* Letter from George A. Riley, O'Melveny & Myers, to Haig H. Kazazian, Jr., M.D. (Aug. 26, 1998)³; Order of Dismissal in *Myriad Genetics, Inc. v. University of Pennsylvania*, No. 2:98-cv-0829-S (D. Utah Apr. 20, 1999).⁴ The Complaint does not allege that Dr. Kazazian has any interest in resuming the research that was the subject of the cease-and-desist letter and the dismissed lawsuit. *See* Compl. ¶ 11. Moreover, the target of the letter and the subsequent lawsuit – the University of Pennsylvania – is not a plaintiff in this case.

The Defendants

The Defendants are each alleged to have some interest as an owner or licensee of the *BRCA1* and *BRCA2* patents. Among the Defendants are the individuals alleged to be the Directors of the University of Utah Research Foundation (the “Foundation”), which is a not-for-profit corporation that is alleged to be operated, supervised, and/or controlled by the University of Utah and located in Salt Lake City, Utah. *See* Compl. ¶ 29. The Foundation is an owner or part-owner of all of the patents at issue in this case. *See id.* The Complaint does not allege any contacts between the Directors (or the Foundation itself) and New York. The declarations of the Directors establish that, in fact, they have not engaged in any continuous and systematic business activities in New York, and have had no contacts in New York related to the patents at issue in this case. *See infra* Part II.

³ A copy of the letter is annexed as Exhibit A to the Declaration of Barry R. Satine in Support of Defendants’ Motion to Dismiss (“Satine Declaration”). Because this letter is referenced in the Complaint, it is properly considered on a motion to dismiss. *See Chambers v. Time Warner, Inc.*, 282 F.3d 147, 152 (2d Cir. 2002).

⁴ Satine Declaration, Exhibit B.

ARGUMENT

I. PLAINTIFFS LACK STANDING TO CHALLENGE THE VALIDITY OF THE DEFENDANTS' PATENTS

A plaintiff cannot bring suit, as a matter of the Article III limitations on federal jurisdiction, unless there is an actual “case or controversy,” not a “a difference or dispute of a hypothetical or abstract character.” *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 240 (1937). In *MedImmune*, the Supreme Court held that a plaintiff has standing to bring a declaratory judgment action with respect to a patent claim only if there is “a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.” 549 U.S. at 127 (internal quotation marks omitted). After *MedImmune*, courts have recognized two requirements for standing: (1) the patent owner must have taken some affirmative action relevant to the plaintiff; and (2) the plaintiff must have a concrete plan to take potentially infringing action. Neither requirement is met here for any of the plaintiffs.⁵ Rather, the plaintiffs essentially seek an advisory opinion declaring the patents invalid, even though there is currently no dispute over potential infringement by any of the plaintiffs. Thus, the Complaint should be dismissed for lack of subject matter jurisdiction under Rule 12(b)(1) of the Federal Rules of Civil Procedure.

A. There Has Been No Action By Any Of The Defendants That Gives Rise To A Case Or Controversy With The Plaintiffs

1. There has been no relevant affirmative act by the Defendants.

Courts have uniformly recognized that there must be some affirmative act by the defendant to create standing for a declaratory-judgment plaintiff in a patent case. Specifically, the Federal Circuit has held that “jurisdiction generally will not arise merely on the basis that a

⁵ This test applies equally to plaintiffs’ constitutional claims as it does to their statutory claims. *See, e.g., Davis v. Fed. Election Comm’n*, 128 S. Ct. 2759, 2768 (2008) (applying the usual “case or controversy” test for standing to bring First Amendment claims).

party learns of the existence of a patent owned by another or even perceives such a patent to pose a risk of infringement, without some affirmative act by the patentee.” *Prasco, LLC v. Medicis Pharmaceutical Corp.*, 537 F.3d 1329, 1339 (Fed. Cir. 2008) (quoting *SanDisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372, 1380-81 (Fed. Cir. 2007)). As *Prasco* explained, there is a “bedrock rule that a case or controversy must be based on a *real* and *immediate* injury or threat of future injury that is *caused by the defendants*.” *Id.* Thus, the case was dismissed where “not only have the defendants not taken a concrete position adverse to [the plaintiff’s], but they also have taken no affirmative actions at all related to [the plaintiff’s] current product.” *Id.* at 1340.

Numerous district courts have likewise dismissed declaratory-judgment actions based on the lack of any affirmative act by the defendant. *See, e.g., Broadcom Corp. v. Qualcomm Inc.*, No. 08cv1829, 2009 WL 684835, at *6 (S.D. Cal. Mar. 12, 2009) (finding no case or controversy where the plaintiff “fail[ed] to specify any affirmative act by Qualcomm, such as a notification of Qualcomm’s intent to enforce a specific patent right against Broadcom”); *Breckenridge Pharmaceutical, Inc. v. Everett Laboratories, Inc.*, No. 09-80015-CIV, 2009 WL 654214, at *3 (S.D. Fla. Mar. 11, 2009) (finding no case or controversy where “the Complaint does not allege any affirmative acts by [the defendant] with respect to the assertion of the subject patents against [the plaintiff’s] product”); *Innovative Therapies, Inc. v. Kinetic Concepts, Inc.*, No. 07-589-SLR-LPS, 2008 WL 2746960, at *7-*8 (D. Del. July 14, 2008) (“Missing from [the Complaint] is any allegation of an ‘affirmative act’ by [the defendant] directed toward [the plaintiff] that could meet the requirement set out by the Federal Circuit.”).⁶ Indeed, a recent case from this district

⁶ *See also, e.g., Impax Laboratories, Inc. v. Medicis Pharmaceutical Corp.*, No. C-08-0253, 2008 WL 1767044, at *2 (N.D. Cal. Apr. 16, 2008); *The Wooster Brush Co. v. Bercom Int’l, LLC*, No. 5:06CV474, 2008 WL 1744782, *4-*5 (N.D. Ohio Apr. 11, 2008); *Document Sec. Systems, Inc. v. Adler Technologies, Inc.*, No. 03-CV-6044, 2008 WL 596879, *10-*11 (W.D.N.Y. Feb. 29, 2008); *Baker Hughes Oilfield Operations, Inc. v.*

recognized that the plaintiff lacked standing to bring a declaratory judgment suit where the “Plaintiff has not alleged that Defendant asserted any rights under the ’784 Patent against it.” *Indigodental GMBH & Co. KG v. Ivoclar Vivadent, Inc.*, No. 08 Civ. 7657, 2008 WL 5262694, at *2 (S.D.N.Y. Dec. 10, 2008). The *only* cases finding jurisdiction are those where the patentee has taken some action with respect to the plaintiff or has otherwise affirmatively shown a preparedness to litigate against the plaintiff. *See, e.g., Geospan Corp. v. Pictometry Int’l Corp.*, 598 F. Supp. 2d 968, 970 (D. Minn. 2008) (“In the post-*MedImmune* authorities relied on by [the plaintiff], a patentee has either demonstrated a preparedness to litigate against the prospective declaratory judgment plaintiff, accused the prospective declaratory judgment plaintiff of infringement, affirmatively asserted its rights to license fees, or engaged in some combination of all three.”).

With the exception of a single letter, discussed below, the Complaint fails to identify any action by the Defendants directed toward the plaintiffs. Plaintiffs do not allege that the Defendants were even aware of their supposed interest in infringing, let alone that the Defendants acted in any way to challenge or prevent them from such infringement. The Complaint also does not allege that the Defendants have shown an intention to litigate against the plaintiffs.

While the Complaint alleges that the Defendants have enforced their patent rights nine times, including a cease-and-desist letter sent to laboratories at Yale, *see* Compl. ¶ 49, such an allegation is clearly inadequate. To begin with, the Complaint fails to allege when this “enforcement” occurred, and, more importantly, whether it was directed to the kind of research

(continued...)

Reedhycalog UK, Ltd., No. 2:05-CV-931, 2008 WL 345849, at *2-*3 (D. Utah Feb. 6, 2008); *Monsanto Co. v. Syngenta Crop Protection, Inc.*, No. 4:07-CV-543, 2008 WL 294291, at *6 (E.D. Mo. Jan. 31, 2008).

that the plaintiffs wish to pursue. A few cases have held that a defendant's pattern of litigation against other potential infringers can give rise to standing, but they have done so only where the others are similarly situated to the plaintiffs. *See, e.g., Edmunds Holding Co. v. Autobytel Inc.*, 598 F. Supp. 2d 606, 610 (D. Del. 2009) (recognizing that litigation against others has given rise to standing only where such litigation was brought against "a class of alleged infringers to which plaintiff belonged," and concluding that the defendant's litigation against other companies did not suffice in the instant case). Also, the cases suggesting that there can be standing based on other litigation concerned actual lawsuits, not simply cease-and-desist letters to other individuals, which is all that the plaintiffs allege here. In any event, the Complaint itself establishes that there is no pattern of litigation against potential infringers because the Defendants "ha[ve] permitted some researchers to do pure research on the human *BRCA1* and *BRCA2* genes." Compl. ¶ 97.

In sum, there are no post-*MedImmune* cases that have found jurisdiction based on the kinds of allegations here, where there has been no conduct by the Defendants toward the plaintiffs.

2. The cease-and-desist letter of 1998 is insufficient to create a case or controversy now.

The Complaint identifies a letter from Myriad to one plaintiff, Dr. Kazazian, but this letter plainly fails to give rise to standing. The Complaint alleges that Dr. Kazazian received a letter from Myriad requesting that he cease and desist work being done in the Department of Genetics at the University of Pennsylvania. Compl. ¶ 11. However, this letter was sent more than ten years ago, in 1998. *See* Satine Declaration, Ex. A.

Courts have consistently recognized that if a threat to sue was communicated several years earlier, such a stale threat is insufficient for standing. *See, e.g., Sierra Applied Sciences,*

Inc. v. Advanced Energy Indus., Inc., 363 F.3d 1361, 1374 (Fed. Cir. 2004) (“The parties did not communicate for almost four years. By the end of this long interlude, Sierra could no longer have reasonably apprehended an infringement suit”); *Cygnus Therapeutics Systems v. ALZA Corp.*, 92 F.3d 1153, 1159 (Fed. Cir. 1996) (“Any implicit threat that one may argue was conveyed by Dr. Shaw at that time could hardly be said to have had any significant continuing effect on Cygnus five years later, when, as discussed below, ALZA engaged in no threatening conduct in the interim.”), *overruled on other grounds by Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059 (Fed. Cir. 1998)).⁷ As one district court explained in a recent case, where it dismissed for lack of standing, the plaintiff’s “ability to delay this action [from 2004] until now cuts against its argument that its alleged controversy with Autobytel is sufficiently immediate as to require adjudication now.” *Edmunds*, 598 F. Supp. 2d at 610-11. Indeed, it makes little sense to claim that Dr. Kazazian requires this Court to issue a declaratory judgment to adjudicate a dispute over an eleven-year-old letter, where the Complaint fails to allege that the plaintiff or Defendants have taken any relevant action in the interim. Accordingly, the stale letter does not create “a substantial controversy . . . of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.” *MedImmune*, 549 U.S. at 127 (emphasis added, internal quotation marks omitted).

The lack of an immediate and real controversy is especially clear because the prior dispute was dismissed, in 1999, for failure to serve process on the named defendant. *See* Satine Declaration, Ex. B. The Complaint does not allege that Dr. Kazazian has continued or will continue with the same research that was the subject of the prior letter (or, in fact, any research at

⁷ *Micron Technology, Inc. v. Mosaid Technologies, Inc.*, 518 F.3d 897 (Fed. Cir. 2008), is not to the contrary. There, a four-year lapse in time did not deprive the plaintiff of standing only “because [the defendant], during this period, was busy negotiating with other leading DRAM manufacturers” in lawsuits over the same allegedly infringing activity that the plaintiff was pursuing. As discussed above, the Complaint does not allege the existence of any such lawsuits against similarly situated infringers.

all). *See* Compl. ¶ 11. Since there is no allegation that Dr. Kazazian is seeking to conduct the research that created the dispute with Myriad, the letter cannot establish standing for some unknown research that none of the Defendants has addressed at all. *See Insured Deposits Conduit, LLC v. SPFI, LLC*, No. 07-22735-CIV, 2008 WL 5691350, at *5 (S.D. Fla. June 24, 2008) (holding that one cease-and-desist letter does not create standing for different conduct).

B. Plaintiffs Also Lack Standing Because They Fail To Allege Any Concrete Plans For Potentially Infringing Action

The second requirement for standing is clear: “If a declaratory judgment plaintiff has not taken significant, concrete steps to conduct infringing activity, the dispute is neither ‘immediate’ nor ‘real’ and the requirements for justiciability have not been met.” *Cat Tech LLC v. TubeMaster, Inc.*, 528 F.3d 871, 880 (Fed. Cir. 2008). Thus, there is no standing for “merely contemplated activity”; rather, “there must be a showing of meaningful preparation for” the infringing activity. *Id.* at 881 (internal quotation marks omitted).

Here, the Complaint clearly fails to meet this test. It alleges only that the plaintiffs are “ready, willing, and able” to engage in some unspecified infringing conduct. It does not allege that any of the plaintiffs have taken “significant, concrete steps,” toward infringement, and there are certainly no factual allegations describing such steps. Indeed, for Dr. Kazazian, the Complaint does not even suggest that he currently has an interest in infringing the patents. *See* Compl. ¶ 11.

The Federal Circuit and numerous district courts have dismissed declaratory-judgment actions based on the same kind of speculative plans alleged in this case. For example, in *Benitec Australia Ltd. v. Nucleonics, Inc.*, 495 F.3d 1340 (Fed. Cir. 2007), the plaintiff alleged that it had “discussions” with a potential customer and “‘expects’ to begin work ‘shortly.’” *Id.* at 1349. These vague plans are insufficient for standing because “to allow such a scant showing to

provoke a declaratory judgment suit would be to allow nearly anyone who so desired to challenge a patent.” *Id.* Similarly, in a very recent case, a district court held that the plaintiff lacked standing where the “facts give no indication of when [the plaintiff] plans to manufacture or sell” the potentially infringing product, and the “complaint is silent as to any ‘meaningful preparation’ [the plaintiff] has made to potentially infringe the patents at issue.” *Mega Lift Systems, LLC v. MGM Well Services, Inc.*, No. 6:08 CV 420, 2009 WL 1851919, at *4 (E.D. Tex. June 29, 2009).⁸ The Complaint’s sole allegation of plans for potentially infringing activity – *i.e.*, that plaintiffs are “ready, willing, and able” to do so – thus fails to establish a case or controversy.

Furthermore, the Complaint does not allege what the infringing conduct would entail for any individual plaintiff. Thus, the Complaint lacks sufficient factual information to determine whether the conduct would possibly be infringing. As a result, any declaratory judgment would simply be an advisory opinion regarding research in general, rather than deciding a dispute regarding particular research. *See Benitec*, 495 F.3d at 1349 (dismissing for lack of standing where the complaint gave “insufficient information for a court to assess whether Nucleonics’s possible future animal work would be infringing or not”).

Moreover, the Complaint does not even specify which patent claim is at issue for each plaintiff. This deficiency is fatal to the Complaint because “the existence of a case or controversy must be evaluated on a claim-by-claim basis.” *Jervis B. Webb Co. v. Southern Systems, Inc.*, 742 F.2d 1388, 1399 (Fed. Cir. 1984).

⁸ *See also, e.g., Warrior Sports, Inc. v. STX, L.L.C.*, 596 F. Supp. 2d 1070, 1077 (E.D. Mich. 2009) (dismissing for lack of standing where the complaint provided “nothing but speculation and hypothesis that [the plaintiff] might offer a product that allegedly infringes [the defendant’s] patent, and even then, not before several months elapse”); *Shaunnessey v. Monteris Medical, Inc.*, 554 F. Supp. 2d 1321, 1324-25 (M.D. Fla. 2008) (holding that plaintiff’s plans were not determinate enough where defendant had not yet filed an application with the FDA); *Geisha, LLC v. Tuccillo*, 525 F. Supp. 2d 1002, 1015 (N.D. Ill. 2007) (holding that a “bona fide intention” to infringe is insufficient without “actual preparations”).

Finally, the lack of standing is especially clear for the non-researcher plaintiffs who are “ready, willing, and able” to use the research of some unidentified persons who would supposedly infringe the patents. *See* Compl. ¶¶ 17-26. The plaintiffs’ theory seems to be that if the patents are invalidated, then someone would compete with Myriad, thereby increasing the availability of the *BRCA1* and *BRCA2* tests. However, under this theory, anyone could bring a declaratory judgment suit to invalidate a patent, because there will always be the prospect of greater competition if a patent is invalidated. In any event, it is well established that third parties arguably affected by a patent do not have standing to challenge the patent’s validity. *See Animal Legal Defense Fund v. Quigg*, 932 F.2d 920, 930 (Fed. Cir. 1991).

II. THERE IS NO PERSONAL JURISDICTION OVER THE DIRECTORS OF THE UNIVERSITY OF UTAH RESEARCH FOUNDATION

On a motion to dismiss under Rule 12(b)(2), the plaintiff bears the burden to make a prima facie showing of personal jurisdiction. “Determining whether personal jurisdiction exists over an out-of-state defendant involves two inquiries: whether a forum state’s long-arm statute permits service of process, and whether the assertion of personal jurisdiction would violate due process.” *Avocent Huntsville Corp. v. Aten Intern. Co., Ltd.*, 552 F.3d 1324, 1329 (Fed. Cir. 2008). Plaintiffs fail to meet either criteria with respect to the Directors of the Foundation.⁹

A. There Is No Personal Jurisdiction Under The New York Long-Arm Statute

Under the New York long-arm statute, there is general jurisdiction over a non-resident defendant if the defendant engages in “continuous and systematic” business activities within New York. *See* N.Y. C.P.L.R. § 301. There are plainly no such activities alleged in this case for the Directors. The declarations of the Directors establish that they do not reside in New York,

⁹ If the Directors are dismissed for lack of personal jurisdiction, but the Complaint is not dismissed, an issue then would arise as to whether the Directors are necessary and/or indispensable parties in this case. Of course, since the Directors are currently parties, it would be premature to address the issue in this motion.

own property in New York, or engage in any continuous and systematic business activities in New York.¹⁰

Under the New York long-arm statute, there is specific jurisdiction if a defendant “transacts any business within the state and the cause of action arises out of the transactions.” *PDK Labs v. Friedlander*, 103 F.3d 1105, 1109 (2d Cir. 1997) (citing N.Y. C.P.L.R. § 302). There are no allegations of any such transactions by the Directors. Moreover, the declarations make clear that none of the Directors has engaged in any transactions in New York regarding the patents at issue in this case.¹¹ Courts have routinely dismissed similar cases for lack of personal jurisdiction. *See, e.g., Arquest, Inc. v. Kimberly-Clark Worldwide, Inc.*, No. 07 Civ. 11202, 2008 WL 2971775, at *10 (S.D.N.Y. July 31, 2008) (“KCWW has undertaken no activity in New York that gives rise to specific jurisdiction over a declaratory judgment action.”); *Sound Around Inc. v. Audiobahn, Inc.*, No. 07 CV 773, 2008 WL 5093599, at *9 (E.D.N.Y. Nov. 24, 2008) (holding that “minimal contact with the state is insufficient to constitute the transaction of business in New York giving rise to plaintiff’s cause of action”).

B. There Is No Personal Jurisdiction Under The Federal Due Process Standard

Because of their lack of contacts with New York, there is also no personal jurisdiction over the Directors as a matter of due process. To establish minimum contacts sufficient for general jurisdiction, there must be continuous and systematic general business contacts with the forum state. *See Helicopteros Nacionales de Colombia, S. A. v. Hall*, 466 U.S. 408, 415-16 (1984). As discussed above for general jurisdiction under the New York long-arm statute, there are plainly no such contacts here.

¹⁰ *See* Satine Declaration, Exhibits C-L.

¹¹ *See* Satine Declaration, Exhibits C-F ¶¶ 9, 10; Exhibit G ¶¶ 10, 11, Exhibits H-L ¶¶ 9, 10.

To establish minimum contacts sufficient for specific jurisdiction, a plaintiff must show that “the defendant has ‘purposefully directed’ his activities at residents of the forum, and the litigation results from alleged injuries that arise out of or relate to those activities.” *Burger King v. Rudzewicz*, 471 U.S. 462, 472-73 (1985). In the context of a declaratory judgment action against a patentee, this “purposefully directed” test means that the patentee must have engaged in some kind of activity in the forum for the “*enforcement or the defense of the validity of the relevant patents.*” *Avocent*, 552 F.3d at 1334. This case law is binding because “[t]o determine personal jurisdiction in patent cases, this Court applies the law of the Federal Circuit.” *Arquest*, 2008 WL 2971775, at *4. Here, as discussed above, the Directors have engaged in no activity at all in New York regarding the patents, let alone any activity for the enforcement or defense of the patents. Thus, there is no specific jurisdiction under the federal due process standard.

CONCLUSION

For the reasons set forth above, Defendants Myriad and the Directors of the Foundation respectfully request that the Complaint be dismissed in its entirety, or, in the alternative, that the Directors of the Foundation be dismissed for lack of personal jurisdiction.

Dated: New York, New York
July 13, 2009

JONES DAY

By: /s/ Brian M. Poissant
Brian M. Poissant (BP2350)
Barry R. Satine (BS8785)
Laura A. Coruzzi (LC0931)
222 East 41st Street
New York, NY 10017
(212) 326-3939

*Attorneys for Defendants Myriad Genetics,
Lorris Betz, Roger Boyer, Jack Brittain, Arnold
B. Combe, Raymond Gesteland, James U.
Jensen, John Kendall Morris, Thomas Parks,
David W. Pershing, and Michael K. Young*

CERTIFICATE OF SERVICE

The undersigned hereby certifies that the foregoing was served electronically by the Court's ECF system and by first class mail on those parties not registered for ECF pursuant to the rules of this court.

Dated: July 13, 2009

/s/ Barry R. Satine
Barry R. Satine