

**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 BRITAIN, 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

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

-----X

ASSOCIATION FOR MOLECULAR
PATHOLOGY, et al., :

Plaintiffs, :

v. :

: 09 Civ. 4515 (RWS)

UNITED STATES PATENT AND TRADEMARK
OFFICE, et al., :

Defendants. :

-----X

**DEFENDANT UNITED STATES PATENT AND TRADEMARK OFFICE'S
MEMORANDUM OF LAW IN SUPPORT OF MOTION TO DISMISS**

LEV L. DASSIN
Acting United States Attorney for the
Southern District of New York
Attorney for the Defendant United States
Patent and Trademark Office
86 Chambers Street, 3rd Floor
New York, New York 10007
Tel: 212-637-2732

BETH E. GOLDMAN
Assistant United States Attorney

– Of Counsel–

TABLE OF CONTENTS

	Page
Preliminary Statement.	1
Factual Background.	1
ARGUMENT.	3
THE COMPLAINT AGAINST THE USPTO SHOULD BE DISMISSED.	3
A. Plaintiffs Lack Standing to Sue the USPTO.	4
1. Constitutional and Prudential Standing Requirements.	4
2. Plaintiffs Do Not Meet the Prudential or Constitutional Standing Requirements.	6
B. The Complaint Should Be Dismissed For Lack of Subject Matter Jurisdiction.	9
C. Sovereign Immunity Bars the Action Against the USPTO.	11
D. Plaintiffs Fail To State a Claim For a Constitutional Violation.	13
CONCLUSION	15

Preliminary Statement

Defendant the United States Patent and Trademark Office (the “USPTO”) respectfully submits this memorandum of law in support of its motion to dismiss the complaint pursuant to Rules 12(b)(1) and 12(b)(6) of the Federal Rules of Civil Procedure. The complaint against the USPTO should be dismissed because there is no basis under the comprehensive statutory patent scheme for third parties to challenge the USPTO’s issuance of a patent. Accordingly, as is discussed below, plaintiffs lack standing to sue the USPTO, the Court lacks subject matter jurisdiction, and the action is barred by the sovereign immunity. Moreover, plaintiffs’ unsupported legal conclusions fail to state a claim for a constitutional violation and therefore should be dismissed pursuant to Fed. R. Civ. P. 12(b)(6).

FACTUAL BACKGROUND

The Patent Scheme

Congress has provided an extensive statutory framework governing the examination of patent applications and review in the federal courts of USPTO actions in granting or denying patents. In order to receive a patent, an inventor or applicant must file an application with the USPTO, which is reviewed by an examiner who approves or rejects the claims in the patent application. 35 U.S.C. §§ 111, 131. An applicant whose patent claim is rejected may appeal to the Board of Patent Appeals and Interferences (“Board”). *Id.* § 134. If an applicant receives an adverse ruling from the Board, he may appeal directly to the Federal Circuit or may file an action against the USPTO Director in the United States District Court for the District of Columbia. *Id.* §§ 141, 145.

The patent application and examination procedures are entirely *ex parte*, and are not the result of an adversary proceeding. 35 U.S.C. §§ 131-34. The only relevant parties are

the patent applicant and the USPTO examiner. The role of a third party in USPTO practice prior to issuance of a patent is limited to interference proceedings in which the USPTO must resolve a dispute between two inventors who claim the same or similar inventions. 35 U.S.C. §§ 135, 146. Similarly, challenges in the federal courts to the USPTO's denial of claims in a patent application involve only the patent applicant and the USPTO. 35 U.S.C. §§ 141 (limiting relief to "[a]n applicant dissatisfied with the decision in an appeal to the Board of Patent Appeals and Interferences"), 145 (same). Third parties therefore cannot intervene in the prosecution of patent applications in the USPTO except in the limited context of an interference, which involves two patent applicants, as opposed to a patent applicant and a third party not already involved in USPTO proceedings.

After issuance of a patent, the validity and scope of a patent are determined by the federal courts in patent infringement or interference actions and in actions to declare a patent invalid brought against the patent owner, not the USPTO. 35 U.S.C. §§ 281-82, 291. It is only in that context that a third party can raise as a defense proof that the patent is invalid. The patent laws also permit third parties to request that the USPTO reexamine an issued patent in light of prior art not previously considered. 35 U.S.C. §§ 301-07, 311-12. The involvement of the third party is limited to requesting USPTO reexamination in an *ex parte* reexamination, but the third party may participate in the reexamination proceedings in the USPTO – and even appeal an adverse decision by the USPTO to the Federal Circuit – in an *inter partes* reexamination. *Compare* 35 U.S.C. §§ 314-15 (permitting participation by a third-party requester in an *inter partes* reexamination and appeals from it) *with* 35 U.S.C. §§ 305-06 (limiting the rights of participation and appeal to the patent owner). Congress has thus provided only one avenue

through which a third-party potential infringer of a patent may obtain judicial review of the validity of a patent's claim in an action involving the USPTO as a party – an appeal to the Federal Circuit from a Board decision in an *inter partes* reexamination upholding the claim's validity.

The Complaint

The complaint alleges that the patenting of human genes, including the *BRCA1* and *BRCA2* genes at issue in this case, “violates long established legal principles that prohibit the patenting of laws of nature, products of nature, and abstract ideas.” In addition, plaintiffs allege that the patents violate the First Amendment and Article I, section 8, clause 8 of the Constitution. Compl. ¶ 4. The complaint names as defendants various co-owners of the patents, as well as the USPTO, Compl. ¶¶ 27-29, but, according to the complaint, “[t]he Patent office is sued solely on the constitutional claims,” Compl. ¶ 27. The complaint does not, however, seek any relief from the USPTO, *see* Compl. at 30 (“Prayer for Relief”).

ARGUMENT

THE COMPLAINT AGAINST THE USPTO SHOULD BE DISMISSED

The complaint runs afoul of Article III of the Constitution in a number of ways. Plaintiffs lack standing to sue the USPTO; there is no subject matter jurisdiction for their claim against the USPTO; and sovereign immunity bars the action. These legal deficiencies are intertwined. As the Federal Circuit recognized in comparable circumstances: “The standing and reviewability inquiries tend to merge. A plaintiff cannot claim standing based on violation of an asserted personal statutorily-created procedural right when Congress intended to grant that

plaintiff no such right.” *Syntex (U.S.A.) Inc. v. U.S. Patent & Trademark Office*, 882 F.2d 1570, 1573 (Fed. Cir. 1989) (quoting *Banzhaf v. Smith*, 737 F.2d 1167, 1170 n.* (D.C.Cir. 1984)).¹ Here, “[t]he question of jurisdiction (subject matter or standing) requires a focus on the legal rights or interests which devolve from the relevant statute” – *i.e.*, the patent statute. *Id.* As set forth more fully below, it is well established that third parties do not have standing against the USPTO to challenge the issuance of a patent, and the courts lack subject matter jurisdiction over such a challenge because Congress, in enacting the comprehensive patent law scheme, did not provide for suits by third parties against the USPTO to challenge the issuance of patents. On the basis of any one of these threshold issues, the Court should dismiss the action as against the USPTO. In addition, plaintiffs fail to plead anything other than unsupported legal conclusions and seek no relief against the USPTO. Accordingly, the complaint should be dismissed for the further reason that it fails to state a claim upon which relief may be granted.

A. Plaintiffs Lack Standing to Sue the USPTO

1. Constitutional and Prudential Standing Requirements

The “judicial power . . . defined by Art. III is not an unconditioned authority to determine the constitutionality of legislative or executive acts” but, rather, is limited to the resolution of “cases” and “controversies.” *Valley Forge Christian Coll. v. Ams. United for Separation of Church & State, Inc.*, 454 U.S. 464, 471 (1982); *Lujan v. Defenders of Wildlife*,

¹ Because any appeal from a final decision of this Court will be to the United States Court of Appeals for the Federal Circuit, *see* 28 U.S.C. § 1295, the substantive law of the Federal Circuit governs here. On procedural issues, however, the rules of the regional circuit govern, unless the issue is unique to patent law and therefore exclusively assigned to the Federal Circuit. *Madey v. Duke Univ.*, 307 F.3d 1351, 1358 (Fed. Cir. 2002).

504 U.S. 555, 559-60 (1992). An “essential and unchanging part” of that limitation is the doctrine of standing. *Lujan*, 504 U.S. at 560. Indeed, “[t]he Art. III doctrine that requires a litigant to have ‘standing’ to invoke the power of a federal court is perhaps the most important of these doctrines.” *Allen v. Wright*, 468 U.S. 737, 750 (1984).

“At an irreducible minimum, Art. III requires the party who invokes the court’s authority to show (1) that he personally has suffered some actual or threatened injury as a result of the putatively illegal conduct of the defendant, and that (2) the injury fairly can be traced to the challenged action, and (3) is likely to be redressed by a favorable decision.” *Valley Forge*, 454 U.S. at 472 (internal citations omitted).

Beyond these constitutional requirements, a plaintiff must also satisfy certain prudential standing requirements, based on the principle that the judiciary should “avoid deciding questions of broad social import where no individual rights would be vindicated.” *Phillips Petroleum Co. v. Shutts*, 472 U.S. 797, 804 (1985). Prudential standing requires, *inter alia*, that a party “assert his own legal interests rather than those of third parties,” *Id.* at 804, and that a claim not be a “generalized grievance” shared in by all or a large class of citizens, *Warth v. Seldin*, 422 U.S. 490, 499 (1975). Prudential standing also addresses whether “the constitutional or statutory provision on which [a plaintiff’s] claim rests properly can be understood as granting persons in the plaintiff’s position a right to judicial relief.” *See id.* at 499-500. Thus, the litigant’s complaint must fall within the “zone of interests to be protected or regulated by the statute or constitutional guarantee in question.” *Valley Forge*, 454 U.S. at 475. The “source of plaintiff’s claim to relief” “assumes critical importance” with respect to prudential standing, *Warth v. Seldin*, 422 U.S. at 498, 500, and a plaintiff must “demonstrate standing for *each claim* he seeks

to press.” *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 352 (2006) (emphasis added).

2. Plaintiffs Do Not Meet the Prudential or Constitutional Standing Requirements

Plaintiffs cannot meet the prudential standing requirements. It is well established that third parties do not have standing to challenge the USPTO’s issuance of a patent. *See Syntex*, 882 F.2d at 1576 (third party has no standing to challenge USPTO decision on reexamination); *Animal Legal Defense Fund v. Quigg*, 932 F.2d 920, 938-39 (Fed. Cir. 1991) (no standing to seek a declaration that animals are not patentable subject matter and an injunction against issuance of animal patents); *Hitachi Metals, Ltd. v. Quigg*, 776 F. Supp. 3, 12 (D.D.C. 1991) (claims by competitor, third-party protestor, and potential target of infringement suit “do not fall within the ‘zone of interests’ protected by the relevant statute or the implementing regulations”); *Godfredsen v. Banner*, 503 F. Supp. 642, 646 (D.D.C. 1980) (“It is well-established in that system that an individual does not have standing to challenge the decision of the Patent Office to grant a patent to another applicant during the prosecution process. The application process is deemed to be an *ex parte* procedure conducted between the applicant and the Patent Office.”).

The Federal Circuit has held that “a potential infringer may not sue the PTO seeking retraction of a patent issued to another by reason of its improper allowance by the PTO.” *Syntex*, 882 F.2d at 1576. Indeed, the *Syntex* Court stated that “[t]he creation of a right or remedy in a third party to challenge a result favorable to a patent owner after *ex parte* prosecution would be unprecedented.” *Id.* at 1574-75. Thus, that plaintiffs lack standing to sue the USPTO to challenge the patents already issued.

Nor would plaintiffs have standing to seek relief preventing the USPTO from

issuing patents to others for like technologies – relief not requested in the complaint. In *Animal Legal Defense Fund*, public interest groups sought to challenge a USPTO policy that permitted the issuance of patents for nonnaturally-occurring, man-made living microorganisms. The Federal Circuit held that “[a] third party has no right to intervene in the prosecution of a particular patent application to prevent issuance of an allegedly invalid patent.” 932 F.2d at 930. The court further concluded that members of the public are not within the “zone of interests” protected by the patent laws, and as such did not have standing to challenge the USPTO’s application of its policy to patent applicants. *Id.* at 938.

In essence, appellants’ claim the patent statute’s “zone of interests” encompasses any member of the public who perceives they will be harmed by an issued patent which they believe to be invalid. We cannot agree that the “zone of interests” of the patent laws is so broad. Under such an interpretation, we would, for example, be opening the door to collateral attack on the validity of issued patents; any competitor could simply file suit against the [Director] challenging a patent’s validity. This we decline to do.

Id. As made clear in *Syntex* and *Animal Legal Defense Fund*, plaintiffs’ lack of standing results from a statutory scheme that permits challenges to patents only under certain limited, clearly defined circumstances. The fact that plaintiffs in this case have invoked the Constitution cannot confer standing on them to bring a challenge that is not contemplated by the statutory scheme.

Nor can plaintiffs meet either the second or third prong of the constitutional standing prerequisites – traceability and redressibility. Plaintiffs do not satisfy the requirement that their alleged injury be “fairly traceable” to the USPTO’s allegedly improper conduct. The “fairly traceable” requirement “examines the causal connection between the assertedly unlawful conduct and the alleged injury.” *Allen*, 468 U.S. at 753 n.19. The only injuries plaintiffs allege are tied to Myriad’s refusal to license the patents-in-suit broadly and threats to enforce those

patents. *See, e.g.*, Compl. ¶ 2 (“Because of the patents and because Myriad chooses not to license the patents broadly, women who fear they may be at increased risk of breast and/or ovarian cancer are barred from having anyone look at their *BRCA1* and *BRCA2* genes or interpret them except for the patent holder.”) (emphasis added); *see also* Compl. ¶¶ 11-12. Because plaintiffs’ alleged injury would result, if at all, from the actions of Myriad and not the USPTO, plaintiffs cannot meet the traceability requirement for standing.

Plaintiffs also lack standing to assert their claim against the USPTO because they do not meet the redressability prong of the standard. The “redressability” requirement “examines the causal connection between the alleged injury and the judicial relief requested.” *Allen*, 468 U.S. at 753 n.19. In their prayer for relief, plaintiffs seek (1) a declaratory judgment that the patent claims at issue are invalid and/or unenforceable, and (2) to enjoin “defendants from taking any actions to enforce these claims of these patents.” Compl. at 30. Neither request for relief runs against the USPTO, as a third party “may not sue the PTO seeking retraction of a patent issued to another by reason of its improper allowance by the PTO.” *Syntex*, 882 F.2d at 1576. Rather, “[a] remedy must await confrontation with patent owner.” *Id.* Nor does the USPTO take any action after a court holds a patent claim invalid or unenforceable. Finally, the USPTO plays no role in the enforcement of the patents it issues. Thus, the relief plaintiffs seek runs only against Myriad and the patent owners. Because plaintiffs seek no relief from the USPTO to redress the alleged injury – and the USPTO cannot provide such a remedy – plaintiffs lack standing.

Because plaintiffs lack constitutional and prudential standing to challenge the patents’ issuance on any grounds – constitutional or otherwise – their claims against the USPTO

should be dismissed.

B. The Complaint Should Be Dismissed For Lack of Subject Matter Jurisdiction

On a motion to dismiss pursuant to Rule 12(b)(1), plaintiffs bear the burden of establishing, by a preponderance of the evidence, that subject matter jurisdiction exists over their complaint. *See Lunney v. United States*, 319 F.3d 550, 554 (2d Cir. 2003); *Malik v. Meissner*, 82 F.3d 560, 562 (2d Cir. 1996). “[J]urisdiction must be shown affirmatively, and that showing is not made by drawing from the pleadings inferences favorable to the party asserting it.” *APWU v. Potter*, 343 F.3d 619, 623 (2d Cir. 2003) (quoting *Shipping Fin. Servs. Corp. v. Drakos*, 140 F.3d 129, 131 (2d Cir. 1998)).

Plaintiffs point to 28 U.S.C §§ 1331 & 1338 as bases for jurisdiction for their complaint. Compl. ¶ 5.² But neither provides a basis for jurisdiction against the USPTO “because the comprehensive scheme Congress established to govern patent grants reveals Congress’s intent to preclude judicial review of PTO examination decisions at the behest of third parties protesting the issue or reissue of a patent.” *Hitachi Metals, Ltd. v. Quigg*, 776 F. Supp. 3, 7 (D.D.C. 1991) (rejecting jurisdiction under section 1331 and the Administrative Procedure Act); *Hallmark Cards, Inc. v. Lehman*, 959 F. Supp. 539, 543-44 (D.D.C. 1997) (comprehensive scheme precludes jurisdiction under 28 U.S.C. § 1338).

As the Supreme Court explained in *Block v. Cmty. Nutrition Inst.*, 467 U.S. 340,

² Plaintiffs also cite 28 U.S.C. § 2201 as a basis for jurisdiction, but “[i]t is settled law that the Declaratory Judgment Act, 28 U.S.C. § 2201 (1994), does not enlarge the jurisdiction of the federal courts . . . and that a declaratory judgment action must therefore have an independent basis for subject matter jurisdiction.” *Concerned Citizens of Cohocton Valley, Inc. v. New York State Dep’t of Envtl. Conservation*, 127 F.3d 201, 206 (2d Cir. 1997) (citing *Skelly Oil Co. v. Phillips Petroleum Co.*, 339 U.S. 667, 671 (1950)).

349 (1984), “when a statute provides a detailed mechanism for judicial consideration of particular issues at the behest of particular persons, judicial review of those issues at the behest of other persons may be found to be impliedly precluded.” Thus, the question of jurisdiction “requires a focus on the legal rights or interests which devolve from the relevant statute.” *Syntex*, 882 F.2d at 1573. Here, “[t]he Patent Statute is addressed to patent owners and patent applicants. The patent examination process is an *ex parte* proceeding, not an adversarial one, and the Patent Statute’s judicial review provisions contain no gaps requiring the Court to exercise its power.” *Hitachi*, 776 F. Supp. at 8; *Hallmark Cards*, 959 F. Supp. at 543. The court in *Hitachi* went on to enumerate the various remedies available to a patent applicant under the statute, and concluded that “Title 35 contains no provision expressly authorizing administrative or judicial review of a PTO decision at the behest of a third-party protestor.” *Hitachi*, 776 F. Supp. at 8. Thus, the court concluded, “patent grants are not subject to judicial review at the behest of third parties, regardless of whether the challenge is characterized as procedural or substantive.” *Id.* at 10.

This conclusion follows closely the reasoning of the Federal Circuit’s holding in *Syntex*. In that case, a requester of reexamination of another’s patent sought to compel the USPTO to revoke a reexamination certificate and reopen proceedings. The court found that given the existing statutory provisions governing reexamination, “[t]he creation of a right or remedy in a third party to challenge a result favorable to a patent owner after *ex parte* prosecution would be unprecedented, and we conclude that such a right cannot be inferred.” *Syntex*, 882 F.2d at 1574-75; *see also Hallmark Cards*, 959 F. Supp. at 544. The court went on to explain that the patent statute does not contemplate that every injury caused by the USPTO would be remediable in a suit against the agency:

In sum, every perceived injury caused by improper agency action does not carry a right to immediate judicial redress. A right to immediate judicial review must be granted or reasonably inferred from a particular statute. For example, a potential infringer may not sue the PTO seeking retraction of a patent issued to another by reason of its improper allowance by the PTO. A remedy must await confrontation with the patent owner.

Id. at 1576. Accordingly, the complaint against the USPTO should be dismissed for lack of subject matter jurisdiction.

C. Sovereign Immunity Bars the Action Against the USPTO

“The waiver of sovereign immunity is a prerequisite to subject-matter jurisdiction.” *Presidential Gardens Assocs. v. U.S. ex rel. Sec’y of Housing & Urban Dev.*, 175 F.3d 132, 139 (2d Cir. 1999). It is well settled that the “United States, as sovereign, is immune from suit save as it consents to be sued . . . , and the terms of its consent to be sued in any court define that court’s jurisdiction to entertain the suit.” *United States v. Mitchell*, 445 U.S. 535, 538 (1980) (citation omitted). In other words, the Government cannot be sued without its consent, and “the existence of consent is a prerequisite for jurisdiction.” *United States v. Mitchell*, 463 U.S. 206, 212 (1983). *See also Adeleke v. United States*, 355 F.3d 144, 150 (2d Cir. 2004) (“waivers of sovereign immunity must be unequivocally expressed in statutory text”). Sovereign immunity protects not only the United States but also its agencies and officers when they act in their official capacities. *See FDIC v. Meyer*, 510 U.S. 471, 475 (1994).

Although Congress can waive the Government’s sovereign immunity through clear and unequivocal statutory language, waivers of sovereign immunity and their conditions must be strictly applied against the claimant. *See Lane v. Pena*, 518 U.S. 187, 192 (1996); *Millares Guiraldes de Tineo v. United States*, 137 F.3d 715, 719 (2d Cir. 1998). Accordingly, if

the Government has not waived its sovereign immunity, or if the conditions under which the Government has agreed to waive that immunity have not been met, federal subject matter jurisdiction does not exist over the plaintiffs' claims. *See United States v. Sherwood*, 312 U.S. 584, 586 (1941); *Williams v. United States*, 947 F.2d 37, 39 (2d Cir. 1991). Because plaintiffs do not cite a single statute that contains such a waiver, they can not meet their "burden of establishing that [their] claims fall within an applicable waiver." *Makarova v. United States*, 201 F.3d 110, 113 (2d Cir. 2000).

Plaintiffs allege subject matter jurisdiction based on 28 U.S.C. §§ 1331, 1338(a) and 2201, Compl. ¶ 5, but none provides jurisdiction to sue the United States in this case. Section 1331 does not waive sovereign immunity, *Mack v. United States*, 814 F.2d 120, 122 (2d Cir. 1987), and thus is an invalid basis for the claims against the USPTO.³ Section 1338 grants federal courts jurisdiction over claims arising under the patent statutes, but does not waive sovereign immunity. *Turton v. United States*, 212 F.2d 354, 355 (6th Cir. 1954); *Zhengxing v. U.S. Patent & Trademark Office*, 579 F. Supp. 2d 160, 163 (D.D.C. 2008); *Sykes v. Dudas*, 573

³ While the Administrative Procedure Act ("APA") does effect a waiver of sovereign immunity in certain cases, even had the plaintiffs cited it, the APA would not effect such a waiver here. "The APA does not waive sovereign immunity 'where a matter is statutorily committed to agency discretion or where another statute provides a form of relief which is expressly or impliedly exclusive.'" *Dew v. United States*, 192 F.3d 366, 371 (2d Cir. 1999) (quoting *Sprecher v. Graber*, 716 F.2d 968, 974 (2d Cir.1983)). "[W]hen a statute provides a detailed mechanism for judicial consideration of particular issues at the behest of particular persons, judicial review of those issues at the behest of other persons may be found to be impliedly precluded." *Dew*, 192 F.3d at 372 (quoting *Block v. Cmty. Nutrition Inst.*, 467 U.S. at 349). Thus, as set forth above, the comprehensive statutory patent scheme precludes judicial review of claims by third parties, including constitutional claims, challenging the USPTO's issuance of patents.

F. Supp. 2d 191, 200 (D.D.C. 2008). Reliance on the Declaratory Judgment Act, 28 U.S.C. § 2201, is similarly misplaced as it does not constitute a consent by the United States to be sued. *Morpurgo v. Board of Higher Ed. in City of N.Y.*, 423 F. Supp. 704, 714 (S.D.N.Y. 1976) (citing, *inter alia*, *Skelly Oil*).⁴

D. Plaintiffs Fail To State a Claim For a Constitutional Violation

In its recent decision in *Ashcroft v. Iqbal*, 129 S.Ct. 1937 (2009), the Supreme Court elaborated on the pleading standards a plaintiff must meet to survive a motion to dismiss. The Court identified “[t]wo working principles” that should guide a court’s analysis of a complaint’s sufficiency. *Id.* at 1949. “First, the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions.” *Id.* “Second, only a complaint that states a plausible claim for relief survives a motion to dismiss.” *Id.* at 1950. The Court made clear that these requirements apply generally in “all civil actions.” *Id.* at 1953 (citing *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555-556 (2007)).

Here, plaintiffs’ complaint – without any factual support or explanation – asserts that the USPTO’s grant of patent claims related to human genes “violate[s] the First Amendment and Article I, section 8, clause 8 of the United States Constitution.” Compl. ¶ 4. Elsewhere, plaintiffs state that they are suing the USPTO “solely on [their] constitutional claims.” Compl. ¶ 27. But every paragraph in plaintiffs’ complaint concerning the Constitution recites nothing more than unsupported legal conclusions. The following paragraphs are illustrative:

52. The [USPTO’s] policy permits the patenting of products of nature, laws of

⁴ As 42 U.S.C. § 1983 applies only to state actors, not federal officials, plaintiffs cannot rely on this provision as a basis for jurisdiction against the USPTO. *See Yalkut v. Gemignani*, 873 F.2d 31, 35 (2d Cir. 1989).

nature, natural phenomena, abstract ideas, and basic human knowledge and thought. It therefore violates the United States Constitutions Article 1, section 8, clause 8 and the First amendment, as well as 35 U.S.C. § 101 of the patent statute.

54. This practice permits the patenting of laws of nature and abstract ideas and basic human knowledge or thought. It therefore violates Article 1, section 8, clause 8 and the First Amendment of the United States Constitution, as well as 35 U.S.C. § 101.

102. Because human genes are products of nature, laws of nature and/or natural phenomena, and abstract ideas or basic human knowledge or thought, the challenged claims are invalid under Article 1, section 8, clause 8 of the United States Constitution and 35 U.S.C. § 101.

103. All of the challenged claims represent patents on abstract ideas or basic human knowledge and/or thought and as such are unconstitutional under the First and Fourteenth Amendments to the United States Constitution.

“While legal conclusions can provide the framework of a complaint, they must be supported by factual allegations.” *Iqbal*, 129 S.Ct. at 1950. Here, plaintiffs’ allegations are unmoored to any plausible claim of unconstitutionality. Put simply, plaintiffs fail to provide any basis for the conclusion that the USPTO’s issuance of gene patents violates the clause of the Constitution that empowers Congress to “promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries,” U.S. Const. art. 1, § 8, cl. 8. Plaintiffs likewise fail to provide any facts or rationale that might support the conclusion that the USPTO’s issuance of gene patents prohibits plaintiffs’ free exercise of religion, abridges plaintiffs’ freedom of speech or that of the press, or interferes with plaintiffs’ right to assemble or seek redress from the Government, *see* U.S. Const. amend. I. As such, plaintiffs’ naked allegations fail to meet the standards set forth in *Iqbal*. 129 S.Ct. at 1951 (“It is the conclusory nature of respondent’s allegations, rather than their extravagantly fanciful nature, that disentitles them to the presumption of truth.”).

Moreover, plaintiffs' failure to state a claim for which the USPTO could be liable – indeed, the complaint does not seek any relief from the USPTO, *see* Compl. at 30 – demonstrates that the complaint does not “state a claim to relief that is plausible on its face.” 129 S. Ct. at 1949 (quoting *Twombly*, 550 U.S. at 570). Accordingly, plaintiffs' claims against the USPTO should be dismissed for “failure to state a claim upon which relief can be granted” pursuant to Fed. R. Civ. P. 12(b)(6).⁵

CONCLUSION

For the foregoing reasons, the USPTO's motion to dismiss should be granted and the complaint against it dismissed.

Dated: New York, New York
July 13, 2009

LEV L. DASSIN
Acting United States Attorney for the
Southern District of New York
Attorney for U.S. Patent and Trademark Office

By: /s/ Beth E. Goldman
BETH E. GOLDMAN
Assistant United States Attorney
86 Chambers Street -- 3rd Floor
New York, New York 10007
Tel. No.: (212) 637-2732
beth.goldman@usdoj.gov

⁵ Plaintiffs' challenge to the constitutionality of the patents at issue is not, in the absence of an independent basis for jurisdiction or standing against the USPTO, a basis for naming the USPTO as a defendant. Rather, there are well-established procedures for the United States to intervene or otherwise inform courts of its views in connection with a constitutional challenge or any other interest of the United States. *See* 28 U.S.C. § 517; 28 U.S.C. § 2403; Fed. R. Civ. P. 5.1. The decision as to whether the United States will take a position on a constitutional question is made by high level officials within the Department of Justice, *see, e.g.*, 28 C.F.R. § 0.20(c); 28 C.F.R. § 0.21, and cannot be forced by naming a Government agency as a defendant.