

**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

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

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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 reply memorandum and accompanying declaration 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**

Plaintiffs provide this Court with a mountain of declarations, but no case law to support their legal theory of standing, which would allow virtually anyone to challenge any patent at any time. Specifically, plaintiffs’ theory would require this Court to take two steps that are unprecedented and contrary to the basic principles of the Article III case-or-controversy requirement.

First, plaintiffs ask this Court to hold that a patentee can create a case or controversy where the only actions it directed at any of the plaintiffs are letters sent to two plaintiffs, Dr. Kazazian and Dr. Ostrer, more than a decade ago. Courts have consistently rejected the idea that such stale actions can create a controversy now (or, under plaintiffs’ theory, forever). Moreover, there is clearly no ongoing dispute based on these letters: one letter culminated in a lawsuit dismissed in 1999, and the other offered the possibility of collaboration without making any threat of litigation. Plaintiffs try to bolster their claim for standing by relying on Myriad’s actions against others, but courts have accepted such actions as relevant only if there was a recent pattern of extensive litigation against similar potential infringers. Here, there is only one other lawsuit, which occurred in 1998 and was settled at that time.

Second, plaintiffs ask this Court to hold that a person’s desire and ability to infringe a patent is sufficient for standing. However, the Federal Circuit and district courts have uniformly

rejected these kinds of allegations, and plaintiffs fail to cite a single case finding standing based on allegations even remotely similar to the ones at issue here. Indeed, Dr. Kazazian – the only plaintiff who actually received a cease-and-desist letter from Myriad, in 1998, and thus the only plaintiff who has even a plausible argument for satisfying the first part of the standing test – states that he has not yet “decided” whether to undertake potentially infringing activities. And the co-Director of his laboratory, Dr. Ganguly, confirms that she would only “consider” doing so. Such vague expressions of possible interest plainly do not give rise to a case or controversy.

Finally, in the alternative, for reasons explained in Defendants’ opening memorandum of law in support of the motion to dismiss and Defendants’ opposition to plaintiffs’ motion for jurisdictional discovery, this Court should dismiss the Directors for lack of personal jurisdiction.

## **ARGUMENT**

### **I. PLAINTIFFS LACK STANDING TO CHALLENGE THE VALIDITY OF THE DEFENDANTS’ PATENTS**

As explained in Defendants’ opening memorandum, courts after *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007), have uniformly 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. Plaintiffs dispute this test, but they fail to cite a single case finding jurisdiction that did not satisfy these two requirements. Instead, plaintiffs claim that these requirements “may have been true a few years ago,” but are no longer true under *MedImmune*. See Plaintiffs’ Mem. of Law in Opposition to Defendants Myriad and UURF Directors’ Motion to Dismiss (“Pl. Opp. Mem.”) at 2. However, *MedImmune* merely rejected the “reasonable apprehension of suit” test, and did not address either of these requirements. Indeed, post-*MedImmune* cases established the first prong to replace the reasonable apprehension of suit test. See Mem. of Law in Support of Defendants’

Motion to Dismiss (“Def. Opening Mem.”) at 6-8. The second prong, which did pre-date *MedImmune*, was not addressed in that case, and the Federal Circuit has continued to apply the requirement because it is consistent with *MedImmune*. *See id.* at 11-12; *see also Cat Tech LLC v. TubeMaster, Inc.*, 528 F.3d 871, 880 (Fed. Cir. 2008) (“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.”). None of the plaintiffs satisfies either, let alone both, prongs of the test, as required for standing.<sup>1</sup>

**A. Two Cases And Letters To Two Plaintiffs, All Of Which Occurred More Than Ten Years Ago, Do Not Establish Standing For Plaintiffs Now**

The case law, and a basic application of the Article III case-or-controversy requirement, makes clear that there is no standing in a declaratory judgment action challenging a patent unless the defendant has taken an affirmative act relevant to the plaintiff. *See* Def. Opening Mem. at 6-8. Plaintiffs recognize that there must be an affirmative act, but contend that the act can “relat[e] to either the patents in suit *or* plaintiffs.” Pl. Opp. Mem. at 10. However, plaintiffs simply ignore all of the cases Defendants cite holding that the affirmative act must be directed to the plaintiffs or show an intent to litigate against the plaintiffs. *See, e.g., Prasco, LLC v. Medicis Pharmaceutical Corp.*, 537 F.3d 1329, 1340 (Fed. Cir. 2008) (there is no standing where “not only have the defendants not taken a concrete position adverse to [the plaintiff]’s], but they also

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<sup>1</sup> Plaintiffs contend that “[i]f one plaintiff in a DJ action has standing, that is sufficient for all of the co-plaintiffs,” Pl. Opp. Mem. at 15, but there is no support for this bizarre proposition. Even assuming that one plaintiff does have standing, the other plaintiffs would not be part of the case or controversy and would accordingly have to be dismissed. *See, e.g., Allen v. Wright*, 468 U.S. 737, 752 (1984) (“[T]he standing inquiry requires careful judicial examination of a complaint’s allegations to ascertain whether *the particular plaintiff* is entitled to an adjudication of the particular claims asserted.”) (emphasis added); *Bronson v. Swensen*, 500 F.3d 1099, 1106 (10th Cir. 2007) (“Each plaintiff must have standing to seek each form of relief in each claim.”). The case plaintiffs cite, *Horne v. Flores*, 129 S. Ct. 2579 (2009), is not to the contrary. In *Horne*, the Supreme Court simply stated that it need not decide the standing of other plaintiffs because it could decide the substantive issue in the case so long as one plaintiff had standing. *See id.* at 2592 (“Because the superintendent clearly has standing to challenge the lower courts’ decisions, we need not consider whether the Legislators also have standing to do so.”). But that does not eliminate this Court’s duty – one that the Supreme Court would have no reason to exercise on appeal, and that would ordinarily be handled on remand – to dismiss those plaintiffs that lack standing.

have taken no affirmative actions at all related to [the plaintiff's] current product");<sup>2</sup> *Indigodental GMBH & Co. KG v. Ivoclar Vivadent, Inc.*, No. 08 Civ. 7657 (RJS), 2008 WL 5262694, at \*2 (S.D.N.Y. Dec. 10, 2008) (dismissing case where the "Plaintiff has not alleged that Defendant asserted any rights under the '784 Patent *against it*") (emphasis added).

Furthermore, the cases plaintiffs cite, *see* Pl. Opp. Mem. at 10, do not remotely support their theory. In *Adenta GmbH v. OrthoArm, Inc.*, 501 F.3d 1364 (Fed. Cir. 2007), the patent holder sent a letter *to the plaintiff* threatening action in a dispute over royalties. *Id.* at 1366-67. Similarly, in *Sony Electronics, Inc. v. Guardian Media Technologies, Ltd.*, 497 F.3d 1271 (Fed. Cir. 2007), the patent holder "communicated *to [the plaintiff]* Sony its position that certain identified Sony products infringed the . . . patents." *Id.* at 1285 (emphasis added). Finally, in *Micron Technology, Inc. v. Mosaid Technologies, Inc.*, 518 F.3d 897 (Fed. Cir. 2008), the plaintiff had "*receiv[ed] several threats itself*" in addition to the defendant's suing "each of the other leading . . . manufacturers" of the allegedly infringing product. *Id.* at 901 (emphasis added). In short, plaintiffs fail to identify any case in which standing was upheld despite the lack of an affirmative act relevant to the potential infringer.

Here, the affirmative acts plaintiffs rely upon plainly fail to show a "*real and immediate injury or threat of future injury that is caused by the defendants.*" *Prasco*, 537 F.3d at 1339.

*First*, plaintiffs focus on an eleven-year-old letter from Myriad to Dr. Kazazian. *See* Pl. Opp. Mem. at 10-12; Declaration of Arupa Ganguly, PhD, Ex. 3 (Docket No. 46). However, a letter this old has *never* been held to support standing, and has been repeatedly rejected as a basis for standing. *See* Def. Opening Mem. at 9-10. Plaintiffs claim that the staleness cases were effectively overruled by *MedImmune*, but *MedImmune* did not address this issue at all, and its

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<sup>2</sup> At a different point in their brief, plaintiffs attempt to distinguish *Prasco* because the case concerned non-infringement, *see* Pl. Opp. Mem. at 9, but they fail to explain why this matters for purposes of standing.



reasoning supports the idea the controversy must be “of sufficient *immediacy* and reality to warrant the issuance of a declaratory judgment.” 549 U.S. at 127 (emphasis added, internal quotation marks omitted). Moreover, at least two district courts since *MedImmune* have recognized that a stale action does not suffice for standing. *See Avante Int’l Tech., Inc. v. Hart Intercivic, Inc.*, No. 08-832-GPM, 2009 WL 2431993, at \*3 (S.D. Ill. July 31, 2009);<sup>3</sup> *Edmunds Holding Co. v. Autobytel Inc.*, 598 F. Supp. 2d 606, 610-11 (D. Del. 2009). No court has held to the contrary. Plaintiffs rely on *Micron Technology*, but, as discussed above, that case – which involved a four-year gap, not the eleven-year gap at issue here – held the time lapse insufficient only because the defendant engaged in litigation with several other alleged infringers in the interim. *See* 518 F.3d at 901; Def. Opening Br. at 10 n.7. Here, in obvious contrast to *Micron Technology*, the only litigation plaintiffs point to is itself more than a decade old, leaving ten full years without any relevant litigation by Defendants.

In any event, the letter is immaterial because it gave rise to a lawsuit that was, according to plaintiffs, dismissed pursuant to an agreement with the University of Pennsylvania. *See* Pl. Opp. Mem. at 11. Thus, plaintiffs have no support for their argument that “Myriad’s patent assertion forced Drs. Kazazian and Ganguly to completely cease their *BRCA* related activities and to never restart such activities.” *Id.* at 12. Drs. Kazazian and Ganguly cannot restart *BRCA* activities because the owner of their laboratory, the University of Pennsylvania, has agreed not to do so – and plaintiffs do not challenge that agreement here.<sup>4</sup> This fact may be why Dr. Kazazian

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<sup>3</sup> *Avante* involved a situation very similar to the one alleged here: The defendants brought infringement claims, but “within a few weeks [they] stipulated to the dismissal of those infringement claims, and [the defendant] has not raised them again in the intervening period of more than two years.” 2009 WL 2431993, at \*3. The litigation therefore did not give rise to standing. *Id.* Here, there was a dismissal for failure to serve process followed by more than ten years of inactivity. *See* Def. Opening Br. at 4-5.

<sup>4</sup> As for Dr. Ganguly, plaintiffs ignore Defendants’ argument that there was no letter addressed to her, and she therefore must be treated like the other plaintiffs who did not receive a cease-and-desist letter. *See* Def. Opening Br. at 4 n.2.

and Dr. Ganguly, unlike the other plaintiffs, do not actually claim that they would infringe the patents if the patents were invalidated, and instead claim only that they would “consider” infringing. *See infra* at p.8.

*Second*, plaintiffs point to one other, even earlier, instance of litigation, between Myriad and a company called Oncormed. *See* Pl. Opp. Mem. at 12. However, plaintiffs have no support for the idea that one lawsuit with a non-party, concluded more than ten years ago, can establish standing. Plaintiffs cite only *Prasco*, but there the Federal Circuit reasoned that a single lawsuit against a non-party does not support standing. 537 F.3d at 1341 n.10 (“[T]he prior suit has no relevance to whether there is a case or controversy with Imaginative Research Associates, as Imaginative Research Associates was not a party to the prior suit.”). Moreover, the Oncormed lawsuit actually involved claims of infringement by both sides, and the case was settled before it was decided by the court. *See* Christopher M. Holman, *The Impact of Human Gene Patents on Innovation and Access: A Survey of Human Gene Patent Litigation*, 76:2 UMKC L. REV. 295, 347 (2007). Simply put, the idea that two cases from the 1990s – one dismissed pursuant to an agreement of the parties and the other settled – can show that plaintiffs now are threatened by “systematic litigation,” Pl. Opp. Mem. at 12, is meritless.

*Third*, plaintiffs rely on two other letters sent by Myriad, but neither supports plaintiffs’ argument for standing. *See id.* at 13; Ganguly Decl. Ex. 7; Declaration of Harry Ostrer, M.D. (Docket No. 47) Ex. 2. To begin with, one of these letters went to a non-party, *see* Ganguly Decl. Ex. 7, and plaintiffs fail to identify any precedent for the idea that letters to others can suffice for standing. *See* Def. Opening Mem. at 9.<sup>5</sup> Moreover, neither letter suggests, let alone

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<sup>5</sup> Similarly, plaintiffs mention a phone conversation between a Myriad representative and plaintiff Ellen Matloff in 2005, but that conversation concerned the potential activity of the Yale DNA Diagnostics Lab, not the activity of Ms. Matloff (nor the Genetic Counseling Center of which she is the Director). *See* Declaration of Ellen T. Matloff ¶ 8 (Docket No. 49). Ms. Matloff does not allege that she would infringe the patents, only that she would

threatens, litigation; rather, they offer the possibility of collaboration or licensing. *See* Ganguly Decl. Ex. 7; Ostrer Decl. Ex. 2. In addition, because these letters were sent in 1998, they cannot support jurisdiction now.

*Finally*, plaintiffs claim that Defendants’ refusal to assure plaintiffs that they would not sue for infringement gives rise to standing. *See* Pl. Opp. Mem. at 14-15.<sup>6</sup> *Prasco*, where the patentee similarly refused to give such assurances, held that this “is one circumstance to consider in evaluating the totality of the circumstances,” but made clear that “it is not sufficient to create an actual controversy—some affirmative actions by the defendant will also generally be necessary.” 537 F.3d at 1341; *see also, e.g., Avante*, 2009 WL 2431993, at \*4 (rejecting lack of assurance from patent holder as basis for standing). And Defendants’ refusal to give assurances here is particularly inapposite because plaintiffs’ letter came *after* the suit and a motion to dismiss was filed, in an attempt to cure standing deficiencies. *See Benitec Australia, Ltd. v. Nucleonics, Inc.*, 495 F.3d 1340, 1344 (Fed. Cir. 2007) (“The burden is on the party claiming declaratory judgment jurisdiction to establish that such jurisdiction existed at the time the claim for declaratory relief was filed and that it has continued since.”).

**B. Plaintiffs’ Professed Desire To Infringe Or Consideration Of Infringing Fails To Establish Concrete Plans For Potentially Infringing Action**

Plaintiffs also fail to meet the second prong of the test for jurisdiction: the existence of concrete plans for potentially infringing action. *See* Def. Opening Mem. at 11-13. Plaintiffs

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(continued...)

use the services of others if they did so. *See* Compl. ¶ 17; Matloff Decl. ¶ 4. Thus, the alleged threat (which is stale in any event based on the four-year gap since it occurred) was not directed at plaintiffs and cannot support standing.

<sup>6</sup> Plaintiffs purport to attach Defendants’ letter responding to their request for assurance as Exhibit 2 to the Declaration of Daniel B. Ravicher (Docket No. 36). However, plaintiffs appear to have inadvertently attached the wrong letter; the actual letter is attached as Exhibit 1 to the Declaration of Barry R. Satine filed along with this reply memorandum.

concede that there is a requirement of “meaningful preparation,” *see* Pl. Opp. Mem. at 5, but they fail to allege any real preparation in terms of time, money, or any other concrete action.

To begin with, the lack of standing is apparent as to Drs. Kazazian and Ganguly, who do not even allege an intent to infringe. Dr. Kazazian, unlike every other plaintiff, does not even allege that he currently has an interest in infringing the patents, candidly admitting that he has not yet decided if he would undertake “BRCA testing again” if the *BRCA* patents no longer had any legal effect. *See* Declaration of Haig H. Kazazian, Jr., M.D. ¶ 11 (Docket No. 45); Compl. ¶ 11. Similarly, the Complaint alleges that Dr. Ganguly would only “consider” infringing the patents. Compl. ¶ 12; Ganguly Decl. ¶ 14. Plaintiffs admit that unlike the other plaintiffs, Drs. Kazazian and Ganguly would only “consider resuming” their potentially infringing activity, Pl. Opp. Mem. at 6, but they fail to explain how such “considering” can create a case or controversy. Indeed, “[a] party may not obtain a declaratory judgment” based on “merely contemplated activity,” which is exactly what Drs. Kazazian and Ganguly allege here. *Cat Tech*, 528 F.3d at 881 (internal quotation marks omitted).

The rest of the plaintiff researchers allege that they are “readily, willing, and able” to infringe, but they fare no better. Plaintiffs’ attempt to equate desire and ability to infringe with “meaningful preparation” is specious, and courts have uniformly required more – i.e., “significant, concrete steps,” *id.* at 880 – to establish standing. Indeed, plaintiffs fail to cite any case accepting the type of allegations offered here as sufficient, and fail to address nearly all of the cases rejecting jurisdiction based on such allegations. *See* Def. Opening Br. at 11-12. For the one case plaintiffs do address, *Benitec Australia Ltd. v. Nucleonics, Inc.*, 495 F.3d 1340 (Fed. Cir. 2007), they ignore the relevant part of the opinion. Plaintiffs attempt to distinguish *Benitec* because there it would take six to eight years to infringe, *see* Pl. Opp. Mem. at 9, but that was

true of only one product being considered. *See* 495 F.3d at 1346. For the other product, there was no such delay, just the same desire and lack of “concrete steps” at issue here:

Nucleonics merely ‘expects’ to begin work ‘shortly.’ We do not doubt the veracity of Nucleonics’s president’s statements—indeed, there is no evidence to the contrary. However, 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.* at 1349. Plaintiffs cite declarations attesting to the researchers’ professed desire and ability to infringe, *see* Pl. Opp. Mem. at 6-7, but conspicuously absent from every declaration is an allegation that the researchers have taken any action to prepare for infringing. The declarations also fail to specify which patent claim or claims are at issue, which is fatal, *see* Def. Opening Br. at 12, and plaintiffs simply ignore this deficiency.

As for the non-researcher plaintiffs who are “ready, willing, and able” to use the research of others who would supposedly infringe the patents, the argument for standing is even weaker. As an initial matter, plaintiffs cannot be “meaningfully prepared” to use the services of others, *see* Pl. Opp. Mem. at 9, if those services do not exist. And for the reasons discussed above, plaintiffs have failed to identify any “others” who have taken concrete steps that could allow this Court to assume that they would actually infringe. Thus, plaintiffs’ attempt at bootstrapping one plaintiff on top of another improper plaintiff should be rejected. Furthermore, plaintiffs ignore the clear precedent, cited by Defendants, *see* Def. Opening Br. at 13, holding that third parties arguably affected by a patent lack standing to challenge the patent’s validity.

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

In the alternative, this Court should dismiss the Directors of the University of Utah Research Foundation (“UURF”) for lack of personal jurisdiction. *See* Def. Opening Mem. at 13-15. Plaintiffs argue that personal jurisdiction is established, or that they should be entitled to

discovery on the issue, based on the contacts of the University of Utah and the UURF. *See* Pl. Opp. Mem. at 15-25. In their opposition to plaintiffs' motion for jurisdictional discovery, Defendants explained why the contacts of the University of Utah and the UURF are irrelevant, and in any event are insufficient for general or specific jurisdiction. *See* Defendants' Memorandum of Law in Opposition to Plaintiffs' Motion to Conduct Jurisdictional Discovery at 4-14.

The only point that Defendants have not previously addressed – because it does not relate to the jurisdictional discovery motion – is plaintiffs' argument there is specific jurisdiction under the New York long-arm statute because Defendants have caused injury to plaintiffs in New York. *See* Pl. Opp. Mem. at 21. However, the New York statute at issue concerns only tort claims, *see* N.Y. C.P.L.R. § 302(a)(3), and there is no such claim here. Plaintiffs suggest that their constitutional claims should be considered tortious, but the case they cite deals with a constitutional claim predicated on tortious, discriminatory conduct. *See Rios v. Marshall*, 530 F. Supp. 351, 363 (S.D.N.Y. 1981). Plaintiffs fail to cite any authority suggesting that the holding of an allegedly invalid patent is a tort. Moreover, regardless of the New York statute, plaintiffs do not dispute that constitutional claims must meet the same Article III requirements as do other claims, *see* Def. Opening Mem. at 6 n.5, and those requirements are not satisfied here.

### **CONCLUSION**

For the reasons set forth above, in Defendants' opening memorandum of law, and in Defendants' opposition to plaintiffs' motion for jurisdictional discovery, Defendants Myriad and the Directors respectfully request that the Complaint be dismissed in its entirety, or, in the alternative, that the Directors be dismissed for lack of personal jurisdiction.

Dated: New York, New York  
September 23, 2009

JONES DAY

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**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: September 23, 2009

s/ Barry R. Satine  
Barry R. Satine