No. 2010-1406

United States Court of Appeals for the Federal Circuit

THE ASSOCIATION FOR MOLECULAR PATHOLOGY, THE AMERICAN COLLEGE OF MEDICAL GENETICS, THE AMERICAN SOCIETY FOR CLINICAL PATHOLOGY, THE 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, and KATHLEEN RAKER,

Plaintiffs-Appellees,

v.

UNITED STATES PATENT AND TRADEMARK OFFICE,

Defendant,

and

MYRIAD GENETICS, INC.,

Defendant-Appellant,

(caption continued on inside cover)

RECEIVED
2012 MAY 30 PM 1:41
U.S. COURT OF APPEALS FEDERAL CIRCUIT

Appeal From The United States District Court
For The Southern District of New York
In Case No. 09-CV-4515, Senior Judge Robert W. Sweet

APPELLANTS' SUGGESTION OF MOOTNESS, OR, IN THE ALTERNATIVE, MOTION TO REMAND

BRIAN M. POISSANT
LAURA A. CORUZZI
EILEEN FALVEY
JONES DAY
222 East 41st Street
New York, NY 10017
(212) 326-3939

ISRAEL SASHA MAYERGOYZ
DENNIS MURASHKO
JONES DAY
77 West Wacker Drive
Chicago, IL 60601
(312) 782-3939

GREGORY A. CASTANIAS
JENNIFER L. SWIZE
JONES DAY
51 Louisiana Avenue, N.W.
Washington, D.C. 20001
(202) 879-3939

(additional counsel listed on inside cover)

Attorneys for Defendants-Appellants 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

and

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, in their official capacity as Directors of the University of Utah Research Foundation,

Defendants-Appellants.

Of counsel for Defendant-Appellant Myriad Genetics, Inc.:

BENJAMIN G. JACKSON
MYRIAD GENETICS, INC.
320 Wakara Way
Salt Lake City, UT 84108
(801) 883-3328

INTRODUCTION

This declaratory-judgment action has returned to this Court for further proceedings in light of a recent Supreme Court decision regarding 35 U.S.C. § 101. The case should be dismissed now, because subject-matter jurisdiction no longer exists. The case that now stands before the Court presents only abstract, philosophical questions of no immediate relevance to the parties, and which are beyond the constitutional powers of a federal court to decide.

In the initial appellate proceedings, this Court sustained declaratory-judgment jurisdiction as to only one of the twenty plaintiffs—Dr. Harry Ostrer, who was then at New York University ("NYU"). That jurisdictional holding hinged entirely upon the controversy supposedly created when the patentee, Myriad Genetics, Inc., offered NYU a collaborative license in 1998, and the further finding that "the relevant circumstances remain unchanged" since Myriad proposed that license. After this Court's decision, the circumstances upon which Dr. Ostrer's standing depended changed materially: Dr. Ostrer ended his employment at NYU and now works at unrelated institutions. Myriad has never had any communications with those institutions regarding the challenged patents; indeed, unlike the situation with NYU in 1998, Myriad has no knowledge whatsoever of what, if any, activities those institutions have engaged in or engage

in presently. Accordingly, Dr. Ostrer's change in employment mooted any real or immediate dispute that might otherwise have been before this Court.

Appellants (collectively, "Myriad") raise this threshold jurisdictional issue now to preserve the resources of the Court and the parties. The Court has scheduled briefing and argument on the merits, but those proceedings should be unnecessary given Dr. Ostrer's unilateral conduct, which terminated the presence of any case or controversy that could exist. The appeal should therefore be dismissed, and the district court's declaratory judgment of invalidity in favor of plaintiffs should be vacated. At the very least, the case should be remanded for the district court to address in the first instance whether declaratory-judgment jurisdiction exists under the new set of facts.

BACKGROUND

The patents at issue are assigned to Myriad and relate to two genes known as BRCA1 and BRCA2, whose alterations and mutations correlate with an increased risk of breast and ovarian cancers. The patent claims selected for challenge by plaintiffs are drawn to isolated BRCA DNA molecules and methods of using them to diagnose a patient's cancer risk. The isolation of a BRCA gene enables its exact sequence to be characterized for purposes of determining whether a disease-creating mutation is present, and further enables diagnostic services to be provided.

Acting on behalf of twenty individuals and organizations recruited as plaintiffs, two public-interest law firms filed this declaratory-judgment action on May 12, 2009, seeking to invalidate a select number of Myriad's claims. Plaintiffs sought a declaration that certain composition and method claims are ineligible for patent protection under 35 U.S.C. § 101. (Joint Appendix ("A") 4.)

Myriad moved to dismiss for lack of declaratory-judgment jurisdiction as to all plaintiffs. In response, various plaintiffs, including Dr. Ostrer, submitted declarations. At the time the suit was filed, Dr. Ostrer was the Director of the Molecular Genetics Laboratory at the NYU Medical Center. (A2932 ¶ 1.) In his declaration, Dr. Ostrer claimed that he was threatened by Myriad and deterred from conducting testing at his NYU laboratory because of a license agreement that Myriad offered to NYU in May 1998 in exchange for royalty payments. (A2936 ¶ 7; A2964-74.) Dr. Ostrer stated that his NYU laboratory otherwise "has all of the personnel, expertise, and facilities necessary to do various types of sequencing of the BRCA1 and BRCA2 genes," and that the laboratory "could, and would . . . do full sequencing." (A2936 ¶ 9.) NYU did not accept the offer and, according to Dr. Ostrer, did not provide BRCA testing services for fear that Myriad would assert its patent rights. (A2935 ¶ 7; A2934 ¶ 4.)

The district court denied Myriad's motion to dismiss, concluding that all twenty plaintiffs had standing to assert their declaratory-judgment claims. In

finding jurisdiction, the court did not require Myriad to have taken action toward each (or any) specific plaintiff. Rather, the court stated that declaratory-judgment jurisdiction required only "some affirmative act by [Myriad] relating to enforcement of its patent rights," regardless to whom such enforcement was directed. *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 669 F. Supp. 2d 365, 387-88 (S.D.N.Y. 2009).

The case proceeded to the merits. On cross-motions for summary judgment, the court held that all of the challenged patent claims were not patent-eligible. *See Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 702 F. Supp. 2d 181 (S.D.N.Y. 2010).

Myriad appealed. On July 29, 2011, the three-judge panel, while dividing in part on the merits, unanimously held that only "one Plaintiff, Dr. Ostrer, has established standing." *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 653 F.3d 1329, 1344 (Fed. Cir. 2011). The Court observed that, by virtue of his position at NYU, Dr. Ostrer "indicates that his lab has all the personnel, facilities, and expertise necessary to undertake clinical BRCA testing," and that Dr. Ostrer "seeks to undertake specific BRCA related activities—BRCA diagnostic testing—for which Myriad has demanded a license" under the asserted patents. *Id.* at 1341, 1345. The Court then held, separate from Dr. Ostrer's readiness to conduct testing, that this decade-old license offer to NYU established a case or

controversy requiring immediate resolution, even at the time of the suit, because "the relevant circumstances surrounding Myriad's assertion of its patent rights have not changed." *Id.* at 1346. "Myriad and Ostrer have not altered their respective positions"—Dr. Ostrer "remains in the same position with respect to his ability and his desire to provide BRCA testing" as when Myriad asserted its rights in the late 1990s. *Id.*

Shortly after this Court issued its opinion, Dr. Ostrer voluntarily terminated his employment at NYU. (Plaintiffs' Answer to Defendants' Pet. for Reh'g ("Plaintiffs' Rehearing Answer") at 2 (Docket Entry ("D.E.") 264).) Since August 29, 2011, Dr. Ostrer has instead been working at the Albert Einstein College of Medicine and Montefiore Medical Center (collectively, "Montefiore"). (*Id.*)

Both sides filed petitions for panel rehearing, with Myriad's petition addressing Dr. Ostrer's destruction of jurisdiction by his separation from NYU. In response to Myriad's petition, plaintiffs submitted a supplemental declaration from Dr. Ostrer in which he confirmed his departure from NYU, effective August 29, 2011. (Supp. Decl. of Harry Ostrer, M.D., *attached to* Plaintiffs' Rehearing Answer ("Supp. Decl.").) The Court denied both petitions without comment. (D.E. 267, 268.)

Thereafter, plaintiffs filed a petition for a writ of certiorari with the Supreme Court, seeking review of two rulings: first, this Court's conclusion that 19 of the

20 plaintiffs lacked standing, and, second, this Court's judgment that the composition claims were patent-eligible. (The panel had held that one of Myriad's method claims was patent-eligible, but plaintiffs did not seek Supreme Court review of that ruling.)

By summary disposition, the Supreme Court granted plaintiffs' petition, vacated this Court's judgment, and remanded for further consideration in light of its recent decision in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289 (2012). *See Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, No. 11-725 (S. Ct. Mar. 26, 2012). On April 30, 2012, this Court vacated its July 29, 2011 opinion and scheduled briefing and argument on issues related to the applicability of *Mayo v. Prometheus*. (D.E. 275.)

LEGAL STANDARDS

The Declaratory Judgment Act provides that "[i]n a case of actual controversy within its jurisdiction . . . any court of the United States . . . may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought." 28 U.S.C. § 2201(a). The Act's requirement of "a case of actual controversy" is coextensive with Article III of the Constitution, which limits federal courts to the adjudication of "Cases" or "Controversies." U.S. Const. art. III, § 2; *Aetna Life Ins. Co. v.*

Haworth, 300 U.S. 227, 239-40 (1937) (the phrase "cases of actual controversy" refers to "controversies" that satisfy Article III).

In *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007), the Supreme Court reaffirmed the "actual controversy" requirement for subject-matter jurisdiction in a declaratory-judgment action in the context of a patent case. As *MedImmune* explained, to establish jurisdiction, the factual allegations must "show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *Id.* at 127 (quoting *Md. Cas. Co. v. P. Coal & Oil Co.*, 312 U.S. 270, 273 (1941)).[1]

Applying *MedImmune*, this Court has held that a "case or controversy" arises under the Declaratory Judgment Act "where a patentee asserts rights under a patent based on certain identified ongoing or planned activity of another party [*i.e.*, the declaratory-judgment plaintiff], and where that party contends that it has the right to engage in the accused activity without license." *SanDisk Corp. v. STMicroelecs., Inc.*, 480 F.3d 1372, 1381 (Fed. Cir. 2007); *see also 3M Co. v.*

---

[1] On May 21, 2012, the Supreme Court granted the Solicitor General's petition for certiorari to review a case where an assortment of organizational and recruited plaintiffs represented by the ACLU (not unlike here) were found to have Article III standing, even though they asserted only self-imposed injury and not any action directed at them by the defendant. *See Amnesty Int'l USA v. Clapper*, 638 F.3d 118 (2d Cir. 2011), *cert. granted*, *Clapper v. Amnesty Int'l USA*, 566 U.S. __ (May 21, 2012) (No. 11-1025).

Avery Dennison Corp., 673 F.3d 1372, 1377 (Fed. Cir. 2012) ("Following *MedImmune*, [this Court has] held that to establish an injury in fact traceable to the patentee a declaratory judgment plaintiff must allege an affirmative act by the patentee relating to the enforcement of his patent rights."); *Prasco, LLC v. Medicis Pharm. Corp.*, 537 F.3d 1329, 1338 (Fed. Cir. 2008) (the "'immediacy and reality' inquiry can be viewed through the lens of standing," which asks whether there is "(1) an injury-in-fact, *i.e.*, a harm that is 'concrete' and actual or imminent, not 'conjectural' or 'hypothetical,' (2) that is 'fairly traceable' to the defendant's conduct, and (3) redressable by a favorable decision"). In its now-vacated opinion in this case, this Court followed these principles, reiterating that affirmative acts giving rise to declaratory-judgment jurisdiction must be "directed at specific Plaintiffs." *Ass'n for Molecular Pathology*, 653 F.3d at 1348 (citing *SanDisk*, 480 F.3d at 1380-81, and *Prasco*, 537 F.3d at 1338-39).

These principles apply at every stage of a case. For a court to have jurisdiction, "it is not enough that a dispute was very much alive when suit was filed, or when review was obtained in the Court of Appeals." *Lewis v. Cont'l Bank Corp.*, 494 U.S. 472, 477-78 (1990). Rather, a case or controversy must exist "through all stages of federal judicial proceedings, trial and appellate." *Id.* The declaratory-judgment plaintiff bears the burden of establishing that jurisdiction exists throughout the proceedings. *Dow Jones & Co. v. Ablaise Ltd.*, 606 F.3d

1338, 1345 (Fed. Cir. 2010) (the "plaintiff bears the burden of proving the existence of [] a controversy throughout the litigation"); *see also 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.").

If a sufficiently real and immediate controversy does not remain throughout the pendency of the appeal, the appeal should be "dismissed as moot." *Nasatka v. Delta Sci. Corp.*, 58 F.3d 1578, 1580 (Fed. Cir. 1995). Moreover, where an appeal is mooted by the unilateral act of the party that prevailed before the district court, the underlying decision on review should be vacated. *See U.S. Bancorp Mortgage Co. v. Bonner Mall P'ship*, 513 U.S. 18, 23 (1994) ("[V]acatur must be granted where mootness results from the unilateral action of the party who prevailed in the lower court."); *Tafas v. Kappos*, 586 F.3d 1369, 1371 (Fed. Cir. 2009) (en banc) (same).

ARGUMENT

I. THE APPEAL IS MOOT BECAUSE MYRIAD HAS NO REAL AND IMMEDIATE DISPUTE WITH DR. OSTRER, OR WITH MONTEFIORE

Subject-matter jurisdiction no longer exists here because of Dr. Ostrer's change in employment. As a result, the appeal should be dismissed as moot.

Moreover, Dr. Ostrer's unilateral act in destroying jurisdiction requires vacatur of the district court's decision. Plaintiffs bear the burden of establishing that subject-matter jurisdiction continues throughout the case; with Dr. Ostrer's change in employment, a real, live case or controversy no longer exists.

A. The Purported Controversy Between Myriad And NYU No Longer Establishes The Standing Of Dr. Ostrer

There is no "substantial controversy, between . . . parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment," because Dr. Ostrer no longer works for NYU, the addressee and offeree of Myriad's 1998 licensing communications. In its now-vacated opinion, this Court found a real and immediate controversy between Dr. Ostrer and Myriad, for purposes of declaratory-judgment jurisdiction, based solely on Dr. Ostrer's position at NYU.

In upholding Dr. Ostrer's standing, the Court made clear that the controversy with Myriad was not personal to Dr. Ostrer, but instead derived from his position at NYU, and the facilities and past practices there. Indeed, Myriad's 1998 letter was addressed to Dr. Ostrer not in his personal capacity, but rather in his professional capacity as Director of NYU's Molecular Genetics Laboratory. (A2964; *see also* Declaration of Richard Marsh ("Marsh Decl.") ¶ 2, attached hereto.) To that end, Myriad offered a license not to Dr. Ostrer personally, but to NYU as one of the "[u]niversities, laboratories and cancer centers" with whom

Myriad contemplated a licensing arrangement. (A2964.) "Myriad, as holder of [the] U.S. patents . . . was making available *to his [Dr. Ostrer's] institution, NYU Medical Center*, a limited collaborative license" that "required *NYU* to make a payment to Myriad for each non-research BRCA test performed." *Ass'n for Molecular Pathology*, 653 F.3d at 1345 (emphasis added). It was that controversy between Myriad and NYU, informed by NYU's pre-1998 practices, Myriad's knowledge of those practices, Myriad's offer of a license in 1998, and the decisions taken by NYU in response, that formed the basis for Dr. Ostrer's standing as previously sustained by this Court. *Id.* at 1345-48. The Court reasoned that this was a sufficiently real and immediate controversy because "the relevant circumstances remain[ed] unchanged" since Myriad had directed those actions to NYU in 1998. *Id.* at 1346.

Now, "the relevant circumstances" *have* changed. Dr. Ostrer no longer works at NYU—he resigned effective August 29, 2011, and now works at Montefiore. (Supp. Decl. ¶ 3.) Dr. Ostrer thus voluntarily severed his connection with NYU, and by doing so he changed all of the relevant facts and circumstances that led this Court to conclude that he alone had a justiciable controversy with Myriad. Importantly, Dr. Ostrer now works at a university and laboratory with which Myriad has never had or expressed any dispute; indeed, Myriad has no knowledge of any past or present activities at Montefiore that could possibly give

rise to a patent controversy. Dr. Ostrer thus eliminated the existence of an immediately justiciable case or controversy by departing from NYU.[2]

Further, no other plaintiff can stand in Dr. Ostrer's shoes to resurrect declaratory-judgment jurisdiction. For reasons already explained in this Court's now-vacated opinion, the 19 other plaintiffs lack standing. Seventeen plaintiffs never had any communications with Myriad, and the other two (Drs. Kazazian and Ganguly) alleged no intent "to actually and immediately engage in allegedly infringing BRCA-related activities" to establish a sufficiently real and immediate

---

[2] Although Myriad has raised the jurisdictional effect of Dr. Ostrer's change in employment in prior proceedings in this appeal, the issue has not yet been addressed. For instance, although Myriad initially informed this Court of Dr. Ostrer's change in employment on July 27, 2011, two days before the Court issued its opinion holding that Dr. Ostrer had standing, the Court's opinion did not address the issue. As Myriad's letter noted, Dr. Ostrer had not yet departed NYU and he was not expected to do so for another month. (D.E. 261 at 1 (noting Dr. Ostrer's expected departure at the end of August 2011).) The Court's opinion issued in the meantime. Accordingly, that opinion analyzed jurisdiction based on Dr. Ostrer's still-extant affiliation with NYU, explicitly referring to that affiliation to sustain standing.

Myriad then raised Dr. Ostrer's change in employment in its rehearing petition to this Court (and in opposing plaintiffs' petition to the Supreme Court), but those proceedings likewise did not resolve the jurisdictional issue. Neither this Court's denial of Myriad's rehearing petition, nor the Supreme Court's order granting plaintiffs' petition, vacating the judgment, and remanding, decided any of the issues raised in those proceedings. *See Exxon Chem. Patents, Inc. v. Lubrizol Corp.*, 137 F.3d 1475, 1479-80 (Fed. Cir. 1998) (denial of rehearing petition is not a decision on the merits); *Henry v. City of Rock Hill*, 376 U.S. 776, 777 (1964) (per curiam) (Supreme Court order granting petition, vacating the judgment, and remanding is not a "final determination on the merits"). The jurisdictional issue is therefore ripe for this Court's determination.

controversy. *Ass'n for Molecular Pathology*, 653 F.3d at 1340, 1345. Under the well-settled "case or controversy" requirement, the Court's conclusions as to those plaintiffs were correct. Now, with his departure from NYU, and his new affiliation with an institution and a laboratory having no relevant connection or communications with Myriad, Dr. Ostrer, too, lacks standing. The appeal should be dismissed as moot.[3]

B. Dr. Ostrer's New Employment Does Not Reestablish Jurisdiction Because There Is No Controversy Between Myriad And Montefiore

Any standing Dr. Ostrer may have had when he was recruited for this lawsuit was inextricably dependent upon his position at NYU, the true intended recipient of Myriad's license offer. Plaintiffs have offered no evidence that the license was offered to Dr. Ostrer individually. An offer of an individual license would have made no sense. Dr. Ostrer did not own the clinical diagnostic laboratory; NYU did. Dr. Ostrer did not employ the individuals who operate the clinical diagnostic laboratory; NYU did. Dr. Ostrer did not hold the required licenses or permits to conduct clinical diagnostic testing; NYU did. Thus,

---

[3] In the absence of subject-matter jurisdiction due to Dr. Ostrer's lack of standing, this Court would have no authority to reconsider its merits rulings in light of *Mayo v. Prometheus*. "[E]very federal appellate court has a special obligation to" ensure that it has jurisdiction before proceeding to the merits of the case. *Bender v. Williamsport Area Sch. Dist.*, 475 U.S. 534, 541 (1986); *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1369 (Fed. Cir. 2004) ("Subject matter jurisdiction is an inquiry that this court must raise sua sponte, even where . . . neither party has raised this issue.").

Dr. Ostrer's continuing claim to standing must be analyzed in the context of the institution at which he is now employed, and the laboratories and facilities at his disposal. It was the 1998 licensing communication between Myriad and NYU that created whatever standing Dr. Ostrer had. Thus, regardless of any subjective fear Dr. Ostrer may profess of being personally sued, his standing to maintain this suit depends on whether there is any kind of objective controversy between Myriad and Dr. Ostrer at his present institution. "It is the *reality* of the threat of . . . injury that is relevant to the standing inquiry, not the plaintiff's subjective apprehensions." *City of Los Angeles v. Lyons*, 461 U.S. 95, 107 n.8 (1983) (emphasis in original); *see also Hewlett-Packard Co. v. Acceleron LLC*, 587 F.3d 1358, 1363 (Fed. Cir. 2009) ("[I]t is the objective words and actions of the patentee that are controlling").

Dr. Ostrer's new declaration seeks to establish that at Montefiore he still has the same readiness to perform genetic testing that he had when at NYU. (Supp. Decl. at ¶¶ 5, 7-10.) But that is not enough. Aside from an alleged immediate capability to perform testing, there must also be an actual *controversy*—a bilateral dispute—requiring immediate resolution by a judicial ruling. *See MedImmune*, 549 U.S. at 127 (for declaratory-judgment jurisdiction, the parties must "hav[e] adverse legal interests, of sufficient immediacy and reality"). Here, there is no controversy between Myriad and Montefiore (and thus no controversy between Myriad and Dr. Ostrer) because there has never been an affirmative act by Myriad

directed at Montefiore. Indeed, Myriad has never had any communication with any representative from either institution regarding Myriad's challenged patents, whether in 1998 (when it sent the letter to NYU), in 2011 (when Dr. Ostrer left NYU for Montefiore), or since. (Marsh Decl. ¶¶ 4-5.) Nor is Myriad aware of any work ever done in the past (or being done at present) at Montefiore's laboratories—by Dr. Ostrer or anyone else—that would require a license or in any way interfere with Myriad's rights under the patents at issue in this litigation. (*Id.* ¶ 6.) There simply are no facts indicating that Myriad would take any adverse action against Dr. Ostrer as a result of his activities at Montefiore.

As to the controversy arising out of Myriad's 1998 license offer to NYU, that does not establish an ongoing controversy that could sustain this Court's prior conclusion that Dr. Ostrer had standing. Montefiore and NYU are unrelated, so Myriad's 1998 license offer to NYU cannot be imputed to Montefiore. Nor can the controversy supposedly created by that letter simply follow Dr. Ostrer to Montefiore. The 1998 license offer was to NYU, and NYU only. Indeed, had NYU signed the draft license offer, rights under that license would not have followed Dr. Ostrer to Montefiore. (A2965-74.) Any Myriad-NYU controversy likewise did not follow Dr. Ostrer to Montefiore.

Thus, with respect to Montefiore, Myriad's 1998 offer to NYU is no more than a generalized communication insufficient to establish a real and immediate

case or controversy for purposes of declaratory-judgment jurisdiction. Dr. Ostrer therefore now finds himself identically situated to the seventeen plaintiffs with whom Myriad had no contact whatsoever, and who thus had no standing to seek a declaratory judgment against Myriad. *See Ass'n for Molecular Pathology*, 653 F.3d at 1340, 1345. As this Court explained in rejecting those plaintiffs' standing, declaratory-judgment jurisdiction requires "affirmative acts by the patentee *directed at specific Plaintiffs*." *Id.* at 1348 (emphasis added) (citing *SanDisk*, 480 F.3d at 1380-81); *see also Prasco*, 537 F.3d at 1340 (rejecting declaratory-judgment jurisdiction where there was a "complete lack of evidence of a defined, preexisting dispute between" the parties). Myriad's 1998 offer to NYU thus does not establish a controversy with Dr. Ostrer (or with any other scientist now working at Montefiore).

Accordingly, Dr. Ostrer cannot revive his supposed dispute with Myriad by alleging, as he did in his supplemental declaration, that he is ready and willing to conduct clinical BRCA testing at Montefiore but that he is "prevented from doing so as a result of Myriad's assertion of its patents." (Supp. Decl. ¶¶ 5-8, 10.) Myriad has *never* asserted its patents against Montefiore; the "assertion" he refers to was made in the context of the licensing offer to *NYU*. In the absence of a licensing inquiry from Myriad, Montefiore's Dr. Ostrer, like hundreds of other doctors in hundreds of laboratories around the United States, all with the

equipment, capability, and desire to perform genetic sequencing, lacks any real controversy with Myriad requiring an immediate resolution.[4] Dr. Ostrer's claimed forbearance from conducting genetic testing at Montefiore is a unilaterally self-imposed harm. It cannot sustain standing.

When Dr. Ostrer departed from NYU, he walked away from any controversy with Myriad. This supposed controversy did not travel with him to his new institution, whose capabilities, practices, plans, and activities are wholly unknown to Myriad, and whose activities have never been the subject of any licensing offer or any other communication relating to Myriad's BRCA patents. (Marsh Decl. ¶¶ 4-6.) Since no live and present dispute exists, the appeal should be dismissed.

C. Vacatur Of The District Court's Decision Is Required

In addition to dismissing the appeal as moot, this Court should vacate the district court's decision on the merits. *See Ass'n for Molecular Pathology*, 702 F. Supp. 2d 181. "[V]acatur must be granted where mootness results from the

---

[4] Dr. Ostrer's self-imposed forbearance from testing creates no controversy. As the Solicitor General emphasized in his petition in *Clapper*, "'self-inflicted harm doesn't satisfy the basic requirements for standing': It 'does not amount to an "injury" cognizable under Article III' and, even if it did, 'it would not be fairly traceable to the defendant's challenged conduct.' *National Family Planning & Reprod. Health Ass'n v. Gonzales*, 468 F.3d 826, 831 (2006)." Petition for a Writ of Certiorari at 23, *Clapper v. Amnesty Int'l USA*, 566 U.S. __ (No. 11-1025). Indeed, multiple other laboratories are conducting BRCA clinical diagnostic testing today without a license agreement from Myriad; the Genetic Testing Registry lists several of them. *See* http://www.ncbi.nlm.nih.gov/gtr/tests/?condition=C2676676&locations=840:102,112,117,129,125,136,143,147&term=672[geneid] (last visited May 29, 2012).

unilateral action of the party who prevailed in the lower court." *U.S. Bancorp Mortgage*, 513 U.S. at 23; *Tafas*, 586 F.3d at 1371. Here, plaintiffs mounted this lawsuit against Myriad and prevailed on the merits before the district court. However, Dr. Ostrer has now unilaterally rendered the appeal moot. In these circumstances, the district court's decision must be vacated.

II. AT THE VERY LEAST, THE CASE SHOULD BE REMANDED FOR FURTHER PROCEEDINGS ON THIS JURISDICTIONAL QUESTION

If this Court declines to dismiss the appeal outright, this case should be remanded to allow the district court to adjudicate the jurisdictional effect of Dr. Ostrer's departure from NYU and his new position at Montefiore. These facts arose after the district court concluded its proceedings, and thus have not been addressed by that court.

Myriad did not have the opportunity to test these and other averments in Dr. Ostrer's new declaration, via deposition or otherwise. In particular, despite Dr. Ostrer's averments of "immediate" willingness and capability to perform BRCA testing (Supp. Decl. ¶¶ 5, 7-10), it is likely that no such testing could take place "immediately," and certainly not until any regulation-required licensures and other permissions—*e.g.*, CLIA certification and New York State licensure—have occurred. (*See* Marsh Decl. ¶ 6.)

For example, Dr. Ostrer's declaration states that he will be Director of "Genetic and Genomic Diagnostics at Montefiore Medical Center." (Supp. Decl. ¶ 3.) Almost a year later, a review of the websites for Montefiore fails to show any evidence that such a diagnostic entity exists. Further, Montefiore has an existing molecular diagnostic laboratory, directed by Dr. Qiulu Pan, that performs genetic testing. *See* http://www.montefiore.org/pathology-services-clinical-laboratory (last visited May 29, 2012). Unlike with his position at NYU, Myriad has no current evidence that Dr. Ostrer is involved in or plans to direct any BRCA clinical genetic testing. There is nothing in the record that Montefiore will allow Dr. Ostrer to conduct BRCA clinical genetic testing with Montefiore's laboratory facilities. This lack of any evidence of readiness to infringe, other than his own assertion that he would conduct such tests *if* the Myriad patents were invalidated, requires remand for redetermination of facts.

Of equal importance, remand would allow for the determination of whether other, unchallenged claims of the Myriad patents, also directed to BRCA clinical diagnostic testing, would make a declaratory judgment on the limited number of claims challenged by plaintiffs a sufficient remedy for redressing the alleged harms. This is a required element to sustain declaratory-judgment jurisdiction. *See Prasco*, 537 F.3d at 1338 ("To satisfy standing, the plaintiff must allege . . . an injury-in-fact . . . redressable by a favorable decision" in the case). This determination has

now become necessary due to Dr. Ostrer's new position at Montefiore, and including in light thereof, determining what BRCA clinical diagnostic testing he would there be allowed to undertake.

As this Court has made clear, where jurisdictional facts are in dispute, "finding those facts in the first instance would overstep [this Court's] bounds as a reviewing court and [it] cannot resolve the parties' factual disputes on appeal." *3M Co. v. Avery Dennison Corp.*, 673 F.3d at 1378. When that happens, the case should be remanded. *See id.*

CONCLUSION

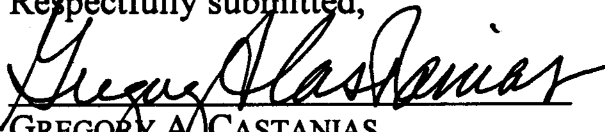
The Court should dismiss the appeal and vacate the district court's declaratory judgment. In the alternative, the case should be remanded to the district court to address in the first instance the change in circumstances relevant to whether declaratory-judgment jurisdiction exists.

STATEMENT OF CONSENT OR OPPOSITION

Counsel for appellees has declined to consent, and has indicated that a response will be filed.

Dated: May 30, 2012

Respectfully submitted,



GREGORY A. CASTANIAS
JENNIFER L. SWIZE
JONES DAY
51 Louisiana Avenue, N.W.

Washington, D.C. 20001
(202) 879-3939

BRIAN M. POISSANT
LAURA A. CORUZZI
EILEEN FALVEY
JONES DAY
222 East 41st Street
New York, NY 10017
(212) 326-3939

ISRAEL SASHA MAYERGOYZ
DENNIS MURASHKO
JONES DAY
77 West Wacker Drive
Chicago, IL 60601
(312) 782-3939

Attorneys for Defendants-Appellants 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

BENJAMIN G. JACKSON
MYRIAD GENETICS, INC.
320 Wakara Way
Salt Lake City, UT 84108
(801) 883-3328

Of counsel for Defendants-Appellant Myriad Genetics, Inc.

CERTIFICATE OF INTEREST

Counsel for the appellants, 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, certifies the following:

1. The full name of every party or amicus represented by me is:

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.

2. The name of the real party in interest represented by me is:

Myriad Genetics, Inc.; the University of Utah Research Foundation.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

None.

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court are:

Jones Day (Gregory A. Castanias; Brian M. Poissant; Laura A. Coruzzi; Barry R. Satine; Eileen Falvey; Lynda Q. Nguyen; Israel Sasha Mayergoyz; Jennifer L. Swize; Dennis Murashko).

DECLARATION OF RICHARD MARSH

I, Richard Marsh, hereby declare that:

1. I am Executive Vice President, General Counsel, and Secretary at Myriad Genetics, Inc., one of the appellants in this case. I have served in these positions since November 2002. My responsibilities include, among other things, offering licenses to, and negotiating with, other parties with respect to Myriad's intellectual property.

2. I am aware that, on May 21, 1998, Myriad sent a letter addressed to Dr. Harry Ostrer in his professional capacity as the Director of New York University's Molecular Genetics Laboratory ("NYU"). In that letter, Myriad offered a license to NYU and enclosed a draft collaboration agreement between Myriad and NYU. (A2964-74.) The offer of license was not to Dr. Ostrer.

3. I understand that, effective August 29, 2011, Dr. Ostrer no longer works at NYU, and that, on or around that date, he became employed instead at Montefiore Medical Center and the Albert Einstein College of Medicine (collectively, "Montefiore").

4. Myriad has never sent a letter or otherwise communicated with Montefiore regarding any of Myriad's patents, including the patents at issue in this litigation.

5. Myriad has never offered a license or other collaboration agreement to Montefiore.

6. Myriad is not aware of any present or planned actions by Montefiore that would interfere with Myriad's rights under the patents at issue in this litigation. By way of example, Myriad is not aware of any BRCA clinical genetic testing currently performed by Montefiore, nor is Myriad aware of whether Montefiore possesses the necessary authorizations—such as CLIA certification (under the Clinical Laboratory Improvement Amendments) or New York State certification—to perform such testing for individual patient diagnoses, or, if uncertified, how long it would take Montefiore to obtain those authorizations. In short, because Myriad is completely unaware of what (if any) activities have been (or are presently being) undertaken by Montefiore's facilities, let alone what activities Dr. Ostrer or any other scientist affiliated with Montefiore have engaged in or are engaging in, Myriad does not have any dispute with Montefiore or any of its personnel, and never has.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

Executed on: May 25, 2012

Richard Marsh

PROOF OF SERVICE

The undersigned counsel hereby certifies that the original and three copies of Appellants' Suggestion of Mootness, Or, in the Alternative, Motion to Remand were filed, by hand delivery, in the Office of the Clerk, United States Court of Appeals for the Federal Circuit, on May 30, 2012.

The undersigned counsel further certifies that two copies of the foregoing were served, by UPS (overnight delivery) and e-mail, on May 30, 2012, upon the following counsel:

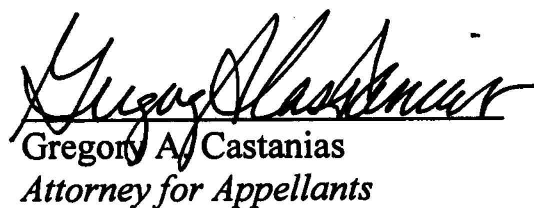
Christopher A. Hansen, Esq. American Civil Liberties Union 125 Broad Street 18th Floor New York, New York 10004 *Counsel for Plaintiffs-Appellees*	Barbara R. Rudolph, Esq. Finnegan, Henderson, Farabow, Garrett & Dunner 901 New York Avenue, N.W. Suite 1100 Washington, DC 20001-4413 *Counsel for Amicus Curiae American Intellectual Property Law Association*
Mary M. Calkins, Esq. Foley & Lardner 3000 K Street, N.W. Suite 500 Washington, DC 20007 *Counsel for Amicus Curiae Alnylam Pharmaceuticals*	Seth P. Waxman, Esq. Wilmer Hale 1875 Pennsylvania Avenue, N.W. Washington, DC 20006 *Counsel for Amici Curiae Biotech Industry Organization et al.*

Erik P. Belt, Esq. McCarter & English 265 Franklin Street Boston, MA 02110 *Counsel for Amicus Curiae Boston Patent Law Association*	J. Timothy Keane, Esq. Harness, Dickey & Pierce 7700 Bonhomme Avenue Suite 400 St. Louis, MO 63105 *Counsel for Amici Curiae Gilead Sciences et al.*
Jennifer Gordon, Esq. Baker Botts 30 Rockefeller Center New York, New York 10112 *Counsel for Amicus Curiae Croplife International*	Herbert C. Wamsley, Esq. McDonnell, Boehnen, Hulbert & Berghoff 300 South Wacker Drive Chicago, Illinois 60606 *Counsel for Amicus Curiae Intellectual Property Owners Association*
Maxim H. Waldbaum, Esq. Schiff Hardin 900 Third Avenue 23rd Floor New York, New York 10022 *Counsel for Amicus Curiae Fédération Internationale des Conseils en Propriété Industrielle (FICPI)*	Brian R. Dorn, Esq. Merchant & Gould 80 South 8th Street Suite 3200 Minneapolis, MN 55402-2215 *Counsel for Amicus Curiae Kane Biotech*
David S. Forman, Esq. Finnegan, Henderson, Farabow, Garrett & Dunner 901 New York Avenue, N.W. Washington, DC 20001-4413 *Counsel for Amicus Curiae Genetic Alliance*	Judy Deleon Jarecki-Black, Esq. Merial Limited 3239 Satellite Boulevard Duluth, GA 30096 *Counsel for Amicus Curiae Merial Limited*

William G. Gaede, III, Esq. McDermott, Will & Emery 275 Middlefield Road Suite 100 Menlo Park, CA 94025 *Counsel for Amici Curiae Genomic Health et al.*	Kent D. McClure, Esq. Animal Health Institute 1325 G Street, N.W. Suite 700 Washington, DC 20005 *Counsel for Amicus Curiae Animal Health Institute*
Aaron Stiefel, Esq. Kaye Scholer 425 Park Avenue New York, New York 10022 *Counsel for Amicus Curiae Novartis Corp.*	Kurt G. Calia, Esq. Covington & Burling 1201 Pennsylvania Avenue, N.W. Washington, DC 20004-2401 *Counsel for Amicus Curiae Pharmaceutical Research and Manufacturers of America*
Jacqueline D. Wright-Bonilla, Esq. Foley & Lardner 3000 K Street, N.W. Suite 500 Washington, DC 20007 *Counsel for Amici Curiae Rosetta Genomics, et al.*	Mark R. Freeman, Esq. U.S. Department of Justice 950 Pennsylvania Avenue, N.W. Room 7644 Washington, D.C. 20530-0001 *Counsel for Amicus Curiae United States of America*
Ann M. McCrackin, Esq. University of New Hampshire School of Law 2 White Street Concord, NH 03301 *Counsel for Amicus Curiae University of New Hampshire School of Law*	Erika R. George, Visiting Professor of Law, Esq. Loyola University Chicago School of Law 25 East Pearson Chicago, IL 60611 *Counsel for Amici Curiae Erika R. George and Kali N. Murray*

Christopher M. Holman, Esq. 5100 Rockhill Road Kansas City, MO 64110 *Counsel for Amici Curiae Christopher Holman et al.*	Bruce Vignery, Esq. AARP Foundation Litigation 601 E Street, NW Washington, DC 20049 *Counsel for Amicus Curiae AARP*
George A. Kimbrell, Esq. The International Center for Technology Assessment 660 Pennsylvania Avenue Suite 302 Washington, DC 20003 *Counsel for Amici Curiae The International Center for Technology Assessment et al.*	Andrew Chin, Esq. University of North Carolina School of Law 160 Ridge Road, CB #3380 Chapel Hill, NC 27599-3380 *Counsel for Amici Curiae Scholars of Biotechnology Patent Law*
Francis Pizzulli, Esq. 718 Wilshire Boulevard Santa Monica, CA 90401 *Counsel for Amicus Curiae The Southern Baptist Convention*	Krista L. Cox, Esq. Universities Allied for Essential Medicines 2625 Alcatraz Avenue, #180 Berkeley, CA 94705 *Counsel for Amicus Curiae Universities Allied for Essential Medicines*
Larry Frierson, Esq. The Law Offices of Larry Frierson 3265 Lake County Highway Calistoga, CA 94515 *Counsel for Amici Curiae Cancer Council Australia and Luigi Palombi*	Debra L. Greenfield, Esq. UCLA Center for Society and Genetics Box 957221, 1323 Rolfe Hall Los Angeles, CA 90095 *Counsel for Amici Curiae The National Women's Health Network et al.*

Eileen M. Kane, Esq. Penn State Dickinson School of Law 328 Katz Building University Park, PA 16802 *Counsel for Amicus Curiae Professor Eileen M. Kane*	John L. Hendricks, Esq. Hitchcock Evert LLP 750 North St. Paul Street Suite 1110 Dallas, TX 75201 *Counsel for Amici Curiae Canavan Foundation et al.*
James P. Evans, MD, Ph.D. Department of Genetics CB# 7264 University of North Carolina Campus Box 7264 Chapel Hill, NC 27599-7264 *Counsel for Amici Curiae E. Richard Gold, James P. Evans, and Tania Bubela*	Professor Lori B. Andrews, Esq. Chicago-Kent College of Law 565 West Adams Street Chicago, Il 60661 *Counsel for Amici Curiae American Medical Association et al.*



Gregory A. Castanias
Attorney for Appellants