

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

-----X
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,

09 Civ. 4515 (RWS)

Plaintiffs,

v.

ECF Case

UNITED STATES PATENT AND TRADEMARK
OFFICE; 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,
in their official capacity as Directors of the University
of Utah Research Foundation,

Defendants.

-----X
**PLAINTIFFS' MEMORANDUM OF LAW IN OPPOSITION TO
DEFENDANTS MYRIAD AND UURF DIRECTORS' MOTION TO DISMISS**

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INTRODUCTION

Lisbeth Ceriani is a 43 year-old single mother. Complaint ¶ 21; D. Ceriani ¶ 2.¹ She was diagnosed with breast cancer last year. Complaint ¶ 21; D. Ceriani ¶ 3. To determine whether she should undergo additional surgery to protect her life, Ms. Ceriani's doctors want someone to look at two of her genes to see if she has any genetic mutations. Complaint ¶ 21; D. Ceriani ¶ 4, 10. Myriad is the only lab in the entire country offering such service, but it is unwilling to provide it to Ms. Ceriani. Complaint ¶ 21; D. Ceriani ¶¶ 5-7. Ms. Ceriani desperately wishes someone else would look at her genes for her. Complaint ¶ 21; D. Ceriani ¶ 8, 11.

Dr. Harry Ostrer of NYU Medical Center has all the tools and expertise necessary to look at Ms. Ceriani's genes and he wants to do so. Complaint ¶ 14; D. Ostrer, ¶¶ 8-9. There is only one thing preventing Dr. Ostrer from helping Ms. Ceriani: he is afraid that if he does, he will be sued by Myriad for patent infringement. *See infra* Section I.A.

This fear isn't irrational. Since being granted patents covering the “*BRCA1*” and “*BRCA2*” genes in the late 1990's, Myriad and its silent partners, the co-defendant Directors of the University of Utah Research Foundation (UURF), have maintained a systematic and constant campaign of suing or threatening to sue anyone who treads on what they see as their turf. *Id.*

Each of the other plaintiffs in this suit (fellow medical professionals, women and advocates) has the same fear and is similarly restrained from undertaking potentially infringing activity despite also having the capability and desire to do so. *Id.* As such, Dr. Ostrer, Ms. Ceriani and the other plaintiffs have brought this case to have defendants' *BRCA* patents declared invalid for violating both the Patent Act and the Constitution.

Defendants argue in their motion to dismiss that plaintiffs have no basis to bring this case

¹ The designation “D. ____” refers to the declaration of the identified individual filed herewith.

because there is no “case or controversy.” *Memorandum of Law in Support of Defendants' Motion to Dismiss*, filed July 13, 2009 (“Myriad Mem.”) at 6-13. Nothing could be further from the truth. This case is not a mere “policy disagreement”; it is about real doctors who have the ability and desire to help real patients with serious medical issues, but who are restrained from doing so solely because they fear being sued for patent infringement by defendants. Thus, defendants' motion to dismiss should be denied.

The UURF Directors also argue that the Court has no personal jurisdiction over them. Plaintiffs sued the Directors in their official capacities, however, and do have personal jurisdiction over them in that capacity.

I. EACH PLAINTIFF HAS STANDING UNDER THE SUPREME COURT’S “ALL THE CIRCUMSTANCES” TEST

Defendants' characterization of both the law and facts is inaccurate. On the law, defendants assert that a pair of “requirements” must be met for the Court to have declaratory judgment (“DJ”) jurisdiction. Myriad Mem. at 6. While that may have been true a few years ago, when the Federal Circuit's “reasonable apprehension of suit” test prevailed, the current standard set forth by the Supreme Court in *MedImmune, Inc. v. Genentech, Inc.* looks to “all the circumstances” and contains no “bright line” rules. 549 U.S. 118, 127 (2007); *Prasco, LLC v. Medicis Pharm. Corp.*, 537 F.3d 1329, 1336 (Fed. Cir. 2008). The *MedImmune* analysis is “more lenient” than the reasonable apprehension of suit test and has resulted in a greater “ease of achieving declaratory judgment jurisdiction.” *Micron Tech., Inc. v. Mosaid Techs., Inc.*, 518 F.3d 897, 902 (Fed. Cir. 2008).

On the facts, plaintiffs first note that, when evaluating a motion to dismiss, allegations contained in the Complaint are to be taken as true. *Prasco*, 537 F.3d at 1334. Here, plaintiffs

allege that they each have the ability and desire to undertake activities that potentially infringe defendants' patents. *See infra* Section I.A.1. Some of the plaintiffs are medical professionals who want to provide *BRCA* genetic screening services and have all the tools and expertise necessary to do so. Others are patients who have been advised by their doctors or genetic counselors to get such screening. Others are counselors and advocacy groups that want to assist patients with finding appropriate medical professionals and laboratory services. None of the plaintiffs is undertaking these activities despite having the desire and ability to do so, because all of those activities could constitute infringement of the defendants' *BRCA* patents.

Plaintiffs also allege that defendants' actions have caused plaintiffs to forgo pursuing their desired activities because of a fear that if they did so, defendants would sue them for patent infringement. *See infra* Section I.A.2. Defendants' actions include: (i) filing patent infringement lawsuits against everyone that has ever offered *BRCA* genetic services to the general public, (ii) sending threatening cease-and-desist letters, (iii) making patent infringement assertions during in-person meetings, and (iv) refusing to grant licenses except for very limited circumstances. *Id.* Taking all of these allegations as true, DJ jurisdiction under the “more lenient” *MedImmune* standard is easily established. However, to even more fully establish standing, plaintiffs submit declarations to support their allegations. Moreover, so long as standing is established for one plaintiff, the Court need not examine the standing of others. *See infra* Section I.B.

In short, viewing the facts alleged in the Complaint and established with the declarations submitted herewith under the correct legal standard leads to the conclusion that DJ jurisdiction exists in this case and that the defendants' motion to dismiss should be denied.

A. The Correct Analysis For DJ Standing Looks At All The Circumstances

Just over two years ago, the Supreme Court in *MedImmune* dramatically corrected what had been the prevailing standard for standing in patent DJ cases. 549 U.S. 118. Prior to that decision, the Federal Circuit had mandated a two-pronged “reasonable apprehension of suit” test requiring a DJ plaintiff to establish that (1) the patent holder had acted in a way that created an objectively “reasonable apprehension” on the part of the plaintiff that it would be sued if it continued or began allegedly infringing activity and (2) the plaintiff had actually undertaken or was prepared to undertake that activity. See *Sony Elecs., Inc. v. Guardian Media Techs., Ltd.*, 497 F.3d 1271, 1283 (Fed. Cir. 2007). In *MedImmune*, the Supreme Court expressly rejected the “reasonable apprehension of suit” test, declaring that the correct analysis for DJ standing focuses on “all the circumstances.” 549 U.S. at 127, 132 n.11.

Under *MedImmune's* “all the circumstances” test, “the question in each case is whether the facts alleged, under all the circumstances, 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.” 549 U.S. at 127 (quoting *Md. Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941)). The Supreme Court further explained that a DJ plaintiff must seek more than “an opinion advising what the law would be upon a hypothetical state of facts.” *Id.* (quoting *Aetna Life Ins. Co. of Hartford, Conn. v. Haworth*, 300 U.S. 227, 240-42 (1937)).

Despite this substantial change in the law, defendants still choose to argue in their motion to dismiss that “[a]fter *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.” Myriad Mem at 6.

Defendants apparently believe *MedImmune* changed little and that the “reasonable apprehension of suit” test is effectively still the law, because these two alleged “requirements” are virtually identical to the two prongs of that now-abrogated test. That is not the case. The Federal Circuit has recognized that the Supreme Court in *MedImmune* “explained that the Federal Circuit’s requirements, specific to patent cases, that there be both a threat or other action by the patentee sufficient to create a reasonable apprehension of infringement suit, and present activity that could constitute infringement or concrete steps taken with the intent to conduct such activity, were more rigorous than warranted by the principle and purpose of declaratory actions.” *Revolution Eyewear, Inc. v. Aspex Eyewear, Inc.*, 556 F.3d 1294, 1297 (Fed. Cir. 2009).

“[T]he now more lenient legal standard facilitates or enhances the availability of declaratory judgment jurisdiction in patent cases,” and, accordingly, to the Federal Circuit, there is now an “ease of achieving declaratory judgment jurisdiction.” *Micron Tech.*, 518 F.3d at 902. The Southern District of New York has similarly recognized that now, “the trend is to find an actual controversy.” *Diamonds.net LLC v. IDEX Online, Ltd.*, 590 F. Supp. 2D 593, 597-98 (S.D.N.Y. 2008). As detailed below, an analysis of all the circumstances in this case supports a finding of DJ jurisdiction.

1. Each Plaintiff Is Meaningfully Prepared To Undertake Potentially Infringing Activity

“[A] party need not have engaged in the actual manufacture or sale of a potentially infringing product to obtain a declaratory judgment.” *Cat Tech LLC v. Tubemaster, Inc.*, 528 F.3d 871, 881 (Fed. Cir. 2008). Rather, “a showing of ‘meaningful preparation’” to undertake potentially infringing activity is sufficient. *Id.* (quoting *Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 736 (Fed. Cir. 1988)). Each plaintiff more than satisfies the

“meaningful preparation” standard. In fact, if defendants' patents were invalidated today, plaintiffs could – and would – begin *BRCA* related activity because they have both the capability and desire to do so. This is not hypothetical; it is actual, real and concrete.

The Individual Medical Professional Plaintiffs. Plaintiffs Drs. Haig H. Kazazian, Jr., M.D., Arupa Ganguly, Ph.D., Wendy Chung, M.D., Ph.D., Harry Ostrer, M.D., David Ledbetter, Ph.D. and Steve Warren, Ph.D. are well known human geneticists who each have the capability and desire to begin or consider beginning (or in the case of at least Drs. Kazazian and Ganguly, resume or consider resuming) performing *BRCA* related genetic testing of the general public. Compl. ¶¶ 11-16; D. Kazazian ¶ 11; D. Ganguly ¶ 14; D. Chung ¶¶ 17-18, 21; D. Ostrer ¶¶ 8-10, 13; D. Ledbetter ¶¶ 18-19 (speaking for himself and Dr. Warren). Each currently analyzes genes other than the *BRCA* genes using methodologies similar to those used by Myriad; thus it would be of no effort to use those same methodologies (and equipment and personnel) to analyze *BRCA* genes. *See, e.g.*, D. Ledbetter ¶¶ 8-10.² The genetic evaluation services these doctors have the ability and desire to perform would include analysis of the complete *BRCA* genes, targeted mutation analysis and detecting large scale rearrangements, and would be more comprehensive than what Myriad offers. *See, e.g.*, D. Ostrer ¶ 9; D. Chung ¶ 18. The only thing preventing them from analyzing *BRCA* genes is the patents in this case. *See, e.g.*, D. Chung ¶¶ 13, 15-18. Were it not for the patents, some would start within a month. *See, e.g.*, D. Ledbetter ¶ 18.³ Thus, these doctors allege “meaningful preparation” that supports their standing to bring this case.

Similarly, plaintiffs Ellen Matloff, M.S. and Elsa W. Reich, M.S., C.G.C. are genetic

² Due to page limitations for this brief, plaintiffs do not expressly provide an analysis regarding each plaintiff; plaintiffs will provide such detail if the Court desires. Plaintiffs have filed declarations from each plaintiff and use those to support the allegations made in the Complaint.

³ Some states may require certification and approval before a lab may offer a new genetic test. To the extent such requirement applies, plaintiffs have the capability and desire to begin such certification and approval process so that they may then begin performing *BRCA* clinical genetic testing.

counselors who have the capability and desire to begin utilizing laboratories other than, or in addition to, Myriad, to perform *BRCA* genetic testing of their patients. Compl. ¶¶ 17-18; D. Matloff ¶¶ 11-14; D. Reich ¶¶ 7-14. If there were another lab offering *BRCA* genetic services (such as the ones identified above), Mses. Matloff's and Reich's utilizing (or even just giving information to their patients about) such other service providers could constitute actionable inducement of infringement of the patents. 35 U.S.C. § 271(b) (“Whoever actively induces infringement of a patent shall be liable as an infringer”); *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1364-65 (Fed. Cir. 2004) (disseminating medical information and a directory of medical service providers was sufficient to trigger liability for inducing infringement). Thus, plaintiffs Matloff and Reich are also “meaningfully prepared” to undertake potentially infringing activity, which supports their standing to bring this case.

The Medical Organization Plaintiffs. Under the “doctrine of associational standing,” an organization may bring actions for injunctive relief for its members if: “(a) its members would otherwise have standing to sue in their own right; (b) the interests it seeks to protect are germane to the organization's purpose; and (c) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit.” *United Food & Commercial Workers Union Local 751 v. Brown Group, Inc.*, 517 U.S. 544, 553 (1996) (quoting *Hunt v. Washington State Apple Advertising Comm'n*, 432 U.S. 333, 343, (1977)). Plaintiffs Association for Molecular Pathology, American College of Medical Genetics, American Society for Clinical Pathology and College of American Pathologists each satisfy all three of these prongs.

First, the medical organization plaintiffs are each organizations with members who have the desire and capability (*i.e.*, are “meaningfully prepared”) to begin engaging in research and

clinical practice involving the *BRCA* genes similar to that alleged for the individual medical professional plaintiffs. Compl. ¶¶ 7-10; D. Sobel ¶ 3; D. Hegde ¶¶ 10-12; D. Watson ¶ 3; D. Chung ¶¶ 17-18, 21; D. Ball ¶ 3; D. Hubbard ¶¶ 8-9; D. Scott ¶ 3; D. Kant ¶ 6. Second, the medical organization plaintiffs are participating in this case because they each seek to protect interests that are “germane to the organization's purpose.” Compl. ¶¶ 7-10; D. Sobel ¶ 4; D. Watson ¶¶ 4-5; D. Ball ¶¶ 4-5; D. Scott ¶¶ 4-5. Third, the claim asserted in this case is that defendants' *BRCA* patents are invalid for violating both the Patent Act and the Constitution. Compl. ¶ 102. Those claims are not personal to any individual. The relief sought is a declaration of invalidity of certain patent claims and an injunction barring any enforcement of those patent claims. Compl. at 30 (“Prayer for Relief”). This relief is not personal to any individual. Thus, “neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit,” satisfying the final prong of the associational standing doctrine for the medical organization plaintiffs. *United Food*, 517 U.S. at 553.

The Individual Women Plaintiffs. Plaintiffs Lisbeth Ceriani, Runi Limary, Genae Girard, Patrice Fortune, Vicky Thomason and Kathleen Raker are individual women who have the capability and desire to utilize the services of medical geneticists and laboratories other than or in addition to Myriad, including those identified above, to receive *BRCA* genetic testing. Compl. ¶¶ 21-26; D. Ceriani ¶¶ 8-9, 11; D. Limary ¶¶ 8-9; D. Girard ¶¶ 10-11; D. Fortune ¶¶ 5-6, 8-9; D. Thomason ¶¶ 8-10; D. Raker ¶¶ 8-13. If they were to utilize the services of doctors or labs other than the defendants, knowing that such actions could constitute direct infringement of the defendants' patents, these women could be liable for inducing infringement of those patents. *Symantec Corp. v. Computer Assocs. Int'l, Inc.*, 522 F.3d 1279, 1292 (Fed. Cir. 2008). The

individual women plaintiffs are more than “meaningfully prepared” to undertake this potentially infringing activity, because all they need to do to potentially induce infringement is ask a medical professional to perform the analysis and then provide the medical professional with a genetic sample (by cheek swab or blood withdrawal).

The Advocacy Organization Plaintiffs. Plaintiffs Breast Cancer Action and Boston Women's Health Book Collective, Inc., dba Our Bodies Ourselves, are organizations that have the capability and desire to (i) encourage researchers and clinicians to perform *BRCA* related activities, including *BRCA* genetic testing and research, and/or (ii) advertise the services of laboratories other than or in addition to Myriad, including those identified above, to perform *BRCA* genetic testing services for the general public. Compl. ¶¶19-20; D. Brenner ¶¶ 5-9; D. Norsigian ¶¶ 6-8. Their encouragement and/or advertisement of others undertaking such activities could constitute actionable inducement of infringement of the patents, because they know that *BRCA* related activities by persons other than defendants could constitute direct infringement of defendants' patents. 35 U.S.C. § 271(b); *Metabolite Labs.*, 370 F.3d at 1364. Thus, the plaintiff advocacy organizations are also “meaningfully prepared” to undertake potentially infringing activity.

Circumstances relevant to all plaintiffs. In the very few cases where the Federal Circuit has not found an actual controversy post-*MedImmune*, that finding was influenced by the following circumstances: (i) the DJ plaintiff only sued for a DJ of non-infringement, not invalidity (*Prasco*, 537 F.3d at 1342, n.12); (ii) the DJ plaintiff could not undertake the potentially infringing activity for at least six to eight years from when the complaint was filed (*Benitec Australia Ltd. v. Nucleonics, Inc.*, 495 F.3d 1340, 1346 (Fed. Cir. 2007)); and (iii) the

DJ plaintiff conceded that at the time the district court granted the motion to dismiss, another patent not in the suit prevented it from undertaking potentially infringing activities for at least another eight months (*Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353, 1357, 1360 (Fed. Cir. 2008)). None of these circumstances exists here: (i) plaintiffs have indeed sued for a DJ of invalidity of defendants' patent claims, not non-infringement, and (ii) plaintiffs allege and support with submitted declarations that they can – and will – undertake potentially infringing activity upon a victorious resolution of this case. Thus, these cases are distinguishable and actually support standing in this case.

2. Defendants' Actions In Asserting The *BRCA* Patents Justify Standing

Defendants' claim that a DJ defendant must have “taken some affirmative action relevant to the plaintiff” and “shown an intention to litigate against the plaintiffs,” *Myriad* Mem. at 6, 8, is not accurate. Quite to the contrary, any act by the patentee relating to either the patents in suit *or* plaintiffs supports DJ standing. *SanDisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372, 1381 (Fed. Cir. 2007); *Prasco*, 537 F.3d at 1341. For example, the following circumstances support a finding of an actual controversy: (i) patent holder sends a letter threatening “to protect its rights” to a licensee (*Adenta GmbH v. OrthoArm, Inc.*, 501 F.3d 1364, 1370 (Fed. Cir. 2007)); (ii) a patentee makes accusations of infringement through letters and meetings (*Sony Elecs.*, 497 F.3d at 1285-87); and, (iii) the patentee “pursues a systematic licensing and litigation strategy” (*Micron Tech.*, 518 F.3d at 899). Each of these circumstances is alleged by the plaintiffs in this case.

Myriad's assertion – including litigation - against Drs. Kazazian and Ganguly. In the late 1990s, plaintiffs Drs. Kazazian and Ganguly of the University of Pennsylvania were

performing *BRCA* related activity. Compl. ¶¶ 11-12; D. Kazazian ¶¶ 5-10; D. Ganguly ¶¶ 4-10. Myriad sent a series of cease-and-desist letters to Dr. Kazazian and counsel for the University of Pennsylvania repeatedly asserting that it had patents covering *BRCA*, that Dr. Kazazian was violating those patents, and demanding that all such activity cease immediately. *Id.* Myriad also met with Dr. Kazazian and made their threat of patent infringement face-to-face. D. Kazazian ¶ 6 (Mark Skolnick, Myriad's Chief Science Officer, told Dr. Kazazian in an in-person meeting that they “planned to stop the *BRCA* testing activity that Dr. Ganguly and [he] were performing”). This was despite the fact that Drs. Kazazian and Ganguly were using a different methodology than that used by Myriad (Myriad’s gene patents do not cover particular methodologies; rather, they cover the genes themselves and any method for looking at, comparing or analyzing the genes). D. Kazazian ¶ 9.

Myriad's threat wasn't empty. In November 1998, Myriad sued the University of Pennsylvania for infringing the *BRCA* patents. *Myriad Genetics v. University of Pennsylvania*, 2:98-cv-00829 (D.Utah). At that time, Drs. Kazazian and Ganguly's laboratory was the only one in the nation offering *BRCA* genetic testing to the public other than Myriad. D. Kazazian ¶ 10; D. Ganguly ¶ 12. That lawsuit was dismissed after the University agreed that Drs. Kazazian and Ganguly would stop their *BRCA* related activity. Christopher M. Holman, *The Impact of Human Gene Patents on Innovation and Access: A Survey of Human Gene Patent Litigation*, 76:2 UKMC L.Rev. 295, 348 (2007). However, the lawsuit was dismissed “without prejudice” and, as such, could be refiled at any time. *See* 2:98-cv-00829 (D.Utah) (docket entry 3). Thus, Drs. Kazazian and Ganguly have no doubt that should they resume *BRCA* related activities, Myriad will definitely sue them again. Compl. ¶¶ 11-12; D. Ganguly ¶ 10. Although the letters and

lawsuit may have taken place in the late 1990's, a “lapse in time” is not a basis to diminish the effect of the previous lawsuit and threats on the instant DJ jurisdiction analysis. *Micron Tech.*, 518 F.3d at 901.⁴ Here, Myriad's patent assertion forced Drs. Kazazian and Ganguly to completely cease their *BRCA* related activities and to never restart such activities until the patents expire or are declared invalid. D. Ganguly ¶ 14. This is still the case today.

Because this assertion became so well known throughout the relatively small *BRCA* community, it not only provides more than sufficient basis for Drs. Kazazian and Ganguly to have DJ standing, it also caused others who had considered performing *BRCA* related genetic activity to avoid doing so for fear of similarly being sued by Myriad for patent infringement. Compl. ¶¶ 82, 84; D. Ostrer ¶¶ 5-6; D. Chung ¶¶ 13-15; D. Ledbetter ¶ 16; D. Matloff ¶¶ 7-9. Thus, these circumstances support DJ jurisdiction for all plaintiffs in this case.

Myriad's litigation against others. It was also well known that prior to suing the University of Pennsylvania, Myriad had twice sued the only other company to undertake *BRCA* related activity for allegedly infringing *BRCA* patents at issue in this case. *Myriad Genetics v. Oncormed*, 2:97-cv-00922 (D.Utah); *Myriad Genetics v. Oncormed*, 2:98-cv-00035 (D.Utah). The Federal Circuit has recognized that such, “[p]rior litigious conduct [against third parties] is one circumstance to be considered in assessing whether the totality of circumstances creates an actual controversy.” *Prasco*, 537 F.3d at 1341. Thus, Myriad's previous lawsuits involving the patents in this case also weigh in favor of a finding of DJ jurisdiction here.

Myriad's assertion against others. In addition to suing the only other labs that have ever offered testing to the general public, defendants' systematic litigation and threat-letter writing

⁴ The cases cited by defendants supporting the argument that a passage of time nullifies the effect of past assertions are pre-*MedImmune* Federal Circuit opinions and one district court opinion, all of which are of less precedential value than the Federal Circuit's post-*MedImmune* *Micron Tech* decision cited here.

campaign has included similar assertions against professors performing *BRCA* related activity at Yale, Georgetown and NYU, amongst others. Compl. ¶ 49; D. Matloff ¶ 7; D. Ganguly ¶ 12-13; D. Ostrer ¶ 7. In fact, in a letter to Dr. Susan G. Nayfield of the National Cancer Institute, Myriad emphasized that, “[o]ver the past several months we have contacted several laboratories engaged in *commercial testing* of the BRCA1 gene.” D. Ganguly ¶ 12 (emphasis in original). While the letter purports to only apply to “commercial testing,” Myriad defined that term later to include any genetic service where “results are provided to patients.” *Id.* Myriad's letter also stated that the “contact” it had with each lab demanded that they enter into a “Collaboration Agreement,” which was principally a license to defendants' *BRCA* patents that are at issue in this case. *Id.* An example of this assertion is Myriad's letter to Dr. Ostrer, prohibiting him from engaging in any *BRCA* testing without a license. D. Ostrer ¶ 7.

As another example, in 2005, even though Yale's *BRCA* related activities had been previously shut down by Myriad, plaintiff Matloff contacted Myriad to see if it would allow the Yale DNA Diagnostic Lab to do screening for mutations caused by large rearrangements, which Myriad was not offering at the time. D. Matloff ¶ 7-8. Myriad refused. *Id.* These circumstances add even more weight to support a finding that DJ jurisdiction exists in this case, especially because Myriad's aggressive patent assertion against any and all *BRCA* related activity has been well documented in publications and by the media. Compl. ¶ 49; Mildred K. Cho, et al., *Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services*, 5 J. Molecular Diagnostics 3, 6 (2003) (comprehensive study found that nine respondents had stopped performing *BRCA* testing as a result of Myriad's patent assertion).

The effect of Myriad's systematic assertion. Defendants' campaign of patent assertion to

comprehensively stamp out any other party from undertaking *BRCA* related activity has been successful. Compl. ¶ 49. Myriad is now the sole provider of *BRCA* related genetic services to the public and their patent-entrenched monopoly in the *BRCA* genetic services market provides defendants the ability to reap and share substantial profits. Compl. ¶ 99.⁵ That defendants have not filed patent infringement lawsuits or sent threatening letters recently is not a result of there being no controversy if a party wants to undertake *BRCA* related activity. Rather, it is solely because defendants have always successfully asserted their *BRCA* patents in a way to create a chill that has restrained anyone else from undertaking such activities.

Even if defendants have not asserted the *BRCA* patents against every plaintiff in this case, plaintiffs' awareness of defendants' systematic assertion against others supports a finding of DJ jurisdiction. *See Micron Tech.*, 518 F.3d at 899-901 (where the defendant was “unrelenting in the assertion of [its] patent portfolio”). It is well known that Myriad has taken the position that any *BRCA* related activity infringes its patents and that it will seek to threaten and sue anyone that begins such activity. As such, the DJ plaintiffs here are put in the position of either proceeding with the *BRCA* related activity that they have the ability and desire to undertake and risk being liable for patent infringement, or continue to refrain from such activity despite believing they have the right to do so because the patents are invalid for violating both the Patent Act and the Constitution. This is precisely the “dilemma” that the DJ Act was meant to address, and why there is DJ jurisdiction in this case. *MedImmune*, 549 U.S. at 129.

Defendants' refusal to offer assurances. To give defendants an opportunity to

⁵ Plaintiffs are aware of only one lab in the entire country that is allowed to do any *BRCA* genetic testing. That lab is at UCLA and has a royalty-bearing license from Myriad that only allows the lab to perform limited forms of testing (single mutation tests and multiple mutation panels (up to three mutations)) for patients of Ashkenazi Jewish descent and only for patients in the hospital affiliated with the lab. The lab is not allowed to do full sequencing or offer its services to any patients outside of the single hospital affiliated with the lab.

conclusively prove their argument that this case does not involve a real “controversy,” plaintiffs sent a letter to defendants' asking for confirmation in writing that they would not assert their patents against plaintiffs if they undertook their desired *BRCA* related activity. D. Ravicher Exh. 1. Defendants responded by failing to give any assurance that defendants would not assert their *BRCA* patents against plaintiffs. D. Ravicher Exh. 2. This refusal to give assurances leads to only one reasonable conclusion, that defendants very much wish to reserve the right to sue plaintiffs should they undertake their intended *BRCA* activities. This fact weighs in favor of finding DJ standing in this case. *Prasco*, 537 F.3d at 1341.

B. If One Plaintiff Has Standing, The Court Need Not Analyze The Others

If one plaintiff in a DJ action has standing, that is sufficient for all of the co-plaintiffs. *Horne v. Flores*, 129 S.Ct. 2579, 2592-93 (2009) (citing *Arlington Heights v. Metro. Hous. Dev. Corp.*, 429 U.S. 252, 264 & n.9 (1977)). Thus, even if the Court is unsure whether every plaintiff has standing in this case, so long as the Court finds that at least one of the plaintiffs has standing, that is sufficient to defeat defendants' motion to dismiss with respect to all of the plaintiffs.

II. THE COURT HAS PERSONAL JURISDICTION OVER THE OFFICIAL CAPACITY DEFENDANTS

The Court has jurisdiction over the Directors if (1) New York’s long-arm statute permits service of process on them and (2) the assertion of personal jurisdiction does not violate due process. *See, e.g., Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 471-76 (1985). Due process is satisfied if there is general or specific jurisdiction over a defendant. General jurisdiction requires that a defendant have “continuous and systematic” contacts with the forum state. *Helicopteros Nacionales de Colombia, S.A. v. Hall*, 466 U.S. 408, 415-16 (1984). In a DJ patent invalidity action, specific jurisdiction exists if: (1) the defendant purposefully directed its

activities at residents of the forum; (2) the claim arises out of or relates to those activities; and, (3) the assertion of personal jurisdiction is reasonable and fair. *Breckenridge Pharm., Inc. v. Metabolite Labs., Inc.*, 444 F.3d 1356, 1363 (Fed. Cir. 2006). Plaintiffs need only make a *prima facie* showing that the Directors are subject to personal jurisdiction and “the pleadings and affidavits are to be construed in the light most favorable” to plaintiffs, because discovery has not yet been conducted. *Avocent Huntsville Corp. v. Aten Int’l Co.*, 552 F.3d 1324, 1329 (Fed. Cir. 2008).

A. Because The Directors Were Sued In Their Official Capacities, The Court Should Determine Whether There Is Personal Jurisdiction Over The State Entities, Not The Directors Individually

Defendants treat the claims against the Directors as if they were brought against the Directors as individuals, in their personal capacities. That is not the case. This lawsuit was brought against the Directors in their official capacities, pursuant to the Supreme Court’s decision in *Ex parte Young*, 209 U.S. 123 (1908). That distinction is critical. Under the *Young* doctrine, state officials are treated as private (non-state) actors for Eleventh Amendment sovereign immunity issues, but as the state for other purposes. *See, e.g., Home Tel. and Tel. v. Los Angeles*, 227 U.S. 278, 283-84 (1913); *Florida Dep’t of State v. Treasure Salvos, Inc.*, 458 U.S. 670, 697 (1982). Because an official capacity suit “is not a suit against the official but rather is a suit against the official’s office,” *Will v. Michigan Dep’t of State Police*, 491 U.S. 58, 71 (1989), official capacity defendants may assert only those defenses available to the state entity, not personal defenses. *See, e.g., Kentucky v. Graham*, 473 U.S. 159, 167 (1985); *Owen v. City of Independence*, 445 U.S. 622 (1980).

Indeed, state officials sued in their official capacities need not be identified by name and

are automatically replaced as parties by their successors, and any relief granted is automatically binding not just on the named individual, but on his or her successor. Fed. R. Civ. P. 17(d); 25(d); *Hafer v. Melo*, 502 U.S. 21, 25 (1991). To consider this case a suit against Mr. Betz, *et. al* personally or to look at Mr. Betz’s willingness to vacation in New York is to miss the thrust of *Ex parte Young*. Thus, for personal jurisdiction purposes, as opposed to Eleventh Amendment purposes, courts should treat an *Ex parte Young* defendant not as a private individual, but as the state entity. *See, e.g., Hafer*, 502 U.S. at 25 (“the only immunities available to the defendant in an official-capacity action are those that the governmental entity possesses”).⁶ Defendants’ personal jurisdiction defense thus turns on whether there is jurisdiction over the state entities, not the Directors as individuals.

Only a few courts have ever had circumstances raising this procedural issue. Those cases are unavailing because they either specifically decline to reach the issue, fail to recognize the issue entirely, or contain internally inconsistent language leaving it unclear whose contacts are being evaluated. *See, e.g., Grand River Enterprises Six Nations, Ltd. v. Pryor*, 425 F.3d 158, 166 & n.2 (2d Cir. 2005) (declining to consider whether the state’s contacts are imputed to the defendants); *Stroman Realty, Inc. v. Antt*, 528 F.3d 382 (5th Cir. 2008) (containing no discussion of the *Ex parte Young* issue); *Stroman Realty, Inc. v. Wercinski*, 513 F.3d 476, 485 (5th Cir. 2008) (inconsistently stating that it would likely be improper to treat the official capacity defendant as an “individual,” but then holding jurisdiction did not exist because, in part, the official, as opposed to the State, did not derive any benefit from her actions in Texas);

⁶ If courts were required to have personal jurisdiction over the named state officials, rather than the state entities, *Ex parte Young* would be severely narrowed, as it would not permit lawsuits to enjoin unconstitutional actions by states if the person whose rights were violated resided in another state. That cannot and should not be the law. *See, e.g., Pennhurst State School & Hosp. v. Halderman*, 465 U.S. 89, 105 (1984) (discussing importance of *Ex parte Young*); *Perez v. Ledesma*, 401 U.S. 82, 110 (1971) (Brennan, J., concurring and dissenting in part) (describing *Ex parte Young* as “indispensable”).

Pennington Seed, Inc. v. Produce Exchange No. 299, 457 F.3d 1334 (Fed. Cir. 2006) (containing no discussion about whose contacts should be examined); *United States v. Ferrara*, 54 F.3d 825, 831 (D.C. Cir. 1995) (expressly declining to rule on the issue).

The only case that has directly addressed the impact of *Ex parte Young* on personal jurisdiction is *Great Western United Corp. v. Kidwell*, 577 F.2d 1256 (5th Cir. 1978), *rev'd* on other grounds, *Leroy v. Great Western United Corp.*, 443 U.S. 173 (1979). In that case, the Fifth Circuit rejected the official capacity defendant's argument that the court did not have jurisdiction over him because he should be treated as the state, stating, "We read *Young* to say that a state official enforcing an unconstitutional statute is an individual defendant and nothing more. Under the reasoning of *Ex parte Young*, the state has no interest in the lawsuit ..." *Id.* at 1265. That interpretation of *Ex parte Young* is at odds with subsequent Supreme Court caselaw, which makes clear that for all but Eleventh Amendment purposes, official capacity suits are to be treated as if they were brought against the state. *Hafer*, 502 U.S. at 26; *Graham*, 473 U.S. at 165-66; *Will*, 491 U.S. 58. The Fifth Circuit has itself noted that its overall personal jurisdiction analysis in *Great Western* is irreconcilable with subsequent Supreme Court decisions. *Wercinski*, 513 F.3d at 488-89. As a result, the *Great Western* decision, which was overturned by the Supreme Court on other grounds, should be disregarded.

B. The Court Has Personal Jurisdiction Over the State Entities

The University of Utah and UURF, the entities for whom the Directors are proxies are amenable to service of process under New York's long-arm statute and exercising jurisdiction over them is consistent with principles of due process.

1. The State Entities Are Amenable to Service of Process Under New York's Long-Arm Statute

General Jurisdiction. New York's C.P.L.R. § 301 confers general jurisdiction over non-resident defendants "who are 'present' within the State by virtue of their 'doing business' here." *McGowan v. Smith*, 52 N.Y.2d 268, 272 (N.Y. 1981). The University of Utah and UURF clearly "do business" in New York on a consistent and regular basis.⁷ The University actively solicits applications from and recruits students and potential faculty members residing in New York, both for its undergraduate and graduate programs. *See, e.g.*, Headcount Enrollment by State of Origin and Academic Level (D. Ravicher Exh. 4) (detailing that for the Autumn 2008 semester, the University had 77 undergraduate students and 57 graduate students from New York). That fact strongly suggests that the University is subject to general jurisdiction. *See, e.g., Hoffritz for Cutlery, Inc. v. Amajac, Ltd.*, 763 F.2d 55, 58 (2d Cir. 1985) ("the solicitation of business in the state" is one of the principal factors for general jurisdiction); *see also Wiwa v. Royal Dutch Petroleum Co.*, 226 F.3d 88, 98 (2d Cir. 2000) (discussing "solicitation").

The University and UURF (through their agents) also attend conferences and meetings in New York. *See, e.g., Alumni Gather in the Big Apple* (D. Ravicher Exh. 5) (discussing meeting in New York attended by University President Michael Young, a UURF Director, and one of the named defendants). The University has also established its presence in New York through the creation of a distinct New York City chapter of its Alumni Association with the express purpose of establishing "ongoing connections" between the University and New York residents and to enable New York residents to "provide service and support to the University and its students."

⁷ UURF and the University should be treated as one and the same, as UURF is simply an instrument of the University operating solely for the University's benefit. *See* University Regulations, Policy 7-002: Patents and Inventions, § III(E) (D. Ravicher Exh. 3).

See New York City Chapter! (D. Ravicher Exh. 6). The University charges money to attend its sponsored events in New York, pays money to New York businesses in connection with expenses associated with these events, enters into contracts with these New York businesses, and, presumably, solicits donations from New York residents at these events and by periodically mailing, emailing and telephoning them. *Id.* (providing a link on the University’s website to purchase tickets to an upcoming event in New York). The Alumni chapter even has a “chapter coordinator” [sic] dedicated to communicating with New York residents. *Alumni Gather in the Big Apple* (D. Ravicher Exh. 5). In view of these facts, there is general jurisdiction over these state entities. *See, e.g., Wiwa*, 226 F.3d at 98 (discussing “solicitation plus” test).⁸

Specific Jurisdiction. Under New York’s C.P.L.R. § 302(a)(1), specific jurisdiction exists if a defendant “transacts any business within the state or contracts anywhere to supply goods or services in the state.” A party “transacts business” when it “purposefully avails [itself] of the privilege of conducting activities within [New York], thus invoking the benefits and protections of its laws.” *McKee Electric Co. v. Rauland-Borg Corp.*, 20 N.Y.2d 377, 382 (N. Y. 1967) (citation omitted). By entering into an exclusive license agreement that permits Myriad to market its products and services in New York and that creates continuing obligations for UURF, the Directors have purposefully availed themselves of the privilege of conducting business in New York as a matter of law. Because the claims in this case are directly related to that license agreement and to defendants’ patent enforcement activities that have occurred within New York, the requisite “articulable nexus” between the cause of action and the business activity is present. *See, e.g., Credit Lyonnais Sec. (U.S.A.), Inc. v. Alcantara*, 183 F.3d 151, 153 (2d Cir. 1999).

⁸ There are undoubtedly additional ties between the University/UURF and New York. If the Court determines that further information is required to find general jurisdiction, plaintiffs should be permitted to conduct limited discovery to uncover additional facts. *See* Plaintiffs’ Motion For Jurisdictional Discovery.

Because defendants are alleged to have violated plaintiffs' constitutional rights, specific jurisdiction also exists under C.P.L.R. §§ 302(a)(2) and 302(a)(3), which provide for jurisdiction over a non-resident who commits a tortious act within New York (§ 302(a)(2)) or outside New York if it causes injury within New York (§ 302(a)(3)). *See, e.g., Rios v. Marshall*, 530 F. Supp. 351, 367 (S.D.N.Y. 1981) (holding that alleged violations of Constitutional rights are tortious acts for the purpose of personal jurisdiction); *Clark v. U.S.*, 481 F. Supp. 1086, 1097 n.12 (S.D.N.Y. 1979), appeal dismissed, 624 F.2d 3 (2d Cir. 1980). There can be no dispute that defendants' actions have caused injury within New York. *See, e.g., DiStefano v. Carozzi N. America, Inc.*, 286 F.3d 81, 84-85 (2d Cir. 2001) (holding that where the first effect of the tort is experienced by the plaintiff determines whether injury was caused in New York). It is also clear that § 302(a)(3)(i) – requiring that defendants “regularly do[] ... business” in New York – or § 302(a)(3)(ii) – requiring that defendants derive substantial revenue from interstate commerce and that they should have expected their actions to have consequences in New York – have also been satisfied. Accordingly, regardless of whether defendant's unconstitutional acts occurred within or outside New York, the Court has jurisdiction under this section as well.

2. Jurisdiction Over The Directors Comports With Due Process

As with New York's long-arm statute, due process requires a defendant's contacts with the forum state to be “continuous and systematic” for general jurisdiction to exist. *Helicopteros*, 466 U.S. at 414-17. For the same reasons as discussed above, that standard is met.

There are also no due process problems with exercising specific jurisdiction over the Directors. The Federal Circuit has established that specific jurisdiction exists over a non-resident patentee in a patent invalidity DJ action where, as here, there are cease and desist efforts and

“other activities,” such as entry into an exclusive license agreement with an entity that markets and sells its products and services in the forum state. *See, e.g., Avocent*, 552 F.3d at 1333-35; *Breckenridge*, 444 F.3d at 1363-66; *Akro Corp. v. Luker*, 45 F.3d 1541, 1546 (Fed. Cir. 1995); *Genetic Implant Systems v. Core-Vent Corp.*, 123 F.3d 1455, 1458-59 (Fed. Cir. 1997). The critical factor is that the license agreement imposes continuing obligations on the patentee, such as the right to enforce or defend the patents, so that there is an ongoing relationship between the patentee and the licensee operating within the forum beyond the receipt of royalty income. *See, e.g., Breckenridge*, 444 F.3d at 1366. If the license agreement creates such continuing obligations, jurisdiction can be created “by the license agreement itself.” *Id.* at 1365 (discussing *Akro*, 45 F.3d at 1546). The personal jurisdiction analysis of a defendant’s contacts with the forum state, thus, turns on “the defendant’s relationship with its exclusive licensee,” not the plaintiff. *Breckenridge*, 444 F.3d at 1365; *see also Akro*, 45 F.3d at 1546-47. Under this doctrine, specific jurisdiction exists here.⁹

The license agreements between Myriad and UURF undoubtedly create such a relationship, providing UURF with continuing obligations.¹⁰ For example, UURF's policy, revealed in its model license terms, is to retain the right to enforce licensed patents and to initiate proceedings regarding them. D. Ravicher Exh. 7. That Myriad has a similar ability to take actions to enforce the patents is obvious from Myriad’s consistent and pervasive enforcement of these patents over the years. *See supra* at Section I.A.2. Because both parties appear to have enforcement obligations for the patents at issue in this lawsuit, the Directors have purposefully directed their activities at New York as a matter of law. *See, e.g., Avocent*, 552 F.3d at 1336.

⁹ There is no dispute that Myriad does business in New York. It both solicits (*Myriad Launches TV Ads*, D. Ravicher Exh. 8) and sells a significant amount of its services to New York residents. D. Ostrer ¶ 5; D. Reich ¶ 4.

¹⁰ Plaintiffs do not have access to the actual licenses between the defendants in this case in order to review them. If necessary, the court should permit discovery regarding them.

Footnote 9 in defendants’ motion to dismiss – not-so-subtly signaling that if the Court grants their personal jurisdiction motion, Myriad would next file a motion to dismiss and/or to transfer the entire case to federal court in Utah on the ground that the Directors are a “necessary and indispensable” party – also suggests that the license agreement imposes continuing obligations on UURF. If UURF had no ongoing obligations under the license, there could be no legitimate argument that the Directors are a necessary or indispensable party. *Prima Tek II, L.L.C. v. A-Roo Co.*, 222 F.3d 1372 (Fed. Cir. 2000). Defendants cannot have it both ways. The fact that Myriad and the Directors are represented by the same attorneys in this action, and filed the same legal brief, further suggests that the license agreement creates the requisite continuing obligations for personal jurisdiction purposes. *Breckenridge*, 444 F.3d at 1367.

Jurisdiction is also appropriate because defendants have sent cease-and-desist letters to plaintiffs, including to the New York plaintiffs. D. Ostrer ¶ 7. Defendants have also sent proposed license agreements to plaintiffs and demanded that plaintiffs enter into them to continue their *BRCA* related activities. *Id.* Defendants have even filed a lawsuit concerning the patents arising out of the activities of two of the plaintiffs. While it was ultimately filed in Utah, not in New York, defendants undertook actions related to that lawsuit in New York. D. Kazazian ¶ 6. Even if these New York-based cease-and-desist efforts are not sufficient on their own to create jurisdiction, they are certainly highly relevant to the inquiry. *See, e.g., Avocent*, 552 F.3d at 1334-35; *Breckenridge*, 444 F.3d at 1366.¹¹

The claims in this suit directly relate to this license agreement between the defendants and their efforts to enforce the patents. *See, e.g., Akro*, 45 F.3d at 1548-49 (“[The patentee’s]

¹¹ That these formal cease-and-desist efforts occurred in the past is not dispositive. *See Genetic Implant Systems*, 123 F.3d at 1458 (that several of the defendant’s forum contacts occurred before the patent at issue was granted is “irrelevant” to the jurisdictional analysis).

exclusive license agreement with [the plaintiff's] local competitor Pretty Products undoubtedly relates to [the plaintiff's] challenge to the validity and enforceability of the '602 patent."). Due process therefore permits the exercise of jurisdiction here unless the Directors have met their burden of demonstrating that other considerations would render it unfair or unjust for the Court to assert jurisdiction over them. *Burger King*, 471 U.S. at 476-77 (listing five factors to consider); *Breckenridge*, 444 F.3d at 1362. Defendants have failed to meet their burden.

C. Myriad And The University Of Utah Cannot Avoid Jurisdiction By Assigning The Patents To UURF

Jurisdiction is also appropriate here because of the judicial distaste for end-runs around jurisdiction through the use of shell patent-holding entities over which jurisdiction is near impossible to achieve. *See, e.g., Dainippon Screen Mfg. Co., Ltd. v. CFMT, Inc.*, 142 F.3d 1266, 1271 (Fed. Cir. 1998) (“[w]hile a patent holding subsidiary is a legitimate creature and may provide certain business advantages, it cannot fairly be used to insulate patent owners from defending declaratory judgment actions in those fora where its parent company operates”).

Myriad was originally a co-owner of each of the *BRCA* patents at issue in this lawsuit. *See, e.g., '282 Patent, Cover*. Myriad later assigned its interest in the patents to UURF.¹² Myriad and UURF then entered into license agreements, giving Myriad back virtually the same rights over the patents it had just assigned to UURF. Regardless of which entity now technically holds the patents, it is clear that Myriad is the real party in interest.

Myriad cannot and does not contest the Court's jurisdiction over it. Instead, Myriad appears to be trying to reach that same result by claiming that there is no jurisdiction over the holding company for the patents (UURF), except in the holding company's (and its) home state

¹² Patent assignment records are available from the USPTO's patent assignment database, *available at* <http://assignments.uspto.gov/assignments/?db=pat>.

of Utah. In this situation, principles of fair play and substantial justice – the hallmarks of personal jurisdiction – clearly favor the exercise of jurisdiction. *See Dainippon Screen*, 142 F.3d at 1273 (asserting jurisdiction in very similar circumstances).

CONCLUSION

For all these reasons, the motion to dismiss made by defendants Myriad and the Directors of UURF should be denied. To the extent any doubt remains, plaintiffs have filed a separate motion for leave to take limited jurisdictional discovery to enable plaintiffs to supplement their showing regarding standing and personal jurisdiction.

Respectfully submitted,

By: /s/ Christopher A. Hansen

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August 26, 2009

DECLARATIONS SUBMITTED HEREWITH

- A. Declaration of Daniel B. Ravicher with attached Exhibits 1-8.
- B. Declaration of Mark Sobel.
- C. Declaration of Madhuri Hegde, PhD attached Exhibit 1.
- D. Declaration of Michael S. Watson, PhD.
- E. Declaration of Wendy Chung, MD, PhD with attached Exhibit 1.
- F. Declaration of John R. Ball.
- G. Declaration of Roger Hubbard, PhD with attached Exhibit 1.
- H. Declaration of John Scott.
- I. Declaration of Jeffrey Kant, MD, PhD attached Exhibit 1.
- J. Declaration of Haig H. Kazazian, Jr., MD attached Exhibit 1.
- K. Declaration of Arupa Ganguly, PhD with attached Exhibits 1-7.
- L. Declaration of Harry Ostrer, MD with attached Exhibits 1-2.
- M. Declaration of David Ledbetter, PhD with attached Exhibit 1.
- N. Declaration of Ellen T. Matloff, MS with attached Exhibit 1.
- O. Declaration of Elsa W. Reich, MS with attached Exhibit 1.
- P. Declaration of Barbara A. Brenner.
- Q. Declaration of Judy Norsigian.
- R. Declaration of Lisbeth Ceriani.
- S. Declaration of Runi Limary.
- T. Declaration of Genae Girard.
- U. Declaration of Patrice Fortune.
- V. Declaration of Vicky Thomason.

W. Declaration of Kathleen Raker.