



MARQUETTE
UNIVERSITY

December 7, 2010

Clerk of the Court
United States Court of Appeals For the Federal Circuit
717 Madison Place
Washington D.C. 20439

Re: *The Association for Molecular Pathology, et. al, v. United States Patent Office and Myriad Genetics, et. al*, No. 2010-1406.

Dear Mr. Horbaly:

Please accept for filing one signed version and twelve copies of Brief of Amici Curiae Erika R. George and Kali N.Murray In Support of the Association of Molecular Pathology, Et. Al., along with a relevant Entry of Appearance, for filing in the above-mentioned matter.

Please let me know if there are any additional concerns.

Yours truly,

A handwritten signature in black ink that reads "Kali N. Murray".

Kali Murray
Asst. Prof. of Law
Marquette University

CC: Chris Hanson, Gregory Constantias, et. al.

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,

and

LORRIS BETZ, ROGER BOYER, JACK BRITAIN, ARNOLD B.
COMBE, RAYMOND GESTELAND, JAMES U. JENSEN, JOHN

KENDALL MORRIS, THOMAS PARKS, DAVID W. PERSHING,
(caption, continued)

and MICHAEL K. YOUNG, in their official capacity as Directors
of the University of Utah Research Foundation,
Defendants-Appellants.

*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.*

**BRIEF OF AMICI CURIAE ERIKA R. GEORGE AND KALI
N. MURRAY IN SUPPORT OF THE ASSOCIATION FOR
MOLECULAR PATHOLOGY, ET. AL**

Erika R. George,
Visiting Professor of Law
Loyola University Chicago
School of Law
25 E. Pearson
Chicago, IL 60611
(312) 915-7120
*Counsel for Amici Curiae Erika
R. George and Kali N. Murray*

United States Court of Appeals for the Federal Circuit
The Association for Molecular Pathology, et. al. v. United States
Patent and Trademark Office, et. al.
No. 2010-1406

CERTIFICATE OF INTEREST

Counsel for the *Amicus Curiae* certifies the following:

1. The full names of every party or amicus represented by me is: **Erika R. George and Kali N. Murray.**
2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is: **NONE.**
3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of *amicus curiae* represented by me are: **NONE.**
4. The names of all law firms and the partners or associates that appeared for the amicus curiae now represented by me in the trial court or agency or that are expected to appear in this Court are: **NONE.**

Date: December 7, 2010



Signature of Counsel

Erika R. George

*Counsel for Amici Curiae Erika
R. George and Kali N. Murray*

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STATEMENT OF INTEREST OF AMICI

Amici submit this brief as *amicus curiae* pursuant to Fed. R. App. P. 29 (a) and Rule 29 of this Court. Amici are professors of law at law schools in the United States. They have concentrated their academic work in patent law, civil procedure, and constitutional law. Given their expertise in these areas, amici offer the Court a unique perspective with respect to the issues presented in the litigation.

Erika R. George is a Visiting Professor of Law at Loyola University Chicago School of Law. She teaches Civil Procedure and Constitutional Law among other subjects. She has written in the area of constitutional law.

Kali N. Murray is an Assistant Professor of Law at Marquette University Law School where she teaches Patent Law among other subjects. She has written on the standing of public interest groups under the Patent Act of 1952, the Administrative Procedure Act and the Declaratory Judgment Act.

Amici, pursuant to Rule 29(c) of the Court, certify, that all relevant parties have consented to the filing of this brief.

SUMMARY OF ARGUMENT

A person, whose invention or discovery, is a useful “process, machine, manufacture, composition of matter”, or any new and useful improvement” of the same may obtain a patent, *see* 35 U.S.C. § 101, unless the patent is one that claims information that concerns the “laws of nature, physical phenomena, and abstract ideas.” *Bilski v. Kappos*, 130 S. Ct. 3218, 3325, 177 L.Ed. 792, 95 U.S. P.Q.2d 1001 (2010). These exceptions remain a key “threshold” inquiry, *see* 130 S.Ct. at 3225, under Section 101 because these exceptions protect information that is “alike open to all”, *Le Roy v. Tatham*, 14 How. 156, 175 (1853), and thus, should not removed from “the storehouse of knowledge of all men.” *Funk Bros. Seed. Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 131 (1948). These exceptions exist, then, to prevent “monopolies of expression” that may prevent searching inquiry in variety of expressive contexts, such as the scientist’s laboratory, or the intimacy of a doctor’s office. *See* David Lange and H. Jefferson Powell, *No Law: Intellectual Property in the Image of An Absolute First Amendment* 305 (2009). Therefore, under those circumstances, where judicial consideration of an inventive claim involves one of the relevant

exceptions, an appropriate element of a Section 101 inquiry, may be to determine its impact on the expressive elements associated with a patent under the First Amendment of the Constitution.

The various plaintiffs, within the context of their declaratory judgment action have alleged a number of significant harms. First, the research organizations at issue have claimed that Myriad's enforcement of its patents in basic genetic information prevents their members from undertaking academic inquiry into the relevant claims of Myriad's respective patents. Second, the individual researchers and clinicians claim that Myriad's enforcement of its patents has chilled research and compromised communications with patients. Finally, the individual plaintiffs themselves are denied access to information important for making crucial medical decisions with respect to an appropriate course of care in consultation with their health care providers. The District Court's exercise of jurisdiction below was proper because under totality of circumstances, the limits placed on the Plaintiffs' freedom of expression presented by continued validity of Myriad's patents establish a substantial controversy between the adverse legal interests between the parties of sufficient

immediacy and reality to warrant judgment.

ARGUMENT

I. This Circuit Must Examine The District Court's Exercise of Jurisdiction Under the Declaratory Judgment Act, Under the Totality of Circumstances, Which Includes the Collective Plaintiffs' Claims Under the First Amendment.

This Court has followed the Supreme Court's holding in *MedImmune, Inc., v. Genentech, Inc.*, 549 U.S. 118 (2007) (citing *Maryland Casualty Co. v. Pacific Coal & Oil Co.*, 312 U.S. 270, 273 (1941)), which provides that actions brought under the Declaratory Judgment Act, 28 U.S.C. § 2201(a) (2006), should be examined to determine “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.” *Id.* at 127. Since *Med-Immune*, this Court has adopted a “totality of circumstances” standard to assess whether a case or controversy exists under the Declaratory Judgment Act. *Cat Tech, LLC. V. Tube Master, Inc.*, 528 F.3d 871, 880 (Fed. Circ. 2008) (“The Court explained that whether a declaratory judgment action contains an Article III controversy must be

determined based on “all the circumstances.”) The “totality of circumstances” test is a flexible approach that allows this Court to consider multiple factors in its jurisdictional approach. *See, e.g., Cat Tech*, 528 F.2d at 881 (a factor to be considered under the “totality of circumstances” is “meaningful preparation to conduct potentially infringing activity”); *Prasco, LLC., v. Medicis Pharmaceutical, Corp.*, 537 F.3d 1329, 1336 (Fed. Cir. 2008)(a factor to be considered under the “totality of circumstances” test is “a reasonable apprehension of suit.”)

We contend, here, that a significant factor to be examined as to whether the District Court’s jurisdictional approach should be upheld, amongst the other factors, is the collective Plaintiffs’ claim that Myriad’s enforcement of its patents rights, under Section 101, violates their First Amendment rights (as discussed in more detail, *supra*, below). Initially, such an inquiry would be consistent with this Court’s flexible inquiry under the “totality of circumstances” test. Moreover, the First Amendment has been increasingly been understood to be relevant to threshold inquiry of Section 101. For instance, as Justice Mayer of this Court suggests in his dissent in *In re*

Bilski, problematic patents, such as so-called “business method” patents, can raise a substantial claim under the First Amendment, because such patents allow:

private parties to claim exclusive ownership of ideas and practices which rightfully belong in the public domain. “It is a matter of public interest that [economic] decisions, in the aggregate, be intelligent and well informed. To this end, the free flow of commercial information is indispensable.”

Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc., 425 U.S. 748, 765, 96 S.Ct. 1817, 48 L.Ed.2d 346 (1976). Thus, “the stringent requirements for patent protection seek to assure that ideas in the public domain remain there for the free use of the public.” *Aronson v. Quick Point Pencil Co.*, 440 U.S. 257, 262, 99 S.Ct. 1096, 59 L.Ed.2d 296 (1979).

In re Bilski, 545 F.3d 943, 1008 (2008)(Mayer, J., dissenting);

Laboratory Corp. of America Holding v. Metabolite Laboratory, et. al., 548 U.S. 124, 128 (2006)(Breyer, J.,dissenting (Exceptions to Section 101 “reflects a basic judgment that protection in such cases, despite its potentially positive incentive effects, would too often severely interfere with, or discourage, development and the further spread of useful knowledge itself.”))

Notably, the standing of parties, under the Declaratory Judgment Act or otherwise, to raise the First Amendment, is

understood to be broad. Courts have been vigilant in barring impediments to freedom of expression to facilitate the “free trade in ideas” and promote competition in the “marketplace of ideas.” *Abrams v. United States*, 250 U.S. 616, 630 (1919). Accordingly, First Amendment jurisprudence disfavors laws, policies and practices that would block access to the marketplace of ideas or diminish the information and ideas that make it into the market. In interpreting the First Amendment, the Supreme Court, as well as other circuit courts, has expanded the availability of standing where restraints exist that risk “chilling” the right of free expression. *Virginia v. American Booksellers, Ass’n, Inc.*, 484 U.S. 383, 384 (1988)(pre-enforcement standing and exception to “injury in fact” requirement granted where booksellers alleged an infringement of the First Amendment rights of book buyers); *Sec’y of State of Md. V. Joseph H. Munson Co.*, 467 U.S. 947, 956 (1984) (“When there is a danger of chilling free speech, the concern that constitutional adjudication be avoided whenever possible may be outweighed by society's interest in having a statute challenged and litigants may then assert the rights of others.”); *Ward v. Utah*, 321 F.3d 1263, 1267 (10th Cir. 2003)(Activist

suffered requisite “injury in fact” to have standing where claim to injury was threat of future prosecution under a hate-crimes statute and activist alleged an intention to engage in a course of conduct arguably affected with a constitutional interest, but proscribed); *Mangual v. Rotger-Sabat*, 317 F.3d 45, 57 (1st Cir. 2003) (“As to whether a First Amendment plaintiff faces a credible threat of prosecution, supporting standing, the evidentiary bar that must be met is extremely low: courts will assume a credible threat of prosecution in the absence of compelling contrary evidence”).

Two circumstances demonstrate the relatively lenient standard as to standing within the context of the First Amendment. First, plaintiffs may bring a pre-enforcement challenge where constitutional interests are at stake. *Doe v. Bolton*, 410 U.S. 179, 188 (1973) (“Plaintiffs may have standing even if they have never been prosecuted or actively threatened with prosecution.”); *Berner v. Delahanty*, 129 F.3d 20, 24 (1st Cir. 1997)(standing to seek declaratory relief where “parties remain[ed] philosophically on a collision course” and plaintiff would continue conduct in controversy, but for policy prohibiting the conduct). Great weight is to be given to the danger of

self-censorship because of the potential ‘chilling’ effect a measure may have on protected activity. *LSO, Ltd. v. Stroh*, 205 F.3d 1146, 1156 (9th Cir. 2000) (“We have noted that the tendency to find standing absent actual, impending enforcement against the plaintiff is stronger “in First Amendment cases, ‘[f]or free expression-of transcendent value to all society, and not merely to those exercising their rights-might be the loser.” (*citations omitted*) Indeed, a “First Amendment plaintiff who faces a credible threat of future prosecution suffers from an ‘ongoing injury resulting from the statute’s chilling effect on his desire to exercise his First Amendment rights.’” *Ward*, 321 F.3d at 1267 (quoting *Wilson v. Stocker*, 819 F.2d 943, 946 (10th Cir. 1987)).

Courts have even recognized injury sufficient to sustain standing in the First Amendment context where plaintiffs claim that they have forgone expression so as to avoid the consequences of enforcement.

Pittman v. Cole, 267 F.3d 1269, 1283 (11th Cir. 2001) (“Plaintiffs do not have to expose themselves to enforcement in order to challenge a law. Rather, an actual injury can exist when the plaintiff is chilled from exercising her right to free expression or forgoes expression in order to avoid enforcement consequences. In such an instance, which is what is

alleged here, the injury is self-censorship”). Indeed, the Supreme Court has recognized that a potentially coercive threat may be associated with the claim of an enforcement of a patent, even where the claimed action is between two private parties. *See MedImmune*, 549 U.S. at 130-35.

Second, a plaintiff may bring a declaratory judgment action where a First Amendment claim is prompted by an actual existence of a controversy. *See, e.g., Steffel v. Thompson*, 415 U.S. 452, 458-59 (1974) (“actual controversy” within the meaning of the Declaratory Judgment Act where the threat of prosecution for distributing handbills was not imaginary or speculative); *New York Times v. Gonzales*, 459 F.3d 160, 167 (2nd Cir. 2006) (no abuse of discretion in entertaining declaratory judgment action where First Amendment at issue and declaration would finalize controversy).

Here, the collective Plaintiffs’ claims range from a pre-enforcement challenge to actual threat of enforcement. While under some circumstances, these claims would not be sufficient under this Court’s “totality of circumstances” standard, *see Innovative Therapy, Inc., v. Kinetic Concepts, Inc.*, 599 F.3d 1377, 1380-1383 (Fed. Cir.

2010), the broad standards typically associated with claims brought under the First Amendment suggest the necessity of a different result under the circumstances alleged by the collective Plaintiffs. This is particularly true, as the Justice Ginsburg, noted in *Eldred v. Ashcroft*, 537 U.S. 186, 217 (2003), the governmental grant of a patent does differ in kind from the grant of a copyright, insofar as the grant of a patent prevents the “full use by others of the inventor’s knowledge.” Therefore, it is only appropriate (as may be the case here), within the context of a Section 101 “threshold” inquiry to ensure that the governmental grant of a patent does not unduly limit the First Amendment rights of others.

II. The District Court Properly Exercised Declaratory Judgment Jurisdiction since Myriad’s Alleged Acts Violate the First Amendment Rights of the Plaintiffs and Establish the Existence of Adverse Legal Interests Between the Parties that are in Real and Immediate Controversy.

A controversy exists between the parties not only because Myriad has previously taken action to protect against infringement of its patents (A35-36; A61-62; A2850-52; A2888-93;) and the plaintiffs are presently prepared to take infringing action (A64-71; A1283); but also

because the plaintiffs have been deterred from engaging in further inquiry and have ceased certain constitutionally protected communicative conduct to avoid infringing the patents at issue. (A2773-74; A2979-80; A1284, A2676-74; A7271-73; A2777, A2937-38; A2982-83; A3037-38; A1284).

A. Myriad and the Collective Plaintiffs Have Adverse Legal Interests.

1. The Plaintiff Physicians and Patients Enjoy a Protected Freedom of Expression in the Physician-Patient Relationship that is Compromised by Myriad's Patents.

The First Amendment “right to receive information” is central to a “threshold” inquiry under Section 101. Numerous Supreme Court cases allude to a right to receive information grounded in the First Amendment of the U.S. Constitution. “The right to know or to hear or receive information, is in theory one of the principal underpinnings of the First Amendment, but it has usually remained in the shadows of legal battles over free speech and press.”¹ The Supreme Court’s holding in *Virginia State Bd. of Pharmacy v. Virginia Citizens*

¹*American Meat Institute v. Ball*, 424 F.Supp. 758, 769 -770 (D.C. Mich. 1976)

Consumer Council, Inc., remains a frequently cited case that supports the right to receive information. There, the Court clearly articulates that the First Amendment protection enjoyed by advertisers seeking to disseminate information is also enjoyed by and could be asserted by consumers. *Id.* at 782.²

The “right to receive information” presumes that the freedom of expression protects the exchange of ideas and information.

Accordingly, the First Amendment protects communication “to its source and to its recipients both.”³ Another important point is that

²The Supreme Court also recognized the right to receive information before *Virginia State Bd. of Pharmacy*. See *Procunier v. Martinez*, 416 U.S. 396, 408-09 (1974) (overruled on other grounds) (censorship of prison inmates' mail infringed the rights of non-inmates to whom mail was addressed); *Kleindienst v. Mandel*, 408 U.S. 753, 762-65 (1972) (American scholars have right to hear, speak, and debate alien Marxian theoretician with no personal entry right); *Red Lion Broadcasting Co. v. FCC*, 395 U.S. 367, 386-90 (1969) (public has right to receive suitable access to social, political, esthetic, moral and other ideas through broadcast media); *Stanley v. Georgia*, 394 U.S. 557, 564 (1969) (right to receive information and ideas extends to possession of obscene materials in one's own home); *Lamont v. Postmaster Gen.*, 381 U.S. 301 (1965) (citizens have First Amendment right to receive communist political publications from abroad).

³*Virginia State Bd. of Pharmacy*, 425 U.S. at 756 (U.S. 1976) (“Freedom of speech presupposes a willing speaker. But where a speaker exists, as is the case here, the protection afforded is to the

“[t]his right [to receive] is an inherent corollary of the rights of free speech. . . the right to receive ideas follows ineluctably from the *sender’s* First Amendment right to send them.”⁴ But this right is “a necessary predicate to the *recipient’s* meaningful exercise of his own rights of speech, press, and political freedom.”⁵

Some courts have conditioned the right to receive on the presence of a willing speaker. In *Pennsylvania Family Institute v. Black*, the court finds no violation of a “right to listen” when there is no “willing speaker.”⁶ Here, willing speakers exist among the plaintiffs who wish to share information (A3034-25; A3036-40; A1284; A7-17; A2775-77), so even if the right to receive is understood as only derivative as extended to patients, it can be derived from those of researchers and physicians.

An early formulation of the right to receive information was advanced in the context of the physician-patient relationship. In

communication, to its source and to its recipients both.”) (footnote omitted).

⁴*Board of Educ., Island Trees Union Free School Dist. No. 26 v. Pico*, 457 U.S. 853, 867 (1982) (emphasis in original).

⁵ *Id.* (emphasis in original).

⁶489 F.3d 156, 165 (3rd Cir. 2007).

Griswold v. Connecticut, the Supreme Court held the “right of freedom of speech and press includes not only the right to utter or to print, but [also] . . . the right to receive . . .”⁷ In *Kleindienst v. Mandel*, the Supreme Court opined that “in a variety of contexts this Court has referred to a First Amendment right to ‘receive information and ideas’” and that “[i]t is now well established that the Constitution protects the right to receive information and ideas.”⁸

The right to receive information, then, is a “fundamental right” because a market of sellers alone becomes one that is “barren” of exchange.⁹ Simply put, “[i]t is the purpose of the First Amendment to

⁷ 381 U.S. 479, 482-83 (1965) (“The right of freedom of speech and press includes not only the right to utter or to print, but the right to distribute, the right to receive, the right to read and freedom of inquiry, freedom of thought, and freedom to teach -indeed the freedom of the entire university community. Without those peripheral rights the specific rights would be less secure. And so we reaffirm the principle of the *Pierce* and the *Meyer* cases.”) (citations omitted).
⁸408 U.S. 753, 762-63 (1972).

⁹ *Lamont v. Postmaster General*, 381 U.S. 301, 308 (1965) (concurring, Brennan) (citations omitted) (“It is true that the First Amendment contains no specific guarantee of access to publications. However, the protection of the Bill of Rights goes beyond the specific guarantees to protect from congressional abridgment those equally fundamental personal rights necessary to make the express guarantees fully meaningful. I think the right to receive publications is such a fundamental right. The dissemination of ideas can accomplish nothing

preserve an uninhibited marketplace of ideas in which truth will ultimately prevail, rather than to countenance monopolization of that market, whether it be by the Government itself or a private licensee.”¹⁰

The First Amendment protects recipients’ rights regardless of the social worth of that information. Indeed, even information that could potentially harm others is constitutionally protected.¹¹

The Supreme Court has rejected restraints on freedom of

if otherwise willing addressees are not free to receive and consider them. It would be a barren marketplace of ideas that had only sellers and no buyers.”).

¹⁰*Red Lion Broadcasting Co. v. FCC*, 395 U.S. 367, 390 (1969) (citations omitted) (“It is the purpose of the First Amendment to preserve an uninhibited marketplace of ideas in which truth will ultimately prevail, rather than to countenance monopolization of that market, whether it be by the Government itself or a private licensee. . . . It is the right of the public to receive suitable access to social, political, esthetic, moral, and other ideas and experiences which is crucial here. That right may not constitutionally be abridged either by Congress or by the FCC.”).

¹¹*Stanley*, 394 U.S. at 564 (“It is now well established that the Constitution protects the right to receive information and ideas. ‘This freedom (of speech and press) * * * necessarily protects the right to receive * * *.’ This right to receive information and ideas, regardless of their social worth, is fundamental to our free society.”) (citations omitted); *Reno v. ACLU*, 521 U.S. 844, 846 (1997) (citations omitted) (“Although the Government has an interest in protecting children from potentially harmful materials, the CDA pursues that interest by suppressing a large amount of speech that adults have a constitutional right to send and receive.”).

expression that would place physicians in an “undesired and uncomfortable straightjacket.” *Planned Parenthood of Missouri v. Danforth*, 428 U.S. 52, 67 (1976). Because it remains the responsibility of physicians to ensure that appropriate information is conveyed to their patients based on the condition of the patient, *City of Akron v. Akron Center for Reproductive Health*, 462 U.S. 416, 443 (1983) the Supreme Court has consistently cleared “obstacles in the path of the doctor” upon whom patients are entitled to rely for advice in connection with health care decisions. *Id.* (citing *Whalen v. Roe*, 429 U.S. 589, 604 n. 33 (1977)). In the physician-patient relationship, patients expect that physicians will not withhold relevant information regarding care options and consequences. *Rust v. Sullivan*, 500 U.S. 173, 211 n. 3 (1990) (Blackmun, J. dissenting) (“in our society, the doctor-patient dialogue embodies a unique relationship of trust...each of us attaches profound importance and authority to the words of advice spoken by the physician.”) *Id.* at 218.

In *Conant v. Walters*, a recent case where, as here, the interest in information exchange in the context of the physician-patient relationship was adverse to other legal interests, the Court of Appeals

for the Ninth Circuit upheld the issuance of an injunction to protect First Amendment rights. In *Conant*, the controversy was, *inter alia*, over a statutory prohibition on the ability of doctors to offer counsel as to the use of medical marijuana to their patients. Writing in concurrence, Judge Kozinski noted that “the right to hear-the right to receive information-is no less protected by the First Amendment than the right to speak” as “the right to hear and the right to speak are flip sides of the same coin.”¹² However, “the harm to patients from being denied the right to receive candid medical advice is far greater than the harm to doctors from being unable to deliver such advice.”¹³ where “for patients who suffer from horrible disabilities enforcement of federal policy [would] cut such patients off from competent medical advice and leave them to decide on their own”¹⁴

Conant is instructive here because the plaintiffs seeking to share information about the predisposition to breast or ovarian cancer allege they have been constrained by an improvidently granted federal patent that permits Myriad to enforce its legal interests. (A1284).

¹² *Conant v. Walters*, 309 F.3d 629, 643 (9th Cir. 2002).

¹³ *Id.*

¹⁴*Id.* at 644.

While researchers and physicians would like to offer gene testing, they are ultimately constrained by patent restrictions. (A149; A151; A1284).

Patients are left to make decisions on their own from a position of uncertainty without the benefit of full information because of various barriers to accessing the genetic testing offered exclusively through Myriad. (A20-25; A 1594-95; A1598-99; A1602-3; A1606-7; A1610-11; A1614-17; A160; A2652; A2937-38; A3065; A3072-73; A3077; A2851).

While cancer patients may seek information from other sources, any such sources would be “poor substitutes for a medical doctor; information from chat rooms and tabloids cannot make up for the loss of individualized advice from a physician with many years of training and experience.”¹⁵

B. Plaintiff's Allegations Demonstrate a Controversy of Sufficient Immediacy and Reality Under The Totality of the Circumstances.

Myriad, in its primary brief, argues that its past actions and plaintiffs' subjective fears are not sufficient to establish jurisdiction. Br. Appellant at 22-24. The past actions of Myriad, though constitute a real, immediate and sufficient threat to warrant for declaratory relief

¹⁵ *Id.*

in this context. Myriad's actions have an actual chilling effect on communications between researchers, physicians and their patients.

Courts evaluate a variety of factors to determine whether a plaintiff faces a realistic threat of direct injury to confer standing in the First Amendment context. *LSO, LTD v. Strogh*, 205 F.3d 1146, 1155 (9th Cir. 2000). These factors include: (1) evidence of past enforcement; (2) the continuing present adverse effects of any such efforts; and (3) the injury of self-censorship, if the plaintiff is chilled from exercising the right to self censorship. *Id.* (standing where officials did not expressly disavow intent to impose sanctions on plaintiffs); *Pittman*, 267 F.3d at 1283. Enforcement history alone, though, is not dispositive. For instance, the Supreme Court in *Virginia v. American Booksellers*, found standing because First Amendment rights were implicated even though the challenged provisions had never been enforced against anyone. 484 U.S. at 393.

A number of these factors exist here. First, Myriad's affirmative actions in the past inform the plaintiffs' perception of the potential risks associated with infringement and the assertion by Myriad of its legal interest. The District Court found the record established that

“within the research community...Myriad has taken the position that any BRCA1/2 related activity infringes its patents and that Myriad will assert its patent rights against parties engaging in such activity.” (A63-64). In the context of First Amendment abridgment “[h]arm to free speech rights...[are] not measured solely in economic terms, nor must concrete punishment be meted out to confer standing to sue. The right to speak one’s views freely is so fundamental that the spectre of punishment, or the uncertainty created...is injurious as well.” *Mallick v. International Brotherhood of Electrical Workers*, 644 F.2d 228, 235 (3rd Cir. 1981).

Second, Myriad’s previous affirmative actions have “chilled” specifically, the freedom of expression enjoyed by patients and physicians. The plaintiffs here are not just researchers but serve in a dual capacity as clinicians as well with responsibility to care for patients. This is a relationship where communication is crucially important. Here, chill is evidenced by physician’s silence on matters of importance to patients, prompted by a fear of induced infringement under the Patent Act. Indeed, at least one of the plaintiffs’ that she is unable to make disclosures to her patients. (A13).

Myriad makes much of its past actions being in the past, but the present looks as it does because Myriad's conduct has chilled physicians into a self-induced silence. Myriad need not take affirmative actions today because their conduct yesterday was so effective as to stop any significant effort to share information among the plaintiffs. The credible threat of present or future prosecution itself works an injury in the First Amendment context sufficient to confer standing. *Minnesota Citizens Concerned for Life v. Federal Election Commission*, 113 F.3d 129, (8th Cir. 1997).

Far from having a subjective fear over what Myriad may do, the plaintiffs have actually changed their conduct because of what Myriad did and may do in the future. (A1284; A2773-74; A2979-80). The consequences of Myriad's conduct to enforce its legal interests have created a specific and present objective adverse legal interest. Specifically, Myriad has created an impediment to free and full information and communication sharing in the care relationship between patients at genetic risk for cancer and the physicians who coordinate their diagnosis and treatment. Allegations are not of a subjective chill but rather an actual freeze as the collective Plaintiffs

in interest claim to have changed their conduct in accord with the risk posed by Myriad. (A1284; A2650; A2753; A2775;A2813; A2828; A2850-51; A2888-92; A2934-36; A2978-81;A3022; A3035-36). Plaintiffs remain without express assurances that no action will be taken by Myriad. Br. Appellant at 33 n.12.

It is, in this context, immaterial that Myriad's prior litigation did not name any of the present plaintiffs in this action because, as discussed *infra*, courts have treated standing under the First Amendment under a lesser degree of scrutiny, given the fundamental rights at stake. Risk of chilling the dissemination of information is an immediate reality. The Complaint specifically alleges that the risk of Myriad's enforcement constrains conversations between patients and physicians.¹⁶ (A13).

First Amendment claims are different such that plaintiffs here are injured when it is widely understood that Myriad may assert its patent rights against parties engaged in sharing information concerning breast or ovarian cancer predisposition, yet they cannot

¹⁶The District Court specifically noted that “[b]ecause of the patents-in-suit, Dr. Chung does not tell the research subjects in her studies the results of the analysis of their BRCA genes.” (A13).

know when they are at risk of running afoul of Myriad's rights.

Similarly, that Myriad says it "*may* never sue the plaintiffs at all", Br. Appellant at 29, is particularly troubling in this context as it operates only to continue the uncertain circumstances of the collective plaintiffs here because the adverse legal interests alleged are First Amendment claims.

Plaintiffs have alleged more than "an inchoate desire to do something in the future if these patents are invalidated" as Myriad represents. *See* Br. Appellant at 21. Plaintiffs here have their lives at stake and the desire to make informed decisions about care and treatment. The immediate and real injury is the impediment the ongoing validity of the Myriad patents place on freedom of expression in the patient-physician relationship. This lack of access to information can be traced to Myriad's coercive conduct.

III. The District Court Properly Applied the "All the Circumstances" Test.

For the reasons detailed above, the District Court did not (as Myriad argues) improperly expand the "all the circumstances" test. The District Court properly applied the test given that the continuing

validity of Myriad's patents may curtail freedom of expression in the critical relationship between physician and patient.¹⁷

The plaintiffs are in precisely the situation the Declaratory Judgment Act was designed to address. It is not sufficient for Myriad to say that it "may never sue at all" in the context of an First Amendment claim. *See* Br. Appellant at 29. Here, Myriad's affirmative act is to place physicians in the position of practicing medicine and conducting research under the sword of Damocles. The uncertainty over whether or not Myriad will enforce its patents make its coercive action continuous and places the plaintiffs in ever-present peril.

Myriad's suggestion that "this is a manufactured controversy

¹⁷The District Court's determination, however, that a theory of constitutional avoidance precluded review, once jurisdiction was appropriate, may have been in error. (*see, e.g.*, A242-44) As discussed *infra*, we contend that a First Amendment inquiry is an aspect of the Section 101 inquiry, and so therefore, should have been considered within the scope of the District Court's determination. Here the constitution is inescapably at issue because the determination that the patents were invalid is at its essence a constitutional issue. Myriad's patents are invalid because the information they permit Myriad to withhold from others remains outside the scope of patentable subject matter yet it remains within the scope of what is protected by the First Amendment where there is a strong preference for the dissemination of information and ideas.

with recruited plaintiffs” bent on advancing the agenda of “public advocacy groups effort to use the courts to dictate public policy on DNA patents” precisely misses the point. (Myriad Br. at 30) Courts have permitted pre-enforcement challenges finding in the First Amendment context injury sufficient to confer standing where, as here, there is a credible threat of present or future liability. *See, infra*.

CONCLUSION

For the foregoing reasons, the judgment of the district court should be affirmed in part and remanded for further determination of the First and Fourteenth Amendment Claims.

United States Court of Appeals for the Federal Circuit
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and Trademark Office, et. al.
No. 2010-1406

Fed. R. App. P. 32(a) (7)(C) Certificate of Compliance

I hereby certify, pursuant to Fed. R. App. 32 (a)(7)(C), the Brief of Amici Curiae, Erika R. George and Kali N. Murray, contains 5,135 words, including footnotes, headings, and quotations, but not including the cover page, table of contents, table of authorities, and certificates, which was derived using the word count function of the word processing system (Microsoft Word) used to prepare the brief.

Dated: December 7, 2010

Respectfully submitted,



Erika George, Visiting Professor
Loyola University Chicago
School of Law
25 E. Pearson
Chicago, IL 606011
*Counsel for Amici Curiae Erika
R. George and Kali N. Murray*

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Certificate of Service

I hereby certify that on this 7th day of December, 2010, I caused twelve true and correct copies of the foregoing Brief for Amici Curiae Erika R. George and Kali N. Murray to be mailed to the Court via third party postal service and for an electronic copy of the Brief to be served upon the following counsel of record listed below via e-mail on December 8, 2010.

Christopher A. Hansen
American Civil Liberties Union
125 Broad Street, 18th Floor
New York, NY 10004
chansen@aclu.org
Counsel for Plaintiffs-Appellees

Gregory A. Castanias
Jones Day
51 Louisiana Avenue, N.W.
Washington, D.C. 20001
gcastanias@jonesday.com
Counsel for Defendants-Appellants

Mary M. Calkins
Foley and Lardner
3000 K Street, N.W., Suite 500
Washington, DC 20007
*Counsel for Amicus Alnylam
Pharmaceuticals*

Barbara R. Rudolph
Finnegan, Henderson, Farabow,
Garrett & Dunner
901 New York Avenue, N.W.
Suite 1100
Washington, DC 20001-4413
*Counsel for Amicus American
Intellectual Property Law
Association*

Seth P. Waxman
Wilmer Hale
1875 Pennsylvania Avenue,
N.W.
Washington, DC 20006
*Counsel for Amici Biotech
Industry Organization et al.*

Erik P. Belt
McCarter & English
265 Franklin Street
Boston, MA 02110

*Counsel for Amicus Boston
Patent Law Association*

Christopher M. Holman
5100 Rockhill Road
Kansas City, MO 64110
*Counsel for Amici Christopher
Holman et al.*

Jennifer Gordon
Baker Botts
30 Rockefeller Center
New York, NY 10112
*Counsel for Amicus Croplife
International*

Maxim H. Waldbaum
Schiff Hardin
900 Third Avenue, 23rd Floor
New York, NY 10022
*Counsel for Amicus Fédération
Internationale des Conseils en
Propriété Industrielle (FICPI)*

David S. Forman
Finnegan, Henderson, Farabow,
Garrett & Dunner
901 New York Avenue, N.W.
Washington, DC 20001-4413
*Counsel for Amicus Genetic
Alliance*

William G. Gaede, III
McDermott, Will & Emery
275 Middlefield Rd., Suite 100
Menlo Park, CA 94025
*Counsel for Amici Genomic
Health et al.*

J. Timothy Keane
Harness, Dickey & Pierce
7700 Bonhomme Avenue, Suite
400
St. Louis, MO 63105
*Counsel for Amici Gilead
Sciences et al.*

Herbert C. Wamsley
McDonnell, Boehnen, Hulbert &
Berghoff
300 South Wacker Drive
Chicago, Illinois 60606
*Counsel for Amicus Intellectual
Property Owners Association*

Brian R. Dorn
Merchant & Gould
80 South 8th Street, Suite 3200
Minneapolis, MN 55402-2215
Counsel for Amicus Kane Biotech

Judy Deleon Jarecki-Black
Merial Limited
3239 Satellite Blvd.
Duluth, GA 30096
*Counsel for Amicus Merial
Limited*

Kent D. McClure
Animal Health Institute
1325 G Street, NW, Suite 700
Washington, DC 20005
*Counsel for Amicus Animal
Health Institute*

Aaron Stiefel

Kaye Scholer
425 Park Avenue
New York, NY 10022
*Counsel for Amicus Novartis
Corp.*

Kurt G. Calia
Covington & Burling
1201 Pennsylvania Avenue,
N.W.
Washington, DC 20004-2401
*Counsel for Amicus
Pharmaceutical Research and
Manufacturers of America*

Jacqueline D. Wright-Bonilla
Foley and Lardner
3000 K Street, N.W., Suite 500
Washington, DC 20007
*Counsel for Amici Rosetta
Genomics et al.*

Mark R. Freeman
U.S. Department of Justice
950 Pennsylvania Avenue, N.W.,
Room 7644
Washington, DC 20530-0001
*Counsel for Amicus United
States*

Ann M. McCrackin
University of New Hampshire
School of Law
2 White Street
Concord, NH 03301
*Counsel for Amicus University of
New Hampshire School of Law*



Erika R. George, Visiting
Professor
Loyola University Chicago
School of Law
25 E. Pearson
Chicago, IL 606011
*Counsel For Amici Curiae Erika
R. George and Kali N. Murray*