

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

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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,

ECF Case

v.

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.

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**PLAINTIFFS' MEMORANDUM OF LAW IN OPPOSITION**  
**TO DEFENDANT USPTO MOTION TO DISMISS**

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## INTRODUCTION AND STATEMENT OF FACTS

This case challenges certain patent claims granted to defendants Myriad Genetics and the Directors of the University of Utah Research Foundation (UURF) by defendant United States Patent and Trademark Office (USPTO). The identified patent claims cover two human genes known as *BRCA1* and *BRCA2*. Compl. ¶¶ 37, 55-80. The patent claims also cover certain mutations in those genes, the mental act of comparing two genes, and the correlations between certain genetic mutations and an increased risk of breast and/or ovarian cancer. *Id.* Plaintiffs allege that these patents are unlawful under each of (i) the Patent Act, 35 U.S.C. § 101 (1952), (ii) Article I, Section 8, Clause 8 of the U. S. Constitution, and (iii) the First and Fourteenth Amendments because they cover products of nature, laws of nature and/or natural phenomenon, and abstract ideas or basic human knowledge or thought. Compl. ¶ 102; See also Memorandum in Support of Plaintiffs' Motion for Summary Judgment, section II (genes are information; the patents essentially preclude not just the genes, but all knowledge about the genes; some of the patent claims – such as those that prevent anyone from comparing two genes and thinking they are the same or different – are patents on pure thought).

Although plaintiffs sued defendants Myriad and the directors of the UURF to invalidate the patents on all grounds, plaintiffs' claims against defendant USPTO are based solely on the constitutional claims. Plaintiffs do not sue the USPTO based on the Patent Act § 101. Compl. ¶ 27. The basis for plaintiffs' claims against the USPTO, as set forth in the Complaint, is that the patents were granted by the USPTO pursuant to the formal, written policy of the USPTO that permits the patenting of human genes under certain circumstances and that the patents were granted pursuant to the practice of the USPTO. Compl. ¶¶ 50, 53-54. The Complaint identifies both the specific policy and practice, describes their relevant terms, their application in this case,

and alleges that the policy and practice violate the Constitution (both Article I, Section 8, Clause 8, and the First Amendment). Compl. ¶¶ 52-54, 102-103.

On July 13, 2009, defendant USPTO moved to dismiss. This memorandum is submitted in opposition to that motion. In essence, the USPTO's argument is that even if it grants a patent that violates the Constitution or that prohibits Americans from exercising their constitutional rights, it can avoid accountability. As explained in more detail below, it is a bedrock principle of our legal system that if an agency of the government commits an unconstitutional act, private citizens are allowed to seek redress for that violation of the Constitution from the courts. The USPTO is not a special case that is exempted from the limitations of the Constitution.

## **ARGUMENT**

### I. The Court Has Jurisdiction and Sovereign Immunity Is Not an Impediment to This Action.

The USPTO variously suggests that the Court lacks subject matter jurisdiction and that this case is precluded by sovereign immunity. Def. USPTO's Mem. of Law in Supp. of Mot. to Dismiss (July 13, 2009) [hereinafter USPTO Mem.] at B, C. Neither argument has merit and, therefore, deserves much discussion.

As long ago as *Marbury v. Madison*, 5 U.S. 137 (1803), the Supreme Court held that an appropriate party may sue the United States, notwithstanding sovereign immunity, for injunctive relief based on violation of constitutional rights. Since *Marbury*, there have been numerous examples of such litigation. *See, e.g., Reno v. ACLU*, 521 U.S. 844 (1997). Jurisdiction is based on 28 U.S.C. § 1331 because this case is indisputably an action “arising under the Constitution . . . of the United States.”

The USPTO's only real response to this black-letter law is to argue that the Patent Act creates a “comprehensive enforcement scheme” that establishes Congress' intent to preclude a

cause of action against the USPTO for violation of constitutional rights. In support of that argument, the USPTO relies exclusively on three cases. USPTO Mem. at 9-11. Even the most expansive reading of those cases establishes, at most, that persons challenging patents for violating the Patent Act are limited to the statutory remedies provided by that Act.<sup>1</sup>

The flaw with the USPTO's argument is that plaintiffs here are not making claims against the USPTO for issuing patents that violate the Patent Act. To the contrary, plaintiffs' claims against the USPTO here are for having a policy and practice of issuing patents that violate the Constitution, and not a single case cited by the USPTO holds that pursuing a claim for a constitutional violation by the USPTO cannot be maintained.

The USPTO does not cite the large body of law holding that the court cannot conclude that Congress intended to preclude enforcement of constitutional rights without the clearest possible statement. In *Webster v. Doe*, 486 U.S. 592, 603 (1988), the Supreme Court held:

We emphasized in *Johnson v. Robison*, 415 U.S. 361 (1974), that where Congress intends to preclude judicial review of constitutional claims its intent to do so must be clear. *Id.*, at 415 U.S. 373-374. In *Weinberger v. Salfi*, 422 U.S. 749 (1975), we reaffirmed that view. We require this heightened showing in part to avoid the "serious constitutional question" that would arise if a federal statute were construed to deny any judicial forum for a colorable constitutional claim. See *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667, 681, n. 12 (1986).

Here, persons such as plaintiffs, who complain about the unconstitutionality of patents issued by the UPSTO and/or policies and practices of the USPTO, have literally no

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<sup>1</sup> *Syntex v. USPTO*, 882 F.2d 1570 (Fed. Cir. 1989); *Hallmark Cards v. Lehman*, 959 F. Supp. 539 (D.D.C. 1997); *Hitachi Metals v. Quigg*, 776 F. Supp. 3 (D.D.C. 1991). The portion of *Syntex* quoted by the USPTO is the purest dicta. 882 F.2d at 1575. The question in the case was whether "the patent statute impliedly grants Syntex, as a third party requester [of reexamination] a right to review of the PTO's final decision." *Id.* at 1572. The court expressed confusion about whether the inquiry was one of subject matter jurisdiction or standing, but the case turned entirely on enforceability rights created by the patent statute and regulations, not on the Constitution. *Hallmark* likewise turned entirely on whether the Patent Act itself created a right that was implied and enforceable. 959 F. Supp. at 542. *Hitachi* was a challenge under the APA arguing that the USPTO did not follow its rules. *Hitachi's* holding appears inconsistent with the Federal Circuit's implied conclusion that such suits may be brought. See *Tafas v. Doll*, *infra*, 559 F.3d 1345 (Fed. Cir. 2009). But, like the other cases, only claims under the Patent Act were asserted; no constitutional claims were asserted.

remedy under the Patent Act. This is confirmed by the fact that the USPTO cites none in its brief. In such circumstances, the Supreme Court has held that Congress did not intend to preclude enforcement of constitutional rights through private actions. *See Wright v. Roanoke*, 479 U.S. 418, 427-28 (1987). Indeed, even when Congress has created a statutory remedy, if that remedy is not coextensive with the remedy provided by the Constitution, plaintiffs may still bring a separate action to enforce the Constitution. *See Fitzgerald v. Barnstable School Committee*, \_\_\_ U.S. \_\_\_, 129 S. Ct. 788 (2009).

Although the Supreme Court has never addressed this issue with respect to the Patent Act specifically, the Court of Appeals for the Federal Circuit (the exclusive Court of Appeals for all patent cases) has in fact permitted suit against the USPTO for violation of constitutional rights, including as recently as this year. *See, e.g. Tafas v. Doll*, 559 F.3d 1345 (Fed. Cir. 2009) *vacated and set for en banc on other grounds*, 91 U.S.P.Q.2d 1153 (Fed. Cir. July 6, 2009). Indeed, in *Tafas*, the Federal Circuit apparently found that, applying the proper analytic framework, jurisdiction was so obvious that none of the judges raised any questions about it. *Id.* Neither jurisdictional concerns nor sovereign immunity merits dismissal of this case.

## II. Plaintiffs Have Standing.

The USPTO also argues that plaintiffs lack standing to bring this case. USPTO Mem. at 4-9. To a large extent, the arguments made by the USPTO overlap with those made by defendants Myriad and UURF in their motion to dismiss. Plaintiffs have responded to those arguments in Plaintiffs' Memorandum of Law in Opposition to Defendants' Motion to Dismiss, Section I, filed simultaneously with this memorandum, and rather than repeat those arguments, incorporate that portion of plaintiffs' brief in this memorandum. The USPTO raises two



additional arguments – that caselaw precludes a finding that plaintiffs have standing in the context of the Patent Act (USPTO Mem. at 6-7) and that plaintiffs do not have standing because their complaints are not traceable and redressable (USPTO Mem. at 7-8).

In support of its argument that caselaw precludes a finding that plaintiffs have standing, the USPTO cites the same three cases it relied on in its argument on jurisdiction. As noted, none had anything to do with the availability of a cause of action under the Constitution. The USPTO additionally cites *Animal Legal Defense Fund v. Quigg*, 932 F.2d 920 (Fed. Cir. 1991), which also did not allege any constitutional violations. Moreover, the holding of that case, that none of the plaintiffs had standing, turned on the precise APA sections invoked. For example, the court found that the action taken by the USPTO in that case was not one that required public notice and comment under the statute. Although stated in standing terms, the court’s holding is really that there is no cause of action because no right was violated. 932 F.2d at 929-30.

The holding in *Quigg* also turned on the fact that no patents on animals had yet been granted and therefore any harm that might occur in the future from such patents was speculative. 932 F.2d at 933. In this case, in contrast, the policy and practice of the USPTO has resulted in patents that have been granted. The rights granted under the patents have explicitly and directly prevented plaintiffs from engaging in clinical analyses of the *BRCA1* and *BRCA2* genes, from informing women about testing options other than by Myriad, and from obtaining genetic testing or second opinions. See Plaintiffs’ Memorandum of Law in Opposition to Defendants’ Motion to Dismiss, Section I. As a result of the patents, women have been prevented from receiving valuable information about their own genes and personal health. Compl. ¶¶ 81-101. Unlike the situation in *Quigg*, plaintiffs in this case have suffered and will continue to suffer injuries that are real, concrete, and traceable to the policy and practice of the USPTO.

Finally, the USPTO argues that plaintiffs do not have standing because any injury caused by the patent policy and practice is not traceable and redressable. USPTO Mem. at 7-8. Plaintiffs allege that the patent claims at issue in this case were issued directly because of the policies and practice of the USPTO. Compl. ¶¶ 50-51, 53. Plaintiffs allege that these policies and practices are unconstitutional. Compl. ¶¶ 52, 54. Thus, the injury suffered by plaintiffs in this case is directly a result of the USPTO's action in issuing the seven (7) patents in suit. That injury is, therefore, directly traceable to the USPTO.

In addition, plaintiffs ask the Court to enjoin all defendants from taking any actions to enforce the claims. Compl. at 30, Prayer 2. That request includes within it a request that the Court declare the policies and practices unconstitutional and enjoin the USPTO from applying its policies and practices with respect to these or any similar claims.<sup>2</sup> If the Court were to declare the policies and practices unconstitutional, then even if Myriad and UURF were not defendants, and even if the Court did not reach the particular provisions of the patent claims at issue in this case, the effect would be to render the patent claims invalid. Thus, plaintiffs' inability to engage in constitutionally protected activities would be restored and their injuries redressed.

For example, the policy permits patenting of a human gene if it is "isolated." Compl. ¶ 50. Several of the patent claims at issue in this case are very simple and purport only to patent "isolated" human genes. Compl. ¶¶ 55-70; *see, e.g.*, Compl. ¶ 57 (discussing Claim 2 of Patent '282). If this Court were to conclude that the policy of patenting "isolated" genes was unconstitutional, then the patent claims at issue would be definitionally invalid. Plaintiffs would, accordingly, be able to engage in acts otherwise prohibited by the patents.

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<sup>2</sup> In the event the Court believes the pleading is insufficiently specific on this point, plaintiffs respectfully ask leave to amend the Complaint to make it more explicit.

In addition, if the Court found that the policies and practices of the USPTO were unconstitutional, the Court would certainly have authority to order the USPTO to initiate a reexamination pursuant to 35 U.S.C. §§303, 307. In that reexamination, the USPTO would have to consider the Court's holding that a policy or practice is unconstitutional. In a reexamination, the USPTO has the authority to invalidate a patent. *Id.* On that basis, the USPTO would have the obligation to invalidate some or all of the patents in this case. In other words, the effect of the Court's ruling that the policies and practices are unconstitutional and the Court's order that the USPTO reexamine the patents taking into consideration that holding would grant plaintiffs the very relief sought. Plaintiffs' claims are thus redressable.

For these reasons, plaintiffs clearly have standing.

III. The USPTO is an Appropriate Defendant Pursuant to Fed. R. Civ. P. 5.1 and 28 U.S.C. § 2403 and, In Any Event, The United States is Unquestionably an Appropriate Defendant.

Both 28 U.S.C. § 2403 and Fed. R. Civ. P. 5.1 provide that when the constitutionality of a federal statute is "drawn into question," the United States must be notified and may intervene. The Complaint in this case does not specifically ask the Court to declare § 101 of the Patent Act unconstitutional. Indeed, plaintiffs allege and argue that the patent claims at issue violate § 101 for much the same reasons they violate the Constitution. However, if the Court were to conclude that the claims at issue did not violate § 101, but did violate the Constitution, that would be essentially a determination that the statute is unconstitutional as applied. Given that possibility, having the federal government as a party in this case, through the USPTO, seems more than prudent.

Plaintiffs recognize that 28 U.S.C. § 2403 and Fed. R. Civ. P. 5.1 are discretionary and that the federal government need not intervene. However, the appropriateness of the USPTO's

involvement as a result of the constitutional claims is a factor the Court should consider in resolving the pending motion.

There is a second reason why the United States is an appropriate party in this case. The United States, though the Secretary of HHS, is an additional owner of four of the patents at issue in this case. Compl. ¶ 30. Plaintiffs could have named the United States in that capacity and the same Department of Justice would have appeared for them. However, if the Court believes it of significance, plaintiffs respectfully ask leave to amend the Complaint to substitute the United States as a defendant.

#### IV. Plaintiffs' Complaint is Sufficient Under *Iqbal*.

The USPTO's final argument is that plaintiffs fail to state a claim pursuant to the Supreme Court's recent decision in *Ashcroft v. Iqbal*, \_\_\_ U.S. \_\_\_, 129 S.Ct. 1937 (2009). *Iqbal* holds that a Complaint must plead plausible, specific facts to support the elements of a claim. In this case, plaintiffs pled the existence of a specific, written policy and the precise parameters of the policy. Compl. ¶ 50. The policy is contained in the Federal Register. Utility Examination Guidelines, 66 Fed. Reg. 1092 (Jan. 5, 2001). Plaintiffs allege that the policy was applied in a series of specific patents and patent claims. Compl. *passim*. Plaintiffs describe each application of the policy in considerable detail, *id.* and particularly ¶¶ 55-80. Similar allegations and specificity apply to plaintiffs' allegations of the USPTO's practices. Compl. ¶¶ 53-54, *passim*. These facts are not only plausible and specific, but undisputable. Further, the alleged facts are sufficient, if the Court accepts plaintiffs' legal argument, to establish a constitutional violation. *Iqbal* does not require more.

## CONCLUSION

For all these reasons, plaintiffs respectfully ask that the motion to dismiss filed by the USPTO be denied.

Respectfully submitted,

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