

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

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ASSOCIATION FOR MOLECULAR  
PATHOLOGY, et al., :

Plaintiffs, :

v. :

: 09 Civ. 4515 (RWS)

UNITED STATES PATENT AND TRADEMARK  
OFFICE, et al., :

Defendants. :

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**DEFENDANT UNITED STATES PATENT AND TRADEMARK OFFICE'S  
MEMORANDUM OF LAW IN SUPPORT OF MOTION TO DISMISS**

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## Preliminary Statement

Defendant the United States Patent and Trademark Office (the “USPTO”) respectfully submits this memorandum of law in support of its motion to dismiss the complaint pursuant to Rules 12(b)(1) and 12(b)(6) of the Federal Rules of Civil Procedure. The complaint against the USPTO should be dismissed because there is no basis under the comprehensive statutory patent scheme for third parties to challenge the USPTO’s issuance of a patent. Accordingly, as is discussed below, plaintiffs lack standing to sue the USPTO, the Court lacks subject matter jurisdiction, and the action is barred by the sovereign immunity. Moreover, plaintiffs’ unsupported legal conclusions fail to state a claim for a constitutional violation and therefore should be dismissed pursuant to Fed. R. Civ. P. 12(b)(6).

### **FACTUAL BACKGROUND**

#### The Patent Scheme

Congress has provided an extensive statutory framework governing the examination of patent applications and review in the federal courts of USPTO actions in granting or denying patents. In order to receive a patent, an inventor or applicant must file an application with the USPTO, which is reviewed by an examiner who approves or rejects the claims in the patent application. 35 U.S.C. §§ 111, 131. An applicant whose patent claim is rejected may appeal to the Board of Patent Appeals and Interferences (“Board”). *Id.* § 134. If an applicant receives an adverse ruling from the Board, he may appeal directly to the Federal Circuit or may file an action against the USPTO Director in the United States District Court for the District of Columbia. *Id.* §§ 141, 145.

The patent application and examination procedures are entirely *ex parte*, and are not the result of an adversary proceeding. 35 U.S.C. §§ 131-34. The only relevant parties are

the patent applicant and the USPTO examiner. The role of a third party in USPTO practice prior to issuance of a patent is limited to interference proceedings in which the USPTO must resolve a dispute between two inventors who claim the same or similar inventions. 35 U.S.C. §§ 135, 146. Similarly, challenges in the federal courts to the USPTO's denial of claims in a patent application involve only the patent applicant and the USPTO. 35 U.S.C. §§ 141 (limiting relief to "[a]n applicant dissatisfied with the decision in an appeal to the Board of Patent Appeals and Interferences"), 145 (same). Third parties therefore cannot intervene in the prosecution of patent applications in the USPTO except in the limited context of an interference, which involves two patent applicants, as opposed to a patent applicant and a third party not already involved in USPTO proceedings.

After issuance of a patent, the validity and scope of a patent are determined by the federal courts in patent infringement or interference actions and in actions to declare a patent invalid brought against the patent owner, not the USPTO. 35 U.S.C. §§ 281-82, 291. It is only in that context that a third party can raise as a defense proof that the patent is invalid. The patent laws also permit third parties to request that the USPTO reexamine an issued patent in light of prior art not previously considered. 35 U.S.C. §§ 301-07, 311-12. The involvement of the third party is limited to requesting USPTO reexamination in an *ex parte* reexamination, but the third party may participate in the reexamination proceedings in the USPTO – and even appeal an adverse decision by the USPTO to the Federal Circuit – in an *inter partes* reexamination. Compare 35 U.S.C. §§ 314-15 (permitting participation by a third-party requester in an *inter partes* reexamination and appeals from it) with 35 U.S.C. §§ 305-06 (limiting the rights of participation and appeal to the patent owner). Congress has thus provided only one avenue

through which a third-party potential infringer of a patent may obtain judicial review of the validity of a patent's claim in an action involving the USPTO as a party – an appeal to the Federal Circuit from a Board decision in an *inter partes* reexamination upholding the claim's validity.

### The Complaint

The complaint alleges that the patenting of human genes, including the *BRCA1* and *BRCA2* genes at issue in this case, “violates long established legal principles that prohibit the patenting of laws of nature, products of nature, and abstract ideas.” In addition, plaintiffs allege that the patents violate the First Amendment and Article I, section 8, clause 8 of the Constitution. Compl. ¶ 4. The complaint names as defendants various co-owners of the patents, as well as the USPTO, Compl. ¶¶ 27-29, but, according to the complaint, “[t]he Patent office is sued solely on the constitutional claims,” Compl. ¶ 27. The complaint does not, however, seek any relief from the USPTO, *see* Compl. at 30 (“Prayer for Relief”).

## **ARGUMENT**

### **THE COMPLAINT AGAINST THE USPTO SHOULD BE DISMISSED**

The complaint runs afoul of Article III of the Constitution in a number of ways. Plaintiffs lack standing to sue the USPTO; there is no subject matter jurisdiction for their claim against the USPTO; and sovereign immunity bars the action. These legal deficiencies are intertwined. As the Federal Circuit recognized in comparable circumstances: “The standing and reviewability inquiries tend to merge. A plaintiff cannot claim standing based on violation of an asserted personal statutorily-created procedural right when Congress intended to grant that

plaintiff no such right.” *Syntex (U.S.A.) Inc. v. U.S. Patent & Trademark Office*, 882 F.2d 1570, 1573 (Fed. Cir. 1989) (quoting *Banzhaf v. Smith*, 737 F.2d 1167, 1170 n.\* (D.C.Cir. 1984)).<sup>1</sup> Here, “[t]he question of jurisdiction (subject matter or standing) requires a focus on the legal rights or interests which devolve from the relevant statute” – *i.e.*, the patent statute. *Id.* As set forth more fully below, it is well established that third parties do not have standing against the USPTO to challenge the issuance of a patent, and the courts lack subject matter jurisdiction over such a challenge because Congress, in enacting the comprehensive patent law scheme, did not provide for suits by third parties against the USPTO to challenge the issuance of patents. On the basis of any one of these threshold issues, the Court should dismiss the action as against the USPTO. In addition, plaintiffs fail to plead anything other than unsupported legal conclusions and seek no relief against the USPTO. Accordingly, the complaint should be dismissed for the further reason that it fails to state a claim upon which relief may be granted.

#### **A. Plaintiffs Lack Standing to Sue the USPTO**

##### 1. Constitutional and Prudential Standing Requirements

The “judicial power . . . defined by Art. III is not an unconditioned authority to determine the constitutionality of legislative or executive acts” but, rather, is limited to the resolution of “cases” and “controversies.” *Valley Forge Christian Coll. v. Ams. United for Separation of Church & State, Inc.*, 454 U.S. 464, 471 (1982); *Lujan v. Defenders of Wildlife*,

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<sup>1</sup> Because any appeal from a final decision of this Court will be to the United States Court of Appeals for the Federal Circuit, *see* 28 U.S.C. § 1295, the substantive law of the Federal Circuit governs here. On procedural issues, however, the rules of the regional circuit govern, unless the issue is unique to patent law and therefore exclusively assigned to the Federal Circuit. *Madey v. Duke Univ.*, 307 F.3d 1351, 1358 (Fed. Cir. 2002).

504 U.S. 555, 559-60 (1992). An “essential and unchanging part” of that limitation is the doctrine of standing. *Lujan*, 504 U.S. at 560. Indeed, “[t]he Art. III doctrine that requires a litigant to have ‘standing’ to invoke the power of a federal court is perhaps the most important of these doctrines.” *Allen v. Wright*, 468 U.S. 737, 750 (1984).

“At an irreducible minimum, Art. III requires the party who invokes the court’s authority to show (1) that he personally has suffered some actual or threatened injury as a result of the putatively illegal conduct of the defendant, and that (2) the injury fairly can be traced to the challenged action, and (3) is likely to be redressed by a favorable decision.” *Valley Forge*, 454 U.S. at 472 (internal citations omitted).

Beyond these constitutional requirements, a plaintiff must also satisfy certain prudential standing requirements, based on the principle that the judiciary should “avoid deciding questions of broad social import where no individual rights would be vindicated.” *Phillips Petroleum Co. v. Shutts*, 472 U.S. 797, 804 (1985). Prudential standing requires, *inter alia*, that a party “assert his own legal interests rather than those of third parties,” *Id.* at 804, and that a claim not be a “generalized grievance” shared in by all or a large class of citizens, *Warth v. Seldin*, 422 U.S. 490, 499 (1975). Prudential standing also addresses whether “the constitutional or statutory provision on which [a plaintiff’s] claim rests properly can be understood as granting persons in the plaintiff’s position a right to judicial relief.” *See id.* at 499-500. Thus, the litigant’s complaint must fall within the “zone of interests to be protected or regulated by the statute or constitutional guarantee in question.” *Valley Forge*, 454 U.S. at 475. The “source of plaintiff’s claim to relief” “assumes critical importance” with respect to prudential standing, *Warth v. Seldin*, 422 U.S. at 498, 500, and a plaintiff must “demonstrate standing for *each claim* he seeks

to press.” *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 352 (2006) (emphasis added).

## 2. Plaintiffs Do Not Meet the Prudential or Constitutional Standing Requirements

Plaintiffs cannot meet the prudential standing requirements. It is well established that third parties do not have standing to challenge the USPTO’s issuance of a patent. *See Syntex*, 882 F.2d at 1576 (third party has no standing to challenge USPTO decision on reexamination); *Animal Legal Defense Fund v. Quigg*, 932 F.2d 920, 938-39 (Fed. Cir. 1991) (no standing to seek a declaration that animals are not patentable subject matter and an injunction against issuance of animal patents); *Hitachi Metals, Ltd. v. Quigg*, 776 F. Supp. 3, 12 (D.D.C. 1991) (claims by competitor, third-party protestor, and potential target of infringement suit “do not fall within the ‘zone of interests’ protected by the relevant statute or the implementing regulations”); *Godfredsen v. Banner*, 503 F. Supp. 642, 646 (D.D.C. 1980) (“It is well-established in that system that an individual does not have standing to challenge the decision of the Patent Office to grant a patent to another applicant during the prosecution process. The application process is deemed to be an *ex parte* procedure conducted between the applicant and the Patent Office.”).

The Federal Circuit has held that “a potential infringer may not sue the PTO seeking retraction of a patent issued to another by reason of its improper allowance by the PTO.” *Syntex*, 882 F.2d at 1576. Indeed, the *Syntex* Court stated that “[t]he creation of a right or remedy in a third party to challenge a result favorable to a patent owner after *ex parte* prosecution would be unprecedented.” *Id.* at 1574-75. Thus, that plaintiffs lack standing to sue the USPTO to challenge the patents already issued.

Nor would plaintiffs have standing to seek relief preventing the USPTO from

issuing patents to others for like technologies – relief not requested in the complaint. In *Animal Legal Defense Fund*, public interest groups sought to challenge a USPTO policy that permitted the issuance of patents for nonnaturally-occurring, man-made living microorganisms. The Federal Circuit held that “[a] third party has no right to intervene in the prosecution of a particular patent application to prevent issuance of an allegedly invalid patent.” 932 F.2d at 930. The court further concluded that members of the public are not within the “zone of interests” protected by the patent laws, and as such did not have standing to challenge the USPTO’s application of its policy to patent applicants. *Id.* at 938.

In essence, appellants’ claim the patent statute’s “zone of interests” encompasses any member of the public who perceives they will be harmed by an issued patent which they believe to be invalid. We cannot agree that the “zone of interests” of the patent laws is so broad. Under such an interpretation, we would, for example, be opening the door to collateral attack on the validity of issued patents; any competitor could simply file suit against the [Director] challenging a patent’s validity. This we decline to do.

*Id.* As made clear in *Syntex* and *Animal Legal Defense Fund*, plaintiffs’ lack of standing results from a statutory scheme that permits challenges to patents only under certain limited, clearly defined circumstances. The fact that plaintiffs in this case have invoked the Constitution cannot confer standing on them to bring a challenge that is not contemplated by the statutory scheme.

Nor can plaintiffs meet either the second or third prong of the constitutional standing prerequisites – traceability and redressibility. Plaintiffs do not satisfy the requirement that their alleged injury be “fairly traceable” to the USPTO’s allegedly improper conduct. The “fairly traceable” requirement “examines the causal connection between the assertedly unlawful conduct and the alleged injury.” *Allen*, 468 U.S. at 753 n.19. The only injuries plaintiffs allege are tied to Myriad’s refusal to license the patents-in-suit broadly and threats to enforce those

patents. *See, e.g.*, Compl. ¶ 2 (“Because of the patents and because Myriad chooses not to license the patents broadly, women who fear they may be at increased risk of breast and/or ovarian cancer are barred from having anyone look at their *BRCA1* and *BRCA2* genes or interpret them except for the patent holder.”) (emphasis added); *see also* Compl. ¶¶ 11-12. Because plaintiffs’ alleged injury would result, if at all, from the actions of Myriad and not the USPTO, plaintiffs cannot meet the traceability requirement for standing.

Plaintiffs also lack standing to assert their claim against the USPTO because they do not meet the redressability prong of the standard. The “redressability” requirement “examines the causal connection between the alleged injury and the judicial relief requested.” *Allen*, 468 U.S. at 753 n.19. In their prayer for relief, plaintiffs seek (1) a declaratory judgment that the patent claims at issue are invalid and/or unenforceable, and (2) to enjoin “defendants from taking any actions to enforce these claims of these patents.” Compl. at 30. Neither request for relief runs against the USPTO, as a third party “may not sue the PTO seeking retraction of a patent issued to another by reason of its improper allowance by the PTO.” *Syntex*, 882 F.2d at 1576. Rather, “[a] remedy must await confrontation with patent owner.” *Id.* Nor does the USPTO take any action after a court holds a patent claim invalid or unenforceable. Finally, the USPTO plays no role in the enforcement of the patents it issues. Thus, the relief plaintiffs seek runs only against Myriad and the patent owners. Because plaintiffs seek no relief from the USPTO to redress the alleged injury – and the USPTO cannot provide such a remedy – plaintiffs lack standing.

Because plaintiffs lack constitutional and prudential standing to challenge the patents’ issuance on any grounds – constitutional or otherwise – their claims against the USPTO

should be dismissed.

**B. The Complaint Should Be Dismissed For Lack of Subject Matter Jurisdiction**

On a motion to dismiss pursuant to Rule 12(b)(1), plaintiffs bear the burden of establishing, by a preponderance of the evidence, that subject matter jurisdiction exists over their complaint. *See Lunney v. United States*, 319 F.3d 550, 554 (2d Cir. 2003); *Malik v. Meissner*, 82 F.3d 560, 562 (2d Cir. 1996). “[J]urisdiction must be shown affirmatively, and that showing is not made by drawing from the pleadings inferences favorable to the party asserting it.” *APWU v. Potter*, 343 F.3d 619, 623 (2d Cir. 2003) (quoting *Shipping Fin. Servs. Corp. v. Drakos*, 140 F.3d 129, 131 (2d Cir. 1998)).

Plaintiffs point to 28 U.S.C §§ 1331 & 1338 as bases for jurisdiction for their complaint. Compl. ¶ 5.<sup>2</sup> But neither provides a basis for jurisdiction against the USPTO “because the comprehensive scheme Congress established to govern patent grants reveals Congress’s intent to preclude judicial review of PTO examination decisions at the behest of third parties protesting the issue or reissue of a patent.” *Hitachi Metals, Ltd. v. Quigg*, 776 F. Supp. 3, 7 (D.D.C. 1991) (rejecting jurisdiction under section 1331 and the Administrative Procedure Act); *Hallmark Cards, Inc. v. Lehman*, 959 F. Supp. 539, 543-44 (D.D.C. 1997) (comprehensive scheme precludes jurisdiction under 28 U.S.C. § 1338).

As the Supreme Court explained in *Block v. Cmty. Nutrition Inst.*, 467 U.S. 340,

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<sup>2</sup> Plaintiffs also cite 28 U.S.C. § 2201 as a basis for jurisdiction, but “[i]t is settled law that the Declaratory Judgment Act, 28 U.S.C. § 2201 (1994), does not enlarge the jurisdiction of the federal courts . . . and that a declaratory judgment action must therefore have an independent basis for subject matter jurisdiction.” *Concerned Citizens of Cohocton Valley, Inc. v. New York State Dep’t of Envtl. Conservation*, 127 F.3d 201, 206 (2d Cir. 1997) (citing *Skelly Oil Co. v. Phillips Petroleum Co.*, 339 U.S. 667, 671 (1950)).

349 (1984), “when a statute provides a detailed mechanism for judicial consideration of particular issues at the behest of particular persons, judicial review of those issues at the behest of other persons may be found to be impliedly precluded.” Thus, the question of jurisdiction “requires a focus on the legal rights or interests which devolve from the relevant statute.” *Syntex*, 882 F.2d at 1573. Here, “[t]he Patent Statute is addressed to patent owners and patent applicants. The patent examination process is an *ex parte* proceeding, not an adversarial one, and the Patent Statute’s judicial review provisions contain no gaps requiring the Court to exercise its power.” *Hitachi*, 776 F. Supp. at 8; *Hallmark Cards*, 959 F. Supp. at 543. The court in *Hitachi* went on to enumerate the various remedies available to a patent applicant under the statute, and concluded that “Title 35 contains no provision expressly authorizing administrative or judicial review of a PTO decision at the behest of a third-party protestor.” *Hitachi*, 776 F. Supp. at 8. Thus, the court concluded, “patent grants are not subject to judicial review at the behest of third parties, regardless of whether the challenge is characterized as procedural or substantive.” *Id.* at 10.

This conclusion follows closely the reasoning of the Federal Circuit’s holding in *Syntex*. In that case, a requester of reexamination of another’s patent sought to compel the USPTO to revoke a reexamination certificate and reopen proceedings. The court found that given the existing statutory provisions governing reexamination, “[t]he creation of a right or remedy in a third party to challenge a result favorable to a patent owner after *ex parte* prosecution would be unprecedented, and we conclude that such a right cannot be inferred.” *Syntex*, 882 F.2d at 1574-75; *see also Hallmark Cards*, 959 F. Supp. at 544. The court went on to explain that the patent statute does not contemplate that every injury caused by the USPTO would be remediable in a suit against the agency:

In sum, every perceived injury caused by improper agency action does not carry a right to immediate judicial redress. A right to immediate judicial review must be granted or reasonably inferred from a particular statute. For example, a potential infringer may not sue the PTO seeking retraction of a patent issued to another by reason of its improper allowance by the PTO. A remedy must await confrontation with the patent owner.

*Id.* at 1576. Accordingly, the complaint against the USPTO should be dismissed for lack of subject matter jurisdiction.

### **C. Sovereign Immunity Bars the Action Against the USPTO**

“The waiver of sovereign immunity is a prerequisite to subject-matter jurisdiction.” *Presidential Gardens Assocs. v. U.S. ex rel. Sec’y of Housing & Urban Dev.*, 175 F.3d 132, 139 (2d Cir. 1999). It is well settled that the “United States, as sovereign, is immune from suit save as it consents to be sued . . . , and the terms of its consent to be sued in any court define that court’s jurisdiction to entertain the suit.” *United States v. Mitchell*, 445 U.S. 535, 538 (1980) (citation omitted). In other words, the Government cannot be sued without its consent, and “the existence of consent is a prerequisite for jurisdiction.” *United States v. Mitchell*, 463 U.S. 206, 212 (1983). *See also Adeleke v. United States*, 355 F.3d 144, 150 (2d Cir. 2004) (“waivers of sovereign immunity must be unequivocally expressed in statutory text”). Sovereign immunity protects not only the United States but also its agencies and officers when they act in their official capacities. *See FDIC v. Meyer*, 510 U.S. 471, 475 (1994).

Although Congress can waive the Government’s sovereign immunity through clear and unequivocal statutory language, waivers of sovereign immunity and their conditions must be strictly applied against the claimant. *See Lane v. Pena*, 518 U.S. 187, 192 (1996); *Millares Guiraldes de Tineo v. United States*, 137 F.3d 715, 719 (2d Cir. 1998). Accordingly, if

the Government has not waived its sovereign immunity, or if the conditions under which the Government has agreed to waive that immunity have not been met, federal subject matter jurisdiction does not exist over the plaintiffs' claims. *See United States v. Sherwood*, 312 U.S. 584, 586 (1941); *Williams v. United States*, 947 F.2d 37, 39 (2d Cir. 1991). Because plaintiffs do not cite a single statute that contains such a waiver, they can not meet their "burden of establishing that [their] claims fall within an applicable waiver." *Makarova v. United States*, 201 F.3d 110, 113 (2d Cir. 2000).

Plaintiffs allege subject matter jurisdiction based on 28 U.S.C. §§ 1331, 1338(a) and 2201, Compl. ¶ 5, but none provides jurisdiction to sue the United States in this case. Section 1331 does not waive sovereign immunity, *Mack v. United States*, 814 F.2d 120, 122 (2d Cir. 1987), and thus is an invalid basis for the claims against the USPTO.<sup>3</sup> Section 1338 grants federal courts jurisdiction over claims arising under the patent statutes, but does not waive sovereign immunity. *Turton v. United States*, 212 F.2d 354, 355 (6th Cir. 1954); *Zhengxing v. U.S. Patent & Trademark Office*, 579 F. Supp. 2d 160, 163 (D.D.C. 2008); *Sykes v. Dudas*, 573

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<sup>3</sup> While the Administrative Procedure Act ("APA") does effect a waiver of sovereign immunity in certain cases, even had the plaintiffs cited it, the APA would not effect such a waiver here. "The APA does not waive sovereign immunity 'where a matter is statutorily committed to agency discretion or where another statute provides a form of relief which is expressly or impliedly exclusive.'" *Dew v. United States*, 192 F.3d 366, 371 (2d Cir. 1999) (quoting *Sprecher v. Graber*, 716 F.2d 968, 974 (2d Cir.1983)). "[W]hen a statute provides a detailed mechanism for judicial consideration of particular issues at the behest of particular persons, judicial review of those issues at the behest of other persons may be found to be impliedly precluded." *Dew*, 192 F.3d at 372 (quoting *Block v. Cmty. Nutrition Inst.*, 467 U.S. at 349). Thus, as set forth above, the comprehensive statutory patent scheme precludes judicial review of claims by third parties, including constitutional claims, challenging the USPTO's issuance of patents.

F. Supp. 2d 191, 200 (D.D.C. 2008). Reliance on the Declaratory Judgment Act, 28 U.S.C. § 2201, is similarly misplaced as it does not constitute a consent by the United States to be sued. *Morpurgo v. Board of Higher Ed. in City of N.Y.*, 423 F. Supp. 704, 714 (S.D.N.Y. 1976) (citing, *inter alia*, *Skelly Oil*).<sup>4</sup>

#### **D. Plaintiffs Fail To State a Claim For a Constitutional Violation**

In its recent decision in *Ashcroft v. Iqbal*, 129 S.Ct. 1937 (2009), the Supreme Court elaborated on the pleading standards a plaintiff must meet to survive a motion to dismiss. The Court identified “[t]wo working principles” that should guide a court’s analysis of a complaint’s sufficiency. *Id.* at 1949. “First, the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions.” *Id.* “Second, only a complaint that states a plausible claim for relief survives a motion to dismiss.” *Id.* at 1950. The Court made clear that these requirements apply generally in “all civil actions.” *Id.* at 1953 (citing *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555-556 (2007)).

Here, plaintiffs’ complaint – without any factual support or explanation – asserts that the USPTO’s grant of patent claims related to human genes “violate[s] the First Amendment and Article I, section 8, clause 8 of the United States Constitution.” Compl. ¶ 4. Elsewhere, plaintiffs state that they are suing the USPTO “solely on [their] constitutional claims.” Compl. ¶ 27. But every paragraph in plaintiffs’ complaint concerning the Constitution recites nothing more than unsupported legal conclusions. The following paragraphs are illustrative:

52. The [USPTO’s] policy permits the patenting of products of nature, laws of

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<sup>4</sup> As 42 U.S.C. § 1983 applies only to state actors, not federal officials, plaintiffs cannot rely on this provision as a basis for jurisdiction against the USPTO. *See Yalkut v. Gemignani*, 873 F.2d 31, 35 (2d Cir. 1989).

nature, natural phenomena, abstract ideas, and basic human knowledge and thought. It therefore violates the United States Constitutions Article 1, section 8, clause 8 and the First amendment, as well as 35 U.S.C. § 101 of the patent statute.

54. This practice permits the patenting of laws of nature and abstract ideas and basic human knowledge or thought. It therefore violates Article 1, section 8, clause 8 and the First Amendment of the United States Constitution, as well as 35 U.S.C. § 101.

102. Because human genes are products of nature, laws of nature and/or natural phenomena, and abstract ideas or basic human knowledge or thought, the challenged claims are invalid under Article 1, section 8, clause 8 of the United States Constitution and 35 U.S.C. § 101.

103. All of the challenged claims represent patents on abstract ideas or basic human knowledge and/or thought and as such are unconstitutional under the First and Fourteenth Amendments to the United States Constitution.

“While legal conclusions can provide the framework of a complaint, they must be supported by factual allegations.” *Iqbal*, 129 S.Ct. at 1950. Here, plaintiffs’ allegations are unmoored to any plausible claim of unconstitutionality. Put simply, plaintiffs fail to provide any basis for the conclusion that the USPTO’s issuance of gene patents violates the clause of the Constitution that empowers Congress to “promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries,” U.S. Const. art. 1, § 8, cl. 8. Plaintiffs likewise fail to provide any facts or rationale that might support the conclusion that the USPTO’s issuance of gene patents prohibits plaintiffs’ free exercise of religion, abridges plaintiffs’ freedom of speech or that of the press, or interferes with plaintiffs’ right to assemble or seek redress from the Government, *see* U.S. Const. amend. I. As such, plaintiffs’ naked allegations fail to meet the standards set forth in *Iqbal*. 129 S.Ct. at 1951 (“It is the conclusory nature of respondent’s allegations, rather than their extravagantly fanciful nature, that disentitles them to the presumption of truth.”).

Moreover, plaintiffs' failure to state a claim for which the USPTO could be liable – indeed, the complaint does not seek any relief from the USPTO, *see* Compl. at 30 – demonstrates that the complaint does not “state a claim to relief that is plausible on its face.” 129 S. Ct. at 1949 (quoting *Twombly*, 550 U.S. at 570). Accordingly, plaintiffs' claims against the USPTO should be dismissed for “failure to state a claim upon which relief can be granted” pursuant to Fed. R. Civ. P. 12(b)(6).<sup>5</sup>

### CONCLUSION

For the foregoing reasons, the USPTO's motion to dismiss should be granted and the complaint against it dismissed.

Dated: New York, New York  
July 13, 2009

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<sup>5</sup> Plaintiffs' challenge to the constitutionality of the patents at issue is not, in the absence of an independent basis for jurisdiction or standing against the USPTO, a basis for naming the USPTO as a defendant. Rather, there are well-established procedures for the United States to intervene or otherwise inform courts of its views in connection with a constitutional challenge or any other interest of the United States. *See* 28 U.S.C. § 517; 28 U.S.C. § 2403; Fed. R. Civ. P. 5.1. The decision as to whether the United States will take a position on a constitutional question is made by high level officials within the Department of Justice, *see, e.g.*, 28 C.F.R. § 0.20(c); 28 C.F.R. § 0.21, and cannot be forced by naming a Government agency as a defendant.