

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK**

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ASSOCIATION FOR MOLECULAR	:	ECF CASE
PATHOLOGY, et al.,	:	
	:	
Plaintiffs,	:	09 Civ. 4515 (RWS)
	:	
v.	:	
	:	
UNITED STATES PATENT AND	:	
TRADEMARK OFFICE, et al.,	:	
	:	
Defendants.	:	
-----	x	

**REPLY MEMORANDUM OF LAW IN FURTHER SUPPORT OF DEFENDANT  
UNITED STATES PATENT AND TRADEMARK OFFICE'S MOTION FOR  
JUDGMENT ON THE PLEADINGS AND IN OPPOSITION TO  
PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT**

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Preliminary Statement

The USPTO demonstrated in its moving brief that, pursuant to the doctrine that courts should avoid unnecessary constitutional issues, the Court should not reach plaintiffs' claims under Article I, Section 8, Clause 8 (the "IP Clause"), and the First Amendment if the Court first invalidates the patents at issue in this case under 35 U.S.C. § 101 and thereby provides plaintiffs with the only relief they seek in their complaint. *See* USPTO Br. at 2-4. If the Court finds that the USPTO properly applied the patent statutes in issuing the patents and therefore reaches plaintiffs' constitutional claims, then those claims should be dismissed. As to plaintiffs' IP Clause claim, even if that Clause imposes a limitation on Congress' power to enact patent laws, Congress rationally exercised its power under the IP Clause to enact 35 U.S.C. § 101, as applied to the patents at issue, because there are multiple plausible bases for those patents. (*See* USPTO Br. at 5-12). As to plaintiffs' First Amendment claim, because 35 U.S.C. § 101 and the exceptions thereunder are consistent with and incorporate plaintiffs' First Amendment interests, patents validly issued under that statute do not violate the First Amendment, unless, under *Eldred v. Ashcroft*, 537 U.S. 186, 192-93 (2003), the statute does not fall within the "traditional contours" of patent law. Because 35 U.S.C. § 101 does fall within the "traditional contours" of patent law, plaintiffs may not maintain their First Amendment claim. (*See* USPTO Br. at 12-23).

In their fifty-page opposition to defendants' motions -- which includes a mere two pages responding specifically to the USPTO's motion, *see* plaintiffs' January 20, 2010 Opposition Brief ("Pl. Opp. Br.") at 42-43 -- plaintiffs do not address the majority of the USPTO's arguments as to why plaintiffs' constitutional claims should be dismissed, or *any* of the Supreme Court and other pertinent authorities supporting those arguments. Nor do plaintiffs cite a single case -- nor is the USPTO aware of one -- upholding a constitutional challenge to a

specific patent claim. As set forth below and in the USPTO's moving papers, the Court should reject plaintiffs' few substantive arguments forthwith and dismiss their constitutional claims.

## ARGUMENT

### THE COURT SHOULD DISMISS PLAINTIFFS' CONSTITUTIONAL CLAIMS

#### A. The Doctrine of Constitutional Avoidance Applies to Plaintiffs' Constitutional Claims

As set forth in the USPTO's moving brief, the Court should only reach plaintiffs' claims that the patents at issue in this case are unconstitutional under the IP Clause and the First Amendment if it *first* rejects plaintiffs' statutory claims, asserted against Myriad, that the USPTO improperly granted these patents under the applicable patent statutes. *See* USPTO Br. at 2-4. If the USPTO failed to properly apply the statutory requirements in issuing the patents -- which the USPTO believes it did not do -- plaintiffs will prevail on their claims against Myriad, the Court will invalidate the patents, and plaintiffs therefore will receive the only relief they seek. (*See* Compl., ¶¶ 102-03 and Prayer for Relief). In this latter circumstance, under the well-established doctrine of constitutional avoidance, *i.e.*, that courts should avoid unnecessary constitutional questions, this Court should not consider plaintiffs' constitutional claims. *See* USPTO Br. at 4.

Plaintiffs do not address any of the authorities cited by the USPTO, choosing instead to argue that "the doctrine of constitutional avoidance is inapplicable" because the invalidation of Myriad's claims pursuant to 35 U.S.C. § 101 "will not necessarily invalidate the USPTO's policy [in granting the patents]." Pl. Opp. Br. at 43. However, plaintiffs' complaint -- which plaintiffs conspicuously fail to mention -- does not seek to invalidate the USPTO's policy. (*See* Compl., ¶¶ 102-03 and Wherefore Clause). Rather, the complaint seeks to have the Court

invalidate certain specific patents issued pursuant to the USPTO's policy, but does *not* assert claims against the policy itself. (*Id.*); *see also* Pl. Opp. Br. at 1 (describing claims). Moreover, this Court has already held that plaintiffs' claims concern only the gene patents at issue. *See* Court's Nov. 1, 2009 Op. at 82-84 (noting that plaintiffs' complaint alleges the existence of a USPTO policy which is "applied to a series of specific patents and patent claims" and that these specific patents and patent claims allegedly violate the First Amendment and the IP Clause). Thus, if the Court invalidates the patents under 35 U.S.C. § 101, plaintiffs will have received the complete relief they seek, and the doctrine of constitutional avoidance precludes this Court from reaching the constitutional claims.<sup>1</sup> *See Allstate Ins. Co. v. Serio*, 261 F.3d 143, 149-50 (2d Cir. 2001); USPTO Br. at 4.

In addition, plaintiffs' assertion that "invalidation of the particular [patent] claims in this case will not necessarily invalidate the USPTO's policy," Pl. Opp. Br. at 43, is misleading. Should a final, binding decision by the Federal Circuit or the Supreme Court invalidate Myriad's patents under section 101, that ruling would apply to issued patents as well as patent applications, and would be binding on all patent holders and applicants, as well as the USPTO.<sup>2</sup>

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<sup>1</sup> Notably, under similar circumstances in a different case, counsel for plaintiffs asked a court to apply the doctrine of constitutional avoidance, by urging that 35 U.S.C. § 101 be interpreted in light of the First Amendment. Brief for *Amicus Curiae* ACLU for Affirmance in Support of Appellee at 15, *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008) (*en banc*), *cert. granted sub nom. Bilski v. Doll*, 129 S. Ct. 2735 (2009) ("[A]micus urges the Court, at a minimum, to interpret traditional patent doctrines so as to preserve the breathing room required by the First Amendment. If the Court finds itself unable to do so, *amicus* urges the Court to apply traditional First Amendment analysis to this claim.").

<sup>2</sup> Plaintiffs' assertion that there "are other such [patent] claims" that would be affected by the USPTO's policy, Pl. Opp. Br. at 43, is meritless. Plaintiffs have asserted claims based on specific patent claims they have identified, and other alleged patent claims are not properly before the Court.

*See Koninklijke Philips Electronics N.V. v. Cardiac Science*, No. 2009-1241, 2010 WL 10913, \*8 (Fed. Cir. Jan. 5, 2010) (“We remind the district court and the [USPTO] Board that they must follow judicial precedent . . .”). If the USPTO examination policies are inconsistent with a final, binding ruling, the USPTO would conform its examination policies to avoid issuing invalid patents.<sup>3</sup>

The Court therefore should only reach plaintiffs’ constitutional claims if it first rejects their statutory claims and concludes that the USPTO properly applied the statutory requirements in issuing the patents. Moreover, the USPTO did not, as plaintiffs contend, assert that plaintiffs’ claims challenge the patent statutes as facially unconstitutional (*see* Pl. Opp. Br. at 43); rather, the USPTO asserted that, if the patents do not run afoul of 35 U.S.C. § 101 but are nevertheless unconstitutional, that must mean that section 101 is unconstitutional as applied to those patents. *See* USPTO Br. at 4 (“If, however, the USPTO properly *applied* the statutory requirements but the patents are nevertheless unconstitutional, then plaintiffs’ complaint must be that one or more of the patent laws is unconstitutional.”) (emphasis added). As the sole case on which plaintiffs rely makes clear, a statute that fails an “as applied” challenge is still “declared invalid” as unconstitutional, but only “to the extent that it reaches too far.” *Ayotte v.*

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<sup>3</sup> A ruling that Myriad’s patents violate both the statute *and* the Constitution would not only run afoul of the doctrine of constitutional avoidance, but it also would invite alleged infringers to bring the USPTO into court in every patent case simply by claiming that, in addition to violating a statute, the patents also violate the Constitution. Such a holding would effectively countermand the Federal Circuit’s rule 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 (U.S.A.) Inc. v. U.S. Patent & Trademark Office*, 882 F.2d 1570, 1574-75 (Fed. Cir. 1989).

*Planned Parenthood*, 546 U.S. 320, 329 (2006) (quoting *Brockett v. Spokane Arcades, Inc.*, 472 U.S. 491, 504 (1985)). As discussed below, and in the USPTO’s moving brief, plaintiffs’ constitutional claims fail.

**B. THE COURT SHOULD DISMISS PLAINTIFFS’ CLAIM UNDER ARTICLE I, SECTION 8, CLAUSE 8 OF THE CONSTITUTION**

In its moving brief, the USPTO demonstrated that, assuming the preamble of the IP Clause limits Congress’s authority to enact patent laws (a debatable proposition, *see* USPTO Br. at 6-7), any challenge to the patent laws under the IP Clause must be tested under the rational basis test. *Id.* at 7-11. Plaintiffs do not dispute this standard. *See* Pl. Opp. Br. at 41 (acknowledging the “rational basis” standard of review). The USPTO advanced several plausible bases for Congress’s establishment of broad categories of statutory subject matter that would encompass the patents that are at issue here. Under rational basis review, that was more than sufficient to support Congress’s legislative choice in enacting section 101, and in failing to narrow it to exclude patents like *Myriad*’s. *See* USPTO Br. at 8-11; *see also id.* at 11 (citing Congress’s 2007 failure to enact proposed legislation to limit gene-related patents).

Plaintiffs’ IP Clause argument is mainly based on the Declaration of Joseph Stiglitz (filed with Pl. Opp. Br.), who opines that the social costs of gene patents outweigh their social benefits, and that patents in this area, in his view, “may” impede innovation. (*See, e.g.,* Stiglitz Decl., ¶¶ 26, 30). Plaintiffs contend that because the USPTO allegedly has failed to produce evidence to the contrary, the Court must find the issuance of gene-related patents “irrational[.]” Pl. Br. 41. But a rational basis is merely a plausible basis, and the USPTO (along with *Myriad* and its amici) have pointed to several plausible bases for the patent system in

general, and for encouraging patents like the ones at issue in particular. For example, the fact that patents are intended to encourage discovery and disclosure of new scientific information -- including about discoveries related to genes -- is a perfectly plausible basis for permitting such patents, and is consistent with the patent system's fundamental purpose of promoting progress in the useful arts. The fact that the gene-related patents attract investment so that new products and processes based on those patents can be developed and marketed is another highly plausible basis. Either of these bases easily clears the low bar set by the rational basis test. *See, e.g.*, USPTO Br. at 9-11; Brief for Amicus Curiae Biotechnology Industry Organization, Dec. 30, 2009, at 22-24. While one might speculate, as does Professor Stiglitz, that some discoveries would have been made without the patent system, that sort of speculation is hardly sufficient to show that the 35 U.S.C. § 101, as applied to the patent at issue, is irrational.

The Supreme Court's decision in *Eldred v. Aschcroft*, 537 U.S. 186, 192-93 (2003), demonstrates why 35 U.S.C. § 101, as applied to the patents at issue, is a rational exercise of Congress' power under the IP Clause. In *Eldred*, Congress had passed a statute extending the term of existing copyrights by 20 years. In an amicus brief, a group of well-known economists contended that the economic incentives created by the statute would have a negligible effect on promoting future creativity. *Id.* at 254-55. The Supreme Court, applying rational basis review, refused to substitute its policy judgments for those of Congress, "however debatable or arguably unwise they may be," and upheld the constitutionality of the statute. *Eldred*, 537 U.S. at 205. If the economic arguments made by the economists in *Eldred* could not serve as a basis for the Supreme Court to overturn Congress's extension of existing copyrights under the IP



Clause, this Court should not rely on the declaration of Professor Stiglitz to hold that 35 U.S.C. § 101, as applied to the patents at issue, is irrational.

Moreover, the Supreme Court has rejected plaintiffs' suggestion that the USPTO must offer evidence in support of 35 U.S.C. § 101. *See, e.g., Vance v. Bradley*, 440 U.S. 93, 110-11 (1979) (rejecting argument that the government has to offer "current empirical proof" in order for a challenged statute to be sustained under rational basis review). Indeed, the Supreme Court has made clear that "a legislative choice is not subject to courtroom factfinding and may be based on rational speculation unsupported by evidence or empirical data," and that to overturn a legislative enactment as "irrational," plaintiffs "have the burden to 'to negative every conceivable basis which might support it.'" *FCC v. Beach Communications, Inc.*, 508 U.S. 307, 314-15 (1993) (quoting *Lehnhausen v. Lake Shore Auto Parts Co.*, 410 U.S. 356, 364 (1973), and citing *Vance v. Bradley*, 440 U.S. at 111). Because plaintiffs have not even attempted to "negative" the multiple bases offered by the USPTO, Myriad, or Myriad's amici for a patent system that permits patents like Myriad's, their IP Clause argument fails.

### **C. THE COURT SHOULD DISMISS PLAINTIFFS' FIRST AMENDMENT CLAIM**

In its moving brief, the USPTO demonstrated that the Supreme Court has held that the patent statutes promote rather than inhibit the dissemination of knowledge and are thus consistent with the First Amendment, *see* USPTO Br. at 13-16, and that those statutes, as judicially-interpreted, contain safeguards -- including the fact that "abstract ideas" and "mental processes" may not be patented under 35 U.S.C. § 101 -- which prohibit the USPTO from issuing patents that unduly restrict speech and violate the First Amendment, *id.* at 16-18. Thus, if the

USPTO properly issued the patents in this case because they fell within one of the categories set forth in 35 U.S.C. § 101 and not within one of the judicially-created exceptions to that statute, those patents do not violate the First Amendment, unless, under the Supreme Court’s decision in *Eldred*, the statute’s categories depart from the “traditional contours” of patent law. *See* USPTO Br. at 18 (citing *Eldred*, 537 U.S. at 220-21). Because 35 U.S.C. § 101 has existed virtually unchanged since the earliest days of the patent system, that statute is consistent with the traditional contours of patent law, and the patents therefore do not violate the First Amendment. *See Eldred*, 537 U.S. at 221 (finding that because Congress’s extension of copyright terms did not “alter[] the traditional contours of copyright protection, further First Amendment scrutiny [was] unnecessary.”).

Plaintiffs do not mention, let alone attempt to distinguish, these principles, or the Supreme Court cases underlying them, choosing instead to argue that the principles are “at such a high level of generality” as to be “meaningless.” Pl. Opp. Br. at 42. Plaintiffs’ argument misses the point. If the patent claims at issue here fall within the one of the categories set forth in 35 U.S.C. § 101 -- *i.e.*, as a “composition of matter” or a “process” -- and are not within one of the judicially-created exceptions to that statute, the only remaining First Amendment scrutiny *is* at a high level: namely, whether the categories in section 101 are within the traditional contours of patent law. Because they are, plaintiffs’ First Amendment claim fails. *See* USPTO Br. at 18 (citing *Eldred*, 537 U.S. at 220-21).

Plaintiffs’ few other substantive arguments should be swiftly rejected. Plaintiff disingenuously asserts that the USPTO has argued that the “First Amendment imposes no . . . substantive limitation . . . on patent law.” Pl. Opp. Br. at 39. This is an abject misstatement of

the USPTO's moving brief; as discussed above, 35 U.S.C. § 101, as judicially interpreted, is consistent with and *incorporates* First Amendment protections. Similarly, plaintiffs' argument that the patents at issue can be seen as "prohibit[ing] thought and knowledge" and thus restricting speech, Pl. Opp. Br. at 39, ignores both these principles and the Supreme Court's analysis in *Eldred*, as well as the fact that the USPTO routinely issues patents that can be said to restrict speech but do not offend the patent laws or the First Amendment. The telephone and telegraph are obvious examples, and contrary to plaintiffs' assertion, *see* Pl. Opp. Br. at 39, a patent on one of these devices does in fact prevent someone from conveying a thought over that device. *See* 35 U.S.C. § 271(a) (giving the patent owner the power to prevent others from "mak[ing], us[ing] . . . or sell[ing]" the invention).<sup>4</sup> Indeed, despite the existence of such patents, as well as tens of thousands of reported patent cases, plaintiffs have not cited a single case that even considers the issue of whether a patent claim violates the First Amendment. Accordingly, plaintiffs' arguments that patents covering genetic subject matter may limit the free flow of information are inapposite.

Plaintiffs' "impossible to invent around" argument, *see* Pl. Opp. Br. at 40, likewise fails to establish a First Amendment claim. As the USPTO previously explained, *see* USPTO Br. at 17, 35 U.S.C. § 112, as well as the judicially-created exceptions to 35 U.S.C. § 101, generally operate to prevent the issuance of patents that are so broad that they cannot be

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<sup>4</sup> When the original telephone patents were in force, telephones were not sold, but rather were licensed under Bell's patents. *See Dolbear v. American Bell Telephone Company*, 126 U.S. 1, 551 (1888) (noting "'that there are now in use more than 100,000 electric speaking-telephones licensed by and paying royalty to' the Bell Company"). Any telephone user who failed to pay the license fee would presumably have been subject to a suit for patent infringement, in which American Bell could have obtained an injunction against further use of the telephone.

“invented around,” and these statutes therefore accommodate any First Amendment interests. Moreover, plaintiffs’ argument fails to establish the connection between the difficulty of inventing around (an attribute of all strong patents, like Bell’s patent on the telephone) and the First Amendment. Plaintiffs contend that Myriad’s patents “prohibit anyone from using the concept ‘carburetor’ or, in other words, consist of a patent on all knowledge about and using the information embodied by the claimed DNA.”<sup>5</sup> Pl. Opp. Br. at 40. But the patents have no such effect; thousands of articles have been written discussing the genes covered by Myriad’s patents,<sup>6</sup> and there is no suggestion that these articles somehow infringe Myriad’s patents, as they would if the patents truly covered “all knowledge about and using the information embodied by the claimed DNA.” Pl. Opp. Br. at 40. If anything, the prevalence of these articles shows that the patents have well served the First Amendment interest in wide dissemination of knowledge.

Plaintiffs’ suggestion that 35 U.S.C. § 101 as applied to the patents here must be considered under the “strict scrutiny” test, Pl. Opp. Br. at 39, is meritless. Plaintiffs rely on *R.A.V. v. St. Paul*, 505 U.S. 377 (1992), which applied strict scrutiny to a content-based restriction on speech. Section 101, as plaintiffs seem to admit, *see* Pl. Opp. Br. at 39, does not

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<sup>5</sup> Plaintiffs again fail to show how a DNA patent is qualitatively different than a carburetor patent for purposes of “inventing around.” Given that carburetors remain in widespread use more than 100 years after the carburetor was invented, it is clear that the carburetor is very difficult if not impossible to invent around for some applications.

<sup>6</sup> *See* Myriad Dec. 23, 2009 Brief at 6 (“More than **18,000 scientists** have researched BRCA1 and BRCA2, and published over **7,000 papers** on the genes.”) (emphases in original).

involve a statute that inhibits speech “based on content or viewpoint,” so strict scrutiny does not apply.<sup>7</sup>

Finally, plaintiffs argue that DNA molecules – unlike other chemicals – are unpatentable because they “constitute natural phenomena and laws of nature,” both of which are judicial exceptions to section 101. *See* Pl. Opp. Br. at 43; *see Gottschalk*, 409 U.S. at 67. This argument therefore raises a statutory issue, and not a constitutional one. The USPTO’s position on this question remains as set forth in its Utility Guidelines, 66 Fed. Reg. 1092 (Jan. 5, 2001).<sup>8</sup>

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<sup>7</sup> Even if the Supreme Court’s guidance in *Eldred* did not apply here -- which it clearly does -- the pertinent First Amendment scrutiny would not be “strict,” but rather the “intermediate level of scrutiny” that is “applicable to content-neutral restrictions that impose an incidental burden on speech.” *Turner Broad. Sys., Inc. v. FCC*, 512 U.S. 622, 662 (1994); *see United States v. O’Brien*, 391 U.S. 367, 375 (1968) (holding that a statute prohibiting the destruction of Selective Service Registration Certificates did not violate the First Amendment because the statute and regulation broadly “deal[t] with conduct having no connection with speech”). The Patent Act “plainly does not abridge free speech on its face,” *O’Brien*, 391 U.S. at 375, because only one who imports, “makes, uses, offers to sell, or sells any patented invention” can be held liable for infringing a patent. 35 U.S.C. § 271(a). Thus, even if the *Eldred* analysis were not appropriate, the Patent Act nevertheless would not violate the First Amendment under the appropriate *O’Brien* intermediate scrutiny standard: the IP Clause explicitly grants Congress the power to create a patent system to promote the progress of the useful arts, which “add[s] to the general store of knowledge,” *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 481 (1974), rather than restricting expression, and any incidental restriction on alleged First Amendment freedoms is accommodated by the judicially-created exceptions to section 101, which preclude patents on “abstract ideas” and “mental processes,” *see Gottschalk v. Benson*, 409 U.S. 63, 67 (1972).

<sup>8</sup> The USPTO discussed this issue in its opening brief only to point out that plaintiffs, in addressing their constitutional claims, incorrectly stated that genes are simply information or thought protected by the First Amendment. *See* USPTO Br. at 20-23. Although plaintiffs criticize the USPTO for not separately addressing Myriad’s method claims, *see* Pl. Opp. Br. at 38, plaintiffs did not address the method claims in their constitutional arguments, and the USPTO therefore had no reason to address them.

## CONCLUSION

For the foregoing reasons, and the reasons set forth in the USPTO's moving papers, the Court should deny plaintiffs' motion for summary judgment as to the USPTO, grant the USPTO's motion for judgment on the pleadings, and dismiss the complaint against the USPTO.

Dated: New York, New York  
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