UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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

MEMORANDUM OF LAW IN 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

Defendant United States Patent and Trademark Office ("USPTO") respectfully submits this memorandum of law in opposition to plaintiffs' motion for summary judgment, and in support of its cross-motion for judgment on the pleadings. The only two claims asserted against the USPTO are plaintiffs' two constitutional claims, *i.e.*, that the USPTO's policy of issuing gene-related patents allegedly violates Article I, Section 8, Clause 8 (the "IP Clause") and the First Amendment to the Constitution. Accordingly, the USPTO does not directly address plaintiffs' statutory claims under 35 U.S.C. § 101 -- that the patents at issue do not meet the statutory requirements for issuance of a patent and hence are invalid -- which are asserted only against the other defendants.

Both of plaintiffs' constitutional claims should be dismissed. As an initial matter, if the Court finds against defendant Myriad Genetics ("Myriad") on plaintiffs' statutory claims, then the Court should not reach the constitutional claims under the well-established principle that courts do not adjudicate unnecessary constitutional issues. If the Court concludes that the USPTO properly applied the patent statutes in issuing the patents, then the issue is whether those statutes violate either the IP Clause or the First Amendment.

The patent statutes clearly do not violate the IP Clause, which provides in relevant part that Congress has the power "[t]o promote the Progress of Science and the useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." Even if the language of that Clause imposes a limitation on Congress' power to enact patent laws -- a proposition for which there is substantial doubt -- Congress had the power under the IP Clause to establish a patent system as it saw fit, subject only, at most, to rational basis review. Moreover, there can be no reasonable dispute that

Congress had a rational basis to believe that a statutory scheme that established broad categories of subject matter eligible for patenting, and which allowed for the patents at issue in this case, would promote innovation and research. Plaintiffs' IP Clause claim should therefore be dismissed. (*See* Point I, *infra*).

Plaintiffs' First Amendment claim fails because the patent statutes are compatible with First Amendment free speech principles, and those statutes accommodate First Amendment concerns. Indeed, Congress enacted the patent statutes in close proximity to the First Amendment, and the Supreme Court has held that those statutes promote free speech interests. (*See* Point II(A)(1), *infra*). In addition, the specific free speech concerns cited by plaintiffs are already accommodated by the patent statutes, as interpreted by numerous courts. In particular, the requirements of 35 U.S.C. §§ 101, 102, 103, and 112 result in patents that do not unduly restrict protected speech. Because plaintiffs have not identified any way in which the Constitution imposes limits on patents beyond those already imposed by the patent laws, plaintiffs' First Amendment claim merges with their statutory claims, and should therefore be dismissed. (*See* Point II(A)(2), *infra*).

ARGUMENT

THE COURT SHOULD DISMISS PLAINTIFFS' CONSTITUTIONAL CLAIMS

Plaintiffs' purported claims that the patents at issue in this case are invalid under Article I, Section 8, Clause 8, and the First Amendment to the Constitution are meritless. As an initial matter, the Court cannot reach these constitutional claims unless it first rejects plaintiffs' claims, asserted against Myriad, that the patents were improperly granted under the applicable patent statutes, and concludes that the USPTO properly applied these statutes in granting the

patents. In issuing the patents in this case, the USPTO merely applied the rules set forth by Congress pursuant to its Article I power to establish the patent system. Thus, the USPTO first considered whether the patent claims fell into one of the statutory categories set forth in 35 U.S.C. § 101 (providing that "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter . . . may obtain a patent therefor") and did not fall within one of the judicially-created exceptions to those categories, *see Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) ("The laws of nature, physical phenomena, and abstract ideas have been held not patentable.") (*citing Parker v. Flook*, 437 U.S. 584 (1978)). The USPTO also tested the patent claims against 35 U.S.C. § 102, to ensure that the patent claims were novel; 35 U.S.C. § 103, to ensure that they were not obvious; and 35 U.S.C. § 112, to ensure that they were not indefinite, were enabled for their full scope, and were described in the specification. *See generally Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 146-51 (1989) (explaining how the various statutory provisions serve the constitutional purpose of promoting progress).

The statutory scheme also gives accused infringers the opportunity to litigate the question whether the USPTO properly applied the statutory requirements. *See* 35 U.S.C. § 282(2), (3). Indeed, plaintiffs' primary claims in this case, asserted against Myriad, are that the patent claims fall into one or more of the judicially-created exceptions to 35 U.S.C. § 101, and thus are not patentable subject matter under that statute (*see* Plaintiffs' Memorandum of Law in Support of Motion for Summary Judgment ("Br.") at 19-32). As the Court has recognized, it is well-established that the USPTO cannot be haled into court to defend against claims that it has issued patents that violate the patent statutes. *See* Court's Nov. 1, 2009 Opinion at 40 (citing

Syntex (U.S.A.), Inc. v. U.S. Patent & Trademark Office, 882 F.2d 1570, 1572-74 (Fed. Cir. 1989)).

If the USPTO failed to properly apply the statutory requirements -- which it believes it did *not* do -- plaintiffs will prevail on their claims against Myriad, and the patents will be held invalid. In such a case, the doctrine of constitutional avoidance, *i.e.*, that courts should not reach unnecessary constitutional questions, requires this Court not to reach plaintiffs' constitutional claims. *See, e.g., Allstate Ins. Co. v. Serio,* 261 F.3d 143, 149-50 (2d Cir. 2001) ("It is axiomatic that the federal courts should, where possible, avoid reaching constitutional questions.") (citing *Spector Motor Serv., Inc. v. McLaughlin*, 323 U.S. 101 (1944) ("If there is one doctrine more deeply rooted than any other in the process of constitutional adjudication, it is that we ought not to pass on questions of constitutionality . . . unless such adjudication is unavoidable"); *see Ashwander v. TVA*, 297 U.S. 288, 347 (1936) (Brandeis, J., concurring) ("[I]f a case can be decided on either of two grounds, one involving a constitutional question, the other a question of statutory construction or general law, the Court will decide only the latter.").

Thus, in order to reach plaintiffs' constitutional claims, the Court would have to first reject plaintiffs' claims against Myriad and conclude that the USPTO properly applied the statutory requirements. If, however, the USPTO properly applied the statutory requirements, then plaintiffs' complaint must be that one or more of the patent laws is unconstitutional. Accordingly, while the USPTO continues to believe that the Court lacks jurisdiction over these claims (*see* Govt. Mot. to Dismiss), plaintiffs' constitutional challenges to the statutory scheme that resulted in the issuance of the patents at issue are meritless and should be rejected for multiple reasons, as set forth below.

POINT I

THE COURT SHOULD DISMISS PLAINTIFFS' CLAIM UNDER ARTICLE I, SECTION 8, CLAUSE 8 OF THE CONSTITUTION

Article I, Section 8, Clause 8 of the Constitution (the "IP Clause"), authorizes Congress "[t]o promote the Progress of Science and the useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." According to plaintiffs, the patent claims "impede rather than promote the progress of science." (Br. at 37-38). Plaintiffs' argument fails for multiple reasons.

As an initial matter, plaintiffs incorrectly contend that the IP Clause requires that patents promote the progress of *science*. To the contrary, the IP Clause "*authorizes* the Congress 'To promote the Progress of . . . *useful Arts*, by securing for limited Times to . . . Inventors the exclusive Right to their . . . Discoveries." *Graham v. John Deere Co.*, 383 U.S. 1, 5 (1966) (quoting U.S. Const. art. I, § 8, cl. 8) (emphases added; alterations in original). As the Court noted in *Graham*, the reference to "science" in the clause is "not relevant" to the patent system, *id*. at 5 n.1, because it is only relevant to the copyright system, *see Eldred v. Ashcroft*, 537 U.S. 186, 192-93 (2003) ("The Copyright and Patent Clause of the Constitution, Art. I, § 8, cl. 8, provides *as to copyrights*: 'Congress shall have Power . . . [t]o promote the Progress of Science . . . by securing [to Authors] for limited Times . . . the exclusive Right to their . . . Writings.'") (quoting U.S. Const. art. I, § 8, cl. 8) (emphasis added; alterations in original); *see also id.* at 243 (Breyer, J., dissenting) (stating that by the word "Science," "the Framers meant learning or knowledge" (citing E. Walterscheid, *The Nature of the Intellectual Property Clause: A Study in Historical Perspective* 125-26 (2002)); Orrin G. Hatch & Thomas R. Lee, *"To Promote the*

Progress of Science": The Copyright Clause and Congress's Power to Extend Copyrights, 16 Harv. J.L. & Tech. 1, 7 (2002) ("Everyone agrees that the notion of 'science' in the founding era referred generally to all forms of knowledge and learning." (citations omitted)). Plaintiffs do not argue that the patent claims fail to promote the useful arts; nor could they. As the Supreme Court has pointed out, "it is assumed" that patents promote the progress of the useful arts because their disclosures "add[] to the general store of knowledge." *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 481 (1974). Plaintiffs' claim therefore can be rejected for this reason alone.

Even assuming that the plaintiffs are arguing that the patents at issue fail to promote progress in the useful arts, and that the USPTO somehow acted unconstitutionally in issuing them, this argument is meritless. It is far from clear that the preamble to the IP Clause imposes a judicially-enforceable limitation on Congress's power to enact patent laws. *See Schnapper v. Foley*, 667 F.2d 102, 112 (D.C. Cir. 1981) (rejecting argument that "the introductory language of [the IP Clause] constitutes a limit on congressional power"); *see also Eldred v. Ashcroft*, 537 U.S. at 211-13 (indicating that "Petitioners acknowledge that 'the preamble of the Copyright Clause is not a substantive limit on Congress' legislative power") (quoting *Eldred v. Reno*, 239 F.3d 372, 378 (D.C. Cir. 2001)); *Figueroa v. United States*, 466 F.3d 1023, 1030 (Fed. Cir. 2006) ("assum[ing], without deciding, that the Patent Clause's preambular language limits congressional authority to actions necessary and proper to 'promot[ing] the progress of science and useful arts,' and that this limitation is judicially enforceable"); *see also District of Columbia v. Heller*, 128 S. Ct. 2783, 2789 (2008) ("Th[e] requirement of logical connection may cause a prefatory clause to resolve an ambiguity in the

operative clause. . . . But apart from that clarifying function, a prefatory clause does not limit or expand the scope of the operative clause.").

To the extent the preamble of the IP Clause imposes a limitation, courts must give broad if not complete deference to Congress's "implement[ation of] the stated purpose of the Framers" in that area:

> It is the duty of the Commissioner of Patents and of the courts in the administration of the patent system to give effect to the constitutional standard by appropriate application, in each case, of the statutory scheme of the Congress.

Graham, 383 U.S. at 6; *see also Bonito Boats*, 489 U.S. at 168 ("It is for Congress to determine if the present system of design and utility patents is ineffectual in promoting the useful arts in the context of industrial design."); Br. for Amici National Women's Health Network et al. at 4 (observing that Congress has "broad power to legislate to 'promote the Progress of science and the useful Arts,'" in the course of making a statutory argument against patent-eligibility of Myriad's claims). [1]

Even if plaintiffs are correct that deference to Congress is "not absolute" (Br. at 37-38), plaintiffs are at most entitled to "rational basis" review of statutes enacted under the IP Clause. *See Eldred*, 537 U.S. at 199-208 (upholding, under rational basis review, Copyright Term Extension Act of 1998); *Figueroa*, 466 F.3d at 1030-34 (upholding, under rational basis review, congressional diversion of fees received by the USPTO in connection with patent applications and patents). Under that standard, courts "accord great deference to Congress's policy determinations," and judicial review "is limited to determining whether Congress's

[1] Notably, plaintiffs rely only on cases involving copyright law, not patent law, in support of their argument that "deference is not absolute" in this area. (Br. at 37-38).

actions were 'a rational exercise of the legislative authority conferred by the [Patent] Clause.'" *Figueroa*, 466 F.3d at 1031-32 (quoting *Eldred*, 537 U.S. at 204, 218). Under rational basis review, the court need not "limit itself to the policy justifications that Congress articulated." *Figueroa*, 466 F.3d at 1032 (citing *Eldred*, 537 U.S. at 206). Indeed, "[w]here . . . there are plausible reasons for Congress's action . . . [i]t is . . . 'constitutionally irrelevant whether this reasoning in fact underlay the legislative decision.'" *Id.* (quoting *U.S.R.R. Retirement Bd. v. Fritz*, 449 U.S. 166, 179 (1980) (quoting *Flemming v. Nestor*, 363 U.S. 603, 612 (1960))).

Moreover, the proper focus of a constitutional challenge to the patent laws must focus on the laws themselves, rather than individual patents issued pursuant to them. *See Bonito Boats*, 489 U.S. at 168 (focusing on "the present system of design and utility patents," rather than individual patents). The fact that some patents issued under the patent system can be argued not to "promote progress" has no bearing on the question of whether the system as a whole has a rational basis. Instead, the question here is whether there is a "rational relationship" between permitting patents on "composition[s] of matter" and "process[es]," 35 U.S.C. § 101 -- which cover the gene-related products and methods in the present case -- and "Congress's legitimate objectives under the IP Clause." *See Figueroa*, 466 F.3d at 1032.

In this case, there are multiple plausible bases on which Congress could have enacted § 101 so as to countenance patents on gene-related inventions. First, it was rational for Congress to set forth in § 101 broad categories of subject matter that could be eligible for patents, as it did in the 1793 Patent Act, shortly after ratification of the Constitution.[2] Choosing broad

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[2] *See* Patent Act of 1793, Ch. 11, 1 Stat. 318-23 (February 21, 1793) (providing for patents on "any new and useful art, machine, manufacture or composition of matter"). The broad statutory categories from the 1793 Act remain essentially intact today. *See* 35 U.S.C. § 101 (providing for

categories of eligible subject matter ensured that the Patent Act would not have to be repeatedly amended to accommodate new and emerging technologies. *See, e.g.*, *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) ("In choosing such expansive terms as 'manufacture' and 'composition of matter,' modified by the comprehensive 'any,' Congress plainly contemplated that the patent laws would be given wide scope."). Even if it could be shown that certain classes of patents within these broad categories impede more "progress" than they "promote," this would not mean that Congress's decision to establish broad categories of eligible subject matter was not rationally based. Indeed, the Supreme Court has specifically found that broad statutory categories fulfill the constitutional goal. *See id.* at 315 ("The subject-matter provisions of the patent law have been cast in broad terms to fulfill the constitutional and statutory goal of promoting 'the Progress of Science and the useful Arts' with all that means for the social and economic benefits envisioned by Jefferson.").

Second, even if it were appropriate to focus the rational basis inquiry on gene-related patents, a patent system that allows such patents is rationally based. Permitting patents in a field of technology can be expected to stimulate investment, research, and innovation within that area, all to the benefit of the national economy. *See, e.g.*, H.R. Rep. No. 98-857, at 17 (1984), *reprinted in* 1984 U.S.C.C.A.N. at 2650 ("Patents are designed to promote innovation by providing the right to exclude others from making, using, or selling an invention. They enable innovators to obtain greater profits than could have been obtained if direct competition existed.

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patents on "any new and useful process, machine, manufacture, or composition of matter"); *see also Diamond v. Diehr*, 450 U.S. 175, 182 (1981) ("Although the term 'process' was not added to 35 U.S.C. § 101 until 1952, a process has historically enjoyed patent protection because it was considered a form of 'art' as that term was used in the 1793 Act.").

These profits act as incentives for innovative activities."); *see also id.* at 15, 1984 U.S.C.C.A.N. at 2648 ("The purpose of Title II of the bill is to create a new incentive for increased expenditures for research and development."); *Biotechnology Indus. Org. v. District of Columbia*, 496 F.3d 1362, 1372 (Fed. Cir. 2007) ("'We have long acknowledged the importance of the patent system in encouraging innovation. Indeed, the encouragement of investment-based risk is the fundamental purpose of the patent grant, and is based directly on the right to exclude.'") (quoting *Sanofi-Synthelabo v. Apotex*, Inc., 470 F.3d 1368, 1383 (Fed. Cir. 2006) (internal quotations omitted)); *Paulik v. Rizkalla*, 760 F.2d 1270, 1276 (Fed. Cir. 1985) ("The reason for the patent system is to encourage innovation and its fruits: new jobs and new industries, new consumer goods and trade benefits.").

Given the high costs of bringing biotechnology products to market, it is well established that strong patent protection is vital to the biotechnology industry. *See, e.g.*, Christopher Holman, *Learning From Litigation: What Can Lawsuits Teach Us About the Role of Human Gene Patents in Research and Innovation*, 18 Kan. J.L. & Pub. Pol'y 215, 222 (Winter 2009) ("It is widely acknowledged that patents, including gene patents, have played a critical role in incentivizing investors to risk capital in the extremely expensive and uncertain business of biotechnology-based drug development. The important role of human gene patents in protecting therapeutic proteins is reflected in the amount of litigation in which human gene patents have been asserted in an attempt to block a competing manufacturer of the therapeutic protein."); Karen Boyd, *Nonobviousness and the Biotechnology Industry: A Proposal for a Doctrine of Economic Nonobviousness*, 12 Berkeley Tech. L.J. 311, 322 (1997) ("[T]he pharmaceutical industry, including biotechnology, is one of the few industries that literally could not survive

without patent protection."). The patent incentive has resulted in the investment needed to encourage research and disclosure into the functions of genes, and the development of gene-related treatments. *See generally* Holman, *supra*.

The disclosure required under the patent system carries an additional benefit -- other researchers learn what has been patented, and are therefore able to focus their research dollars on areas that have yet to be explored. Under rational basis review, the task of performing the "careful balance between the need to promote innovation and the recognition that imitation and refinement through imitation are both necessary to invention itself and the very lifeblood of a competitive economy," *Bonito Boats*, 489 U.S. at 146, must be left to Congress. *See Eldred*, 537 U.S. at 216 ("'It is for Congress to determine if the present system' effectuates the goals of the Copyright and Patent Clause.") (quoting *Bonito Boats*, 489 U.S. at 168). Provided that there is some rational basis for permitting the patents, factual assertions that the patents will impede more progress than they promote (*see* Br. at 37), are simply not relevant. *See, e.g.*, *Eldred*, 537 U.S. at 208 ("In sum, we find that the [Copyright Term Term Extension Act] is a rational enactment; we are not at liberty to second-guess congressional determinations and policy judgments of this order, however debatable or arguably unwise they may be."). Given the multiple plausible reasons in favor of permitting gene-based patents, Congress's allowance of such patents easily survives rational basis review. The fact that Congress has recently considered and failed to pass legislation that would essentially ban patents on gene-related inventions, *see* Genomic Research and Accessibility Act, H.R. 977, 110th Cong. (2007), suggests that courts should tread lightly in this area. Accordingly, plaintiffs' constitutional claim under the IP Clause should be dismissed.

POINT II

THE COURT SHOULD DISMISS PLAINTIFFS' FIRST AMENDMENT CLAIM

Plaintiffs' argument that the patents at issue here violate the First Amendment also is meritless and can be dismissed for multiple reasons. Plaintiffs raise two arguments under the First Amendment: i) the patents directly limit "abstract ideas or thought" in violation of the First Amendment because the patents allegedly preclude a person from studying or thinking about the genes at issue (Br. at 34-36); and ii) the alleged inability of others to "invent around" these patents somehow implicates the First Amendment (Br. at 36-37). Because the Court can only reach these arguments if it first finds that the patent statutes authorized the issuance of the patents, *see supra* at 3-5, plaintiffs' arguments are thus that the patent statutes violate the First Amendment.

The Court should reject plaintiffs' purported First Amendment arguments. Both arguments presuppose that the First Amendment provides a substantive limitation on Congress's authority to enact patent laws. However, the First Amendment imposes no such substantive limitation, and even if it did, the patent laws have already been interpreted to accommodate any First Amendment concerns. Plaintiffs' arguments also fail because they are premised on the incorrect notion that patents on isolated and purified genes are patents on "information."

A. The Patent System Is Compatible With Free Speech Principles

1. The Patent System Promotes Rather Than Inhibits the Dissemination of Knowledge

Because the patent statutes promote the dissemination of knowledge, plaintiffs' First Amendment challenge to those statutes necessarily fails. The patent system, like the copyright system, expanded the amount of knowledge available to the public, and therefore serves the same interests protected by the First Amendment:

> The stated objective of the Constitution in granting the power to Congress to legislate in the area of intellectual property is to 'promote the Progress of Science and useful Arts.' The patent laws promote this progress by offering a right of exclusion for a limited period as an incentive to inventors to risk the often enormous costs in terms of time, research, and development. . . . When a patent is granted and the information contained in it is circulated to the general public and those especially skilled in the trade, such additions to the general store of knowledge are of such importance to the public weal that the Federal Government is willing to pay the high price of 17 years of exclusive use for its disclosure, which disclosure, it is assumed, will stimulate ideas and the eventual development of further significant advances in the art.

Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 480-81 (1974); *Zacchini v. Scripps-Howard Broadcasting Co.*, 433 U.S. 562, 576 (1977) (explaining, in the course of rejecting a news organization's First Amendment claim to broadcast a performer's act, that "Ohio's decision to protect petitioner's right of publicity here rests on more than a desire to compensate the performer for the time and effort invested in his act; the protection provides an economic incentive for him to make the investment required to produce a performance of interest to the public. This same consideration underlies the patent and copyright laws long enforced by this Court."). As *Kewanee* recognizes, the Patent Act promotes free speech and general dissemination of information because it grants a temporary exclusive right to an invention in

exchange for disclosure of information that might otherwise have remained secret. By making the information about the invention available, it creates the possibility for stimulating further research in a related area as well as for one who wants to practice the invention to seek a license.[3] If the information were kept secret – potentially in perpetuity, depending on the nature of the technology – no such opportunity would arise.[4] Indeed, given the proximity in time between the establishment of the patent system and the ratification of the First Amendment, it does not appear that the Framers themselves perceived any tension between the provisions. *See Eldred*, 537 U.S. at 219.

Moreover, the patents at issue here are by no means unique in their alleged impact on First Amendment values. Numerous patents have issued that have had the effect of enabling the inventor to control -- or, more usually, charge a fee for -- the speech of others. Prominent examples include Morse's patent on the telegraph and Bell's patent on the telephone. In each case, individuals wishing to use these devices to communicate their thoughts or to gain access to new knowledge could do so only subject to the rights of the patentholder. Today, any of hundreds of thousands of patents relevant to telecommunications and/or computer networking

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[3] Nothing in the First Amendment requires that the exercise of First Amendment rights be cost-free. Those who wish to publish must pay for the equipment and labor (or internet access) required for publication; indeed, even parade demonstrators may be required to pay to exercise their First Amendment right to march. *See Cox v. New Hampshire*, 312 U.S. 569, 576-77 (1941). *See generally* Eric Neisser, *Charging for Free Speech: User Fees and Insurance in the Marketplace of Ideas*, 74 Geo. L.J. 257 (1985).

[4] Patents tend to level the investment playing field between inventions that cannot be maintained as trade secrets (*i.e.*, inventions that, by their nature, must be disclosed to be exploited) and those that can. Without patents, it would be more attractive to invest in the latter than in the former. Thus, patents serve the asserted First Amendment interest by providing returns on investments in inventions that might not otherwise be pursued, due to the unavailability of trade secret protection.

technology can be said to have an effect on speech. Likewise, the existence of statutory remedies for inducing infringement – *i.e.* by encouraging, typically through conduct that includes speech, someone to infringe another's patent, (*see* 35 U.S.C. § 271(b) or 35 U.S.C. § 271(f)(1)) – could be said to regulate speech and thus, under plaintiffs' theory, to violate the First Amendment.

But in all of these cases, as in the cases of patents on gene-related inventions, any inhibition of First Amendment values is simply a statutory accompaniment of the patent grant, and of the patent system in general -- a temporary burden on the public that Congress has deemed necessary to encourage invention and disclosure of inventions that inure to the public benefit. Despite the incidental limitation on speech imposed by patents on communications technology (or, for that matter, gene-related inventions), these patents should be seen as limitations on conduct, rather than limitations on speech. As such, the First Amendment is not implicated. *See Zemel v. Rusk*, 381 U.S. 1, 16-17 (1965) ("There are few restrictions on action which could not be clothed by ingenious argument in the garb of decreased data flow. For example, the prohibition of unauthorized entry into the White House diminishes the citizen's opportunities to gather information he might find relevant to his opinion of the way the country is being run, but that does not make entry into the White House a First Amendment right. The right to speak and publish does not carry with it the unrestrained right to gather information.").

In this regard, Plaintiffs' contention that "[t]he effect of the patents is to give control of all knowledge of those genes and the functions dictated by nature to the defendants" (Br. at 36) is simply incorrect. Myriad has no control over the knowledge that it discovered and disclosed in its patent application; it merely has the ability to sue someone who has infringed one of its patents, for example by making, selling, or using a claimed product or by practicing a

claimed process. *See* 35 U.S.C. § 271(a). Thus, the free-speech interests here – if any – are subordinate to the interest in a working patent system that provides complete remedies to patentholders. The question is not whether any given patent might inhibit more speech than it promotes, but rather whether in establishing a patent system that awarded such a patent, Congress somehow violated the First Amendment. Because Congress did not, plaintiffs' First Amendment claim should be dismissed.

2. The Patent System Accommodates First Amendment Concerns

Plaintiffs' purported First Amendment claim also can be dismissed because the patent system "contains built-in First Amendment accommodations" in addition to "spurring the creation and publication of new expression." *Eldred*, 537 U.S. at 219. Because the patent statutes account for the First Amendment concerns raised by plaintiffs, plaintiffs may not maintain a separate First Amendment claim against the USPTO.

All of the alleged First Amendment concerns that plaintiffs raise already have found expression in the patents statutes, as interpreted by the courts. Plaintiffs' concern that the patents at issue here cover "abstract ideas" and thus "thought" is dealt with by judicially-created "abstract idea" and "mental process" exceptions to 35 U.S.C. § 101. *See Gottschalk v. Benson*, 409 U.S. 63, 67 (1972) ("Phenomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work."). Indeed, as plaintiffs acknowledge (Br. at 33), the "abstract idea" exception to 35 U.S.C. § 101 is statutory. Plaintiffs' hypothetical that patents on abstract ideas would run afoul of the First Amendment (Br. at 33-36) is thus irrelevant -- such patents are not permitted by the statutory scheme, which permits patents that cover physical products and

physical processes, but not pure thought. *See Gottschalk*, 409 U.S. at 67. If plaintiffs are correct that Myriad's patents cover "abstract ideas" (Br. at 33) or that the USPTO has "give[n] exclusive control over certain thoughts to a single company" (*id.* at 36) – they will be able to establish this in their case against Myriad, and any offending patents will be deemed invalid as not meeting the statutory requirements of 35 U.S.C. § 101.

Likewise, as plaintiffs also acknowledge, 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 "invented around." (Br. at 36). Assuming plaintiffs are correct that an inability to "invent around" implicates First Amendment interests, those interests have already been accommodated in § 112 and the judicially-created exceptions to § 101.

The Supreme Court's decision in *Eldred* is illustrative of why plaintiffs may not maintain their First Amendment claims. The *Eldred* petitioners argued that the 1998 Copyright Term Extension Act ("CTEA") – which extended the duration of copyright in subsisting works by twenty years – violated the First Amendment rights of individuals who intended to make use of copyrighted works after they fell into the public domain. In rejecting this argument, the Supreme Court pointed out that "[t]he Copyright Clause and First Amendment were adopted close in time," and that "this proximity indicates that, in the Framers' view, copyright's limited monopolies are compatible with free speech principles." 537 U.S. at 219. The fact that "copyright's purpose is to promote the creation and publication of free expression" was further evidence of this compatibility. *Id.* In addition, the Court noted that copyright law's "built-in First Amendment accommodations" -- the fair use defense and the idea/expression dichotomy --

help to ensure that copyright remains compatible with the First Amendment. *Id.* at 219-20. In view of the basic compatibility between the First Amendment and copyright laws, the Court quickly disposed of the *Eldred* petitioners' First Amendment argument, holding that, because the CTEA did not "alter[] the traditional contours of copyright protection, further First Amendment scrutiny is unnecessary." *Id.* at 221.

A similar analysis shows that the patent laws (pursuant to which gene-related patents have been granted) are consistent with the First Amendment. Both the IP clause and the 1793 Patent Act were adopted close in time to the First Amendment, which suggests, as the Supreme Court recognized in *Eldred*, that the Framers viewed patent grants as compatible with the First Amendment. Like copyright, patent law promotes First Amendment interests by encouraging the discovery and dissemination of knowledge. Also like copyright, patent law contains built-in accommodations (such as, for example, the "abstract idea" exception) that serve to limit the impact that patent grants have on First Amendment interests. Finally, there is nothing about the granting of gene-related patents that alters the "traditional contours" of patent law – gene-related patents are granted pursuant to a statutory scheme that closely resembles that which Congress established shortly after the framing of the Constitution. Accordingly, based on the framework set forth in *Eldred*, "further First Amendment scrutiny is unnecessary." 537 U.S. at 220. Plaintiffs' First Amendment claim should therefore be dismissed.

B. The Fact That a Patent Might Be Difficult to "Invent Around" Does Not Make It Invalid

Although the Court need not reach the issue to dismiss plaintiffs' First Amendment claim, plaintiffs' argument that the patents at issue prevent them from "inventing

around" them can also be dismissed for an additional reason: many patents, including patents on pharmaceuticals and other compositions of matter, are very difficult to invent around. Were it not so, the value of the patent would be substantially diminished. Although the Federal Circuit has acknowledged the benefits of a patent system that encourages "inventing around," *see State Indus., Inc. v. A.O. Smith Corp.*, 751 F.2d 1226, 1236 (Fed. Cir. 1985) ("One of the benefits of a patent system is its so-called 'negative incentive' to 'design around' a competitor's products, even when they are patented, thus bringing a steady flow of innovations to the marketplace."), it has never suggested that there is an absolute right to successfully "invent around," nor that this right in turn limits the sort of subject matter upon which patents can be granted. Rather, the Federal Circuit's discussions about inventing around make it clear that strong patent rights force competitors to seek non-infringing solutions to the same problem, with the result that additional inventive activity occurs. *See id.*; *accord Hilton Davis Chem. Co. v. Warner-Jenkinson Co.*, 62 F.3d 1512, 1519 (Fed. Cir. 1995) ("The ability of the public successfully to design around – to use the patent disclosure to design a product or process that does not infringe, but like the claimed invention, is an improvement over the prior art – is one of the important public benefits that justify awarding the patent owner exclusive rights to his invention."), *rev'd Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17 (1997). Patents like Myriad's can normally be expected to spur competitors to seek and invent additional non-infringing ways of determining predispositions to cancer, including by conducting research on other genes.

If this Court were to hold that isolated genes (and other polynucleotides) are unpatentable on the basis that they are difficult or impossible to "design around," then many patents in the chemical and pharmaceutical arts would need to be reconsidered, *e.g.*, recombinant

forms of human insulin (used to treat diabetes), human growth hormone (used to treat growth defects), tissue plasminogen activator (used to treat heart attacks), interferon (used to treat a variety of diseases and disorders), follicle stimulating hormone (used in fertility treatments), and erythropoietin (used to treat cancer and kidney failure patients). *See* Christopher M. Holman, *The Impact of Human Gene Patents on Innovation and Access: A Survey of Human Gene Patent Litigation*, 76 UMKC L. Rev. 295, 323-24 (Winter 2007) (discussing litigation involving human-gene-based patents). The implications for the patent system would also extend far beyond biotechnology; patents on the telegraph, the telephone, and countless other inventions (including even plaintiffs' example – the carburetor) were difficult if not impossible to design around when those inventions were first introduced.

Questions of this sort – pertaining to proper scope and strength of the patent reward – must be left to Congress. Yet Congress has given no indication that the difficulty of inventing around can be a basis for denying patent protection. Because the difficulty of inventing around a gene-related patent is no different than the difficulty of inventing around other types of patents, the issuance of gene-related patents cannot be said to "alter[] the traditional contours" of patent law. Accordingly, under *Eldred*, "further First Amendment scrutiny is unnecessary." 537 U.S. at 221.

C. Isolated and/or Purified Genes Are Patentable Chemicals, Not Information or Thought Protected by the First Amendment

Although the Court need not reach the issue to dismiss plaintiffs' First Amendment claim, plaintiffs' First Amendment arguments also are based on the mistaken premise that genes are simply "information." (Br. at 35-36). They are not. As the U.S. Court of

Appeals for the Federal Circuit has held, "a gene is a chemical compound, albeit a complex one." *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1206 (Fed. Cir. 1991). Chemicals – *i.e.*, "compositions of matter" – have been expressly listed as patentable subject matter in every patent act since the 1793 Patent Act. *See* Patent Act of February 1793, ch. 11, §1, 1 Stat. 318, 319; Patent Act of July 1836, ch. 357, § 6, 5 Stat. 117, 119; Patent Act of July 1870, ch. 230, § 24, 16 Stat. 198, 201; Patent Act of July 1952, ch. 950, § 1, 66 Stat. 797.

Plaintiffs do not dispute that chemicals are patentable subject matter. Nor do plaintiffs dispute the fact that isolated genes are chemicals that are made from DNA, which in turn is made from smaller chemicals called nucleic acids. (*See* Br. at 3, 10). Instead, plaintiffs attempt to blur the line between genes, which are chemical compounds, and genetic sequences, which are human-created representations that identify one of the gene's properties: the arrangement of nucleic acids in the gene. (*See* Br. at 35-36). Plaintiffs fail to cite -- nor is the USPTO aware of -- any case law supporting the notion that a chemical (or machine or any other physical structure) that is capable of conveying information no longer qualifies for patent protection based on the fact that it has informational content.

In constructing their argument, plaintiffs place special emphasis on the fact that the chemical structure of genes may be "represented by a series of letters," mutations in genes may be recognized like "typographical errors," and that genes may be compared "like proof-reading a book." (Br. at 35-36). However, the fact that a chemical can be represented using an alphanumeric formula does not mean that the chemical itself is "information." *All* chemicals can be described in letter and number format. *See generally Kirk-Othmer Encyclopedia of Chemical Technology: Nomenclature* (Warren H. Powell ed., Wiley & Sons 2005). For example, the

chemical composition of water is H_2O, but that formulation does not describe all of the properties of water. Plaintiffs articulate no compelling reason why DNA in its isolated and purified form should be treated differently from other types of chemicals. Thus, the basic premise in plaintiffs' reasoning -- that genes are information -- is flawed. [5]

Second, to the extent that plaintiffs argue that genetic sequences are information, the USPTO issues patents on isolated *genes* (and other polynucleotides) (*i.e.*, on chemical compounds), not on genetic (and other polynucleotide) *sequences*.

> [A] DNA sequence – *i.e.*, the sequence of base pairs making up a DNA molecule – is simply one of the properties of a DNA molecule. Like any descriptive property, a DNA sequence itself is not patentable. A purified DNA *molecule* isolated from its natural environment, on the other hand, is a chemical compound and is patentable . . . .

Utility Examination Guidelines, 66 Fed. Reg. 1092, 1094 (Jan. 5, 2001) (hereinafter "Guidelines") at 1094 (emphasis in original). Indeed, an isolated DNA compound may be patented without the disclosure of a corresponding polynucleotide sequence; for example, where the claimed polynucleotide compound is available in a public depository but has not been sequenced (*see Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 964-65 (Fed. Cir. 2002)). Similarly, a genetic sequence alone (*e.g.*, a display of the genetic sequence on a computer monitor or on a piece of paper), which is information, cannot infringe a patent claiming the isolated gene, which is a chemical compound. Because the USPTO does not issue patents on

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[5] The argument also proves too much. As plaintiffs acknowledge, "[n]ew genes can be invented, of course, that have never existed in nature and are created by recombinant methods." (Br. at 36 n.12). Plaintiffs' argument that genes are "information" would apply to these human-made genes as well.

gene sequences, plaintiffs' argument that "a genetic sequence is *biological information itself*" (Br. at 35 (emphasis original)) is irrelevant to their First Amendment claim.

Third, plaintiffs' assertion that the function of a gene in a person or other organism is "to convey information" (Br. at 35) is similarly irrelevant, and confuses genes as they exist in nature with patent claims to isolated genes (*see* Br. at 35 (erroneously asserting that the USPTO has issued patent claims over "genes themselves whether in the natural or wild-type form or mutated form.")). There is no dispute that the USPTO's policy is to issue patent claims only on "isolated" and/or "purified" genes (and other polynucleotides). *See* Guidelines at 1093; (Br. at 24 ("The USPTO policy allows patents on 'isolated and purified' DNA . . . . ")). Claims to isolated and/or purified genes do not embrace genes as they are found in nature or their functions in the natural state. *See* Guidelines at 1093 ("A patent on a gene covers the isolated and purified gene but does not cover the gene as it occurs in nature.").[6] Thus, the function of genes in nature is irrelevant to plaintiffs' First Amendment claims because the USPTO does not issue patents on genes as they are found in nature.

[6] Importantly, isolated and purified genes function in ways that "natural" genes cannot. For example, when genes are isolated from their natural genetic controls, they may be recombined with other polynucleotides in a way that permits researchers and pharmaceutical companies to control their expression. *See* Bruce Alberts, et al., *Molecular Biology of the Cell* (Miranda Robertson et al. eds., 3d ed. 2001) at 319-34. This so-called "recombinant DNA" may then be used by researchers to study the effect of a particular gene on a cell or disease, and also permits the large-scale production of many protein-based drugs that were extremely difficult to isolate and purify from their natural sources. *Id.*

CONCLUSION

For the foregoing reasons, 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.

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