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RE: Docket No. PTO-P-2012-0003; Genetic Testing Study

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Dear Mr. Vishnubhakat:

The American Civil Liberties Union (“ACLU”) appreciates the opportunity to submit this response to the United States Patent and Trademark Office’s (“USPTO” or “the Office”) Request for Comments and Notice of Public Hearing on Genetic Diagnostic Testing, published in the Federal Register on January 25, 2012 (the “Notice”).

The ACLU is a non-partisan civil liberties organization with more than a half million members, countless additional activists and supporters and 53 affiliates nationwide, dedicated to the principles of individual liberty and justice guaranteed in the U.S. Constitution. We have long fought for freedom of thought and scientific inquiry, values that are enshrined in the First Amendment and implicated in the USPTO’s gene testing study.

In short, the ACLU has asserted in litigation pleadings and in legislative and policy advocacy that the issuance of patents claiming naturally occurring DNA, even in an “isolated” form, violates the Patent Act and the United States Constitution. By precluding researchers and clinicians from performing genetic diagnostic testing, developing new genetic diagnostic tests, or conducting pure genetic research, patents covering genetic material hinder rather than promote American invention and innovation.

The ACLU is currently counsel of record for plaintiffs-petitioners in *Association for Molecular Pathology v. U.S. Patent and Trademark Office*, 653 F.3d 1329 (Fed. Cir. 2011), *cert. granted*, (U.S. Mar. 26, 2012) (No. 11-725), commonly referred to as *Myriad*. *Myriad* is currently on remand to the Federal Circuit for further consideration. Additionally, the ACLU was before the Supreme Court as amicus curiae in *Mayo Collaborative Services v. Prometheus Laboratories*, __ S. Ct. __, No. 10-1150, slip op. (Mar. 20, 2012), commonly referred to as *Prometheus*, and *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008), *aff’d*, 129 S. Ct. 3218 (2010).

While *Prometheus* and *Bilski* deal with method patents and not composition patents like those at issue in *Myriad*, each of these cases raises questions about the relationship between the U.S. Constitution and the Patent Act, and the chilling effect improperly issued patents can have on intellectual and scientific freedom.¹

Section 27 of the Leahy-Smith America Invents Act (“AIA”) charged the USPTO with conducting a study and reporting to Congress on the effects of patents or exclusive licenses that cover primary genetic diagnostic testing on second opinion genetic diagnostic testing. Pursuant to that mandate, the USPTO has solicited public comments on numerous questions related to confirming genetic diagnostic test activity. The ACLU appreciates the opportunity to provide the following brief comments to the USPTO.

By way of preview, the following comments first address the legal and economic concerns with gene patents (which, in effect, are one and the same), and then make two concrete policy recommendations, which the ACLU believes are warranted in light of the overwhelming evidence that gene patents² have harmful effects on medical practice, patient welfare, personal autonomy and scientific inquiry:

- The USPTO should expressly adopt the findings of the April 2010 report issued by the Secretary of Health and Human Services’ Advisory Committee on Genetics, Health, and Society (hereinafter “SACGHS” and the “SACGHS Report”).³ The SACGHS Report found that, in plain terms, patents covering genetic material are unnecessary to protect scientific innovation, and harm patient welfare by limiting access to, and reducing the quality of, lifesaving genetic testing.⁴ The SACGHS findings have been echoed by numerous other scholarly and governmental inquiries into the issue, which are cited in the discussion below.

¹ See Br. of the Am. Civil Liberties Union as Amicus Curiae in Support of Petitioners, *Mayo Collaborative Servs. v. Prometheus Labs.*, __ S. Ct. __, No. 10-1150, slip op. (Mar. 20, 2012); Br. for Amicus Curiae Am. Civil Liberties Union for Affirmance in Support of Appellee, *In re Bilski*, 545 F.3d 943 (2008), *aff’d*, 129 S. Ct. 3218 (2010). Shortly before this submission, the Supreme Court ruled unanimously in *Prometheus* that the process patents at issue in that case were not patentable. The Court clearly held that part of the reason for their invalidity was the danger that the patenting of “building blocks” for scientific research creates a bottleneck that violates the policy underlying the patent laws. In other words, patenting essential elements of scientific research like mathematical formulae or a patient’s natural reaction to a drug in *Prometheus* threatens to dampen innovation. See *Prometheus*, slip op. at 16-24 (“The Court has repeatedly emphasized this last mentioned concern, a concern that patent law not inhibit further discovery by improperly tying up the future use of laws of nature.”).

² Please note that references to “gene patents” refer to patents on isolated genetic material that corresponds to naturally occurring nucleotide sequences found in the human cell as well as claims to methods for the detection of nucleotide sequences that do not specify tools or specific steps (such that the patent holder has the ability to preclude others from examining particular nucleotide sequences, or variations thereupon).

³ SACGHS, *Gene Patents and Licensing Practices and their Impact on Patient Access to Genetic Tests* (2010).

⁴ *Id.* at 1-4.

- In light of the SACGHS report, the Supreme Court’s recent decision in *Prometheus* invalidating method patents claiming laws of nature, corroborative studies, the testimony and comments adduced by the USPTO’s current genetic diagnostic testing study and the pressing needs of patients who are denied essential testing by the issuance of these patents, the USPTO should implement an immediate moratorium on the issuance of patents covering naturally occurring genetic sequences, which should remain in place at least until the Supreme Court rules in *Myriad*.

I. Legal and Economic Concerns With Gene Patenting

Preliminarily, the Office should consider the legal and economic implications of gene patents in its final report to Congress.

As a legal matter, patents that preclude confirming genetic diagnostic test activity directly violate the Patent Act and the First Amendment by preventing clinicians and scientists from examining natural phenomena and engaging in fundamental scientific inquiry. *See Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948) (excluding laws of nature, natural phenomena and abstract ideas from scope of patentable subject matter as “part of the storehouse of knowledge of all men . . . free to all men and reserved exclusively to none”).

The First Amendment limits the reach of Congress’ power under the intellectual property clause. Congress’ enumerated powers must yield to the clear prohibitions of the First Amendment, one of which is that Congress shall make no law (including patent laws) abridging the protections embedded in the First Amendment, which have been found by the courts to include a constitutional right to scientific freedom and thought. Patents that claim naturally occurring nucleotide sequences—as do those at issue in genetic diagnostic testing—grant the patentee ultimate “control over a body of knowledge and pure information,” and thus violate this freedom. *See Pet. for a Writ of Cert. at 30, Ass’n for Molecular Pathology v. U.S. Patent and Trademark Office*, 653 F.3d 1329 (Fed. Cir. 2011), *cert. granted*, (U.S. Mar. 26, 2012) (No. 11-725).

Additionally, these patents, by precluding the future examination of naturally occurring nucleotide sequences by researchers and clinicians other than the patentee, run at cross-purposes with the intellectual property clause itself. Rather than promoting research and innovation, gene patents stifle basic scientific inquiry, and are therefore a violation of the spirit and letter of the intellectual property clause of Article I, § 8, of the U.S. Constitution. *See also Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 548 U.S. 124, 126-27 (2006) (Breyer, J., dissenting) (“[S]ometimes *too much* patent protection can impede rather than ‘promote the Progress of Science and useful Arts.’”).

From an economic perspective, patents on abstract ideas and natural phenomena violate the central economic rationale of the patent laws. Patents encourage innovation, creativity and capital investment in research by granting a 20-year government monopoly over the fruit of the inventive process. Such a system spurs follow-on innovation by encouraging subsequent inventors to improve on or work around patented technologies, processes or substances, and by ensuring that the patented invention will enter the body of public knowledge once the patent

expires. By contrast, patents that cover abstract ideas and natural phenomena *preclude* future innovation during their term because they deny future innovators the essential tools with which to innovate.⁵

Accordingly, from both an economic and legal perspective, the Office should resist granting gene patents.

II. The USPTO Should Adopt the Findings of the SACGHS Report

The SACGHS was formed in 2002 under the Bush administration to “explore, analyze, and deliberate on the broad range of human health and societal issues raised by the development and use, as well as potential misuse, of genetic technologies and make recommendations to the Secretary of Health and Human Services (Secretary), and other entities as appropriate.”⁶ Part of its express mandate was to examine “current patent policy and licensing practices for their impact on access to genetic technologies.”⁷ As part of that mandate, SACGHS prepared its April 2010 report based on evidence gathered from a literature review and original case studies of genetic testing for 10 separate conditions.⁸

The SACGHS Report took a holistic approach to the subject. Noting that access to a high quality test requires first the research into correlations between certain genetic mutations and the condition under study, the SACGHS Report expressly examined the effect of gene patents on basic genetic research. The report then studied whether patent enforcement prevents patients from receiving needed tests, and what effect, if any, gene patents have on the quality of genetic testing.

⁵ The USPTO may be able to take guidance from how courts have treated similar issues in the context of antitrust law, which shares similar economic dynamics and arguments. One could even argue that gene patents and patents covering abstract thought present perhaps the most compelling example of an essential facility monopoly in antitrust law. Although lawfully acquired monopolies are not an evil in antitrust (because, so long as entry is available, monopoly profits will promote entry and drive prices down), essential facilities monopolies uniquely present a viable claim for monopolization, even if the monopoly has been acquired lawfully. Although the Supreme Court has left the precise bounds of the essential facilities doctrine in some doubt, what is indisputable is that “the indispensable requirement for invoking the doctrine is the *unavailability of access to the ‘essential facilities’*.” *Verizon Commc’ns, Inc. v. Trinko*, 540 U.S. 398, 411 (2004). Where a regulatory regime controls access, no essential facilities claim can lie. *Id.* By contrast, the patent monopoly, uniquely, prevents all access unless the patentee voluntarily grants it. Broadly speaking, the patentee is entitled to do with the patent as she will, including doing nothing. Compulsory patent licensing is rare, and occurs in only a limited number of areas of patent and antitrust law. Consequently, as nucleotide sequences present the ultimate essential facility in genetic testing and research, the Office should resist furthering these bottlenecks by granting gene patents.

⁶ Notice of Establishment, 67 Fed. Reg. 65,126 (Oct. 23, 2002).

⁷ *Id.*

⁸ Letter from Steven Teutsch, SACGHS Chair, to Kathleen Sebelius, HHS Secretary (Mar. 31, 2010).

SACGHS's findings can be summarized as follows:

- The patent monopoly *does not* play a major role in driving genetic research. Rather, scientists are motivated “typically” by the “desire to advance understanding, the hope of improving patient care through new discoveries, and concerns for their own career advancement.”⁹ Additionally, and crucially, although there is some private investment in genetic research, the primary source of funds for genetic diagnostic testing research is the *federal government*.¹⁰ And, perhaps most importantly, there is evidence that gene patents (which, by their very nature, preclude the use in later diagnostic testing research of naturally occurring genetic sequences) serve the opposite ends of the patent system: they retard innovation.¹¹
- Gene patents block patients from receiving needed diagnostic testing in two ways. Patients of limited means are unable to pay for expensive genetic tests provided by a sole provider when the provider declines to accept the patient’s insurance. And, of particular import for this Notice, patients are unable to seek second opinion diagnostic testing when there is a sole provider.¹²
- Finally, again contrary to the mission of the patent laws, gene patents reduce the quality and accuracy of sole provider genetic tests by preventing competition or sample sharing between multiple testing providers.¹³

Further to these three findings, the SACGHS made six recommendations. These are:

- Create an exemption from liability enforcement for those who use the genetic material under current patent to develop a competing test, or for pure research;

⁹ SACGHS Report at 1.

¹⁰ *Id.*

¹¹ *Id.* at 2 (“Although the patent law requirement of disclosure and description of a claimed invention is meant to expand the public storehouse of knowledge and stimulate follow-on research, there is evidence to suggest that patents on genes discourage follow-on research.”). Note that SACGHS also examined threats to future genetic diagnostic testing by gene patents, and found that gene patents today could block development of new methods of multi-gene testing, including multiplex tests, parallel sequencing and whole-genome sequencing. In other words, to borrow again from antitrust economics, gene patents threaten both “static” innovation (competition between similar products) *and* “dynamic” innovation (that is, game changing new technologies, applications or products that fundamentally alter market dynamics). The patent system is supposed to induce competition at both levels through the “carrot” of the patent monopoly. Gene patents have the opposite effect by completely precluding the research that could lead to “dynamic” change. Because of the chilling effect on scientific inquiry and freedom of thought, guaranteed in the First Amendment, the ACLU submits that this concern rises to the level of a constitutional violation. *Cf.* J. Gregory Sidak & David J. Teece, *Dynamic Competition in Antitrust Law*, 5 J. L. & Econ. 581 (2009).

¹² *Id.* at 3-4.

¹³ *Id.* at 4.

- Develop mechanisms to encourage nonexclusive licensing;
- Enhance transparency in licensing;
- Establish an advisory body at Health and Human Services to explore the health impact of gene patenting and licensing practices;
- Encourage inter-departmental cooperation between the Department of Commerce and Health and Human Services to provide expertise to the USPTO;
- Ensure equal access to clinically useful genetic tests including, for instance, a mandate that all payers include clinically useful tests in their covered benefits.

The ACLU takes particular note of the comprehensiveness of the SACGHS Report's inquiry. Certain proponents of gene patents have argued that the problems identified by the SACGHS are overblown, and limited largely to the BRCA patents at issue in *Myriad* and perhaps a few others.

Giving lie to that assertion is the range of inherited conditions that were presented in the SACGHS case studies. In addition to the inherited susceptibility to breast/ovarian cancer at issue in *Myriad*, the study looked at colon cancer, hearing loss, cystic fibrosis, Alzheimer's disease, hereditary hemochromatosis, spinocerebellar ataxias, familial long QT syndrome and Canavan and Tay-Sachs diseases.¹⁴ These conditions were chosen to present a representative cross-section of hereditary ailments (that is, from a commercial perspective, they feature different patent and licensing strategies, and include a mix of common and uncommon conditions).¹⁵

Additionally, as noted above, numerous studies and experts, both in economics and biotechnology, strongly support the SACGHS's findings, and demonstrate the chilling effect on scientific inquiry resulting from gene patents. For instance:

- Nobel Prize-winning economist Joseph Stiglitz has shown that the innovative benefits of the BRCA patents specifically have been marginal (the BRCA sequence would have been developed in short order irrespective of intellectual property protection, Stiglitz argues), whereas the economic rents imposed by *Myriad* through its patents have been high. Stiglitz argues generally that improper intellectual property protection is strongly *inhibitive* of scientific advancement.¹⁶
- In 2003, Cho et al. surveyed clinical laboratory directors that performed DNA-based genetic tests to determine if any had been deterred from performing a test or developing a

¹⁴ SACGHS Report at 9.

¹⁵ *Id.*

¹⁶ Decl. of Joseph E. Stiglitz, Ph.D., *Assoc. for Molecular Pathology v. U.S. Patent & Trademark Office*, 702 F. Supp. 2d 181 (S.D.N.Y. 2010), *aff'd in part, rev'd in part*, 653 F.3d 1329 (Fed. Cir. 2011), *cert. granted*, (U.S. Mar. 26, 2012) (No. 11-725).

new test because of gene patents or licenses. They found that a quarter of respondents stopped performing a test and a full half decided not to pursue the development of a new test. In all, survey respondents were blocked from performing a full 12 existing tests (and it is unclear how many new tests could have been developed but for the blocking patents in those cases).¹⁷

- In 2009, Huang and Murray published an empirical study (building on the 2005 article showing that 20% of human genes are covered by a patent claim) demonstrating a clear chilling effect from widespread gene patenting and, specifically, a 5-10% reduction in the accumulation of public knowledge flowing directly from the BRCA1 and BRCA2 patents.¹⁸
- In 2010, Heidi Williams with the National Bureau of Economic Research published an empirical study that looked at the period during which certain genes were covered by Celera's patents (before the effective elimination of patent protection by the resequencing of the same genes at the Human Genome Project). She showed that, during this period, there was a reduction in scientific research and product development on the order of a *third*.¹⁹
- And, in 2011, Berthels et al. again showed a similar chilling effect for spinocerebellar ataxia, one of the conditions covered by the SACGHS study and the subject of possibly the most common genetic test in adult neurology.²⁰

Accordingly, in light of the First Amendment considerations highlighted by the SACGHS and other gene patent studies—namely, the dramatic chilling effect on freedom of thought and scientific inquiry—the ACLU urges the USPTO to, at a minimum, endorse and adopt the SACGHS's findings in its final AIA report to Congress.

Moreover, it should be noted that the Office has granted gene patents for many years and thus is not a neutral agency on this issue. Its policy of granting patents on isolated DNA was articulated in its 2001 Utility Guidelines,²¹ and as a consequence of this policy, the USPTO routinely has

¹⁷ See Decl. of Mildred Cho, Ph.D. ¶¶ 9-16, *Assoc. for Molecular Pathology v. U.S. Patent & Trademark Office*, 702 F. Supp. 2d 181 (S.D.N.Y. 2010), *aff'd in part, rev'd in part*, 653 F.3d 1329 (Fed. Cir. 2011), *cert. granted*, (U.S. Mar. 26, 2012) (No. 11-725).

¹⁸ See Decl. of Fiona E. Murray, Ph.D. ¶¶ 16-20, *Assoc. for Molecular Pathology v. U.S. Patent & Trademark Office*, 702 F. Supp. 2d 181 (S.D.N.Y. 2010), *aff'd in part, rev'd in part*, 653 F.3d 1329 (Fed. Cir. 2011), *cert. granted*, (U.S. Mar. 26, 2012) (No. 11-725).

¹⁹ Heidi L. Williams, *Intellectual Property Rights and Innovation: Evidence from the Human Genome 26* (Nat'l Bureau of Econ. Research Working Paper 16,213, 2010).

²⁰ Nele Berthels et al., *Impact of Gene Patents on Diagnostic Testing: A New Patent Landscaping Method Applied to Spinocerebellar Ataxia*, 2011 Eur. J. of Hum. Genetics 1.

²¹ Utility Examination Guidelines, 66 Fed. Reg. 1,092 (Jan. 5, 2001). Note that the additional guidance on process claims following *Bilski* and the emergency guidance following *Prometheus* do not impact the analysis offered in these comments. See Memorandum from Andrew H. Hirshfeld to Patent Examining

approved patents on methods of simply identifying a genetic sequence or correlating a sequence to a condition. Given the USPTO's stated position and past practice supporting these patents, it would be appropriate for the USPTO to defer to and adopt the findings of the SACGHS, which had the requisite expertise and impartiality to conduct an investigation of how gene patents affect research and clinical practice.

III. The USPTO Should Impose an Immediate Moratorium on Gene Patents

In addition to adopting the SACGHS Report's findings in the AIA, and perhaps as part of the Office's supplemental guidance on the *Prometheus* decision, we would urge the USPTO to impose an immediate moratorium on the grant of these patents.²²

The United States, through the Solicitor General, filed a brief in *Myriad* when the case was pending before the Federal Circuit. There, the United States concluded, after consultation with the USPTO, the National Institutes of Health, the Antitrust Division of the Department of Justice, the Centers for Disease Control and Prevention, the Office of Science and Technology Policy and the National Economic Council, that isolated genetic material is not patentable, but that cDNA is. Br. for the United States as Amicus Curiae in Supp. of Neither Party at 1, 37, *Ass'n for Molecular Pathology v. U.S. Patent and Trademark Office*, 653 F.3d 1329 (Fed. Cir. 2011), *cert. granted*, (U.S. Mar. 26, 2012) (No. 11-725).

Given that position, the negative impact of these patents as documented by the SACGHS Report, and the current petition for certiorari pending before the Supreme Court on the question of whether isolated DNA is patentable subject matter,²³ we believe it would be prudent for the Office to re-examine its policy on these patents.

These outstanding questions and issues have introduced a significant amount of commercial, medical, diagnostic and scientific uncertainty around gene patents. The USPTO is only exacerbating this commercial uncertainty (as well as all of the other negative human effects that flow from gene patents) by continuing its gene patent policy without deeper study. Adopting a moratorium, at the very least, is the prudent and appropriate step to take.

* * *

The ACLU thanks the USPTO for its diligent efforts to implement § 27 of the AIA, and we hope these comments will be of aid to the Office as it prepares its report. If you have questions or

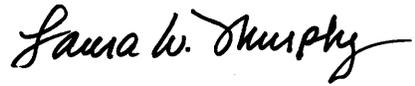
Corps Regarding Supreme Court Decision in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* (Mar. 21, 2012); Memorandum from Robert W. Bahr to Patent Examining Corps Regarding Interim Guidance for Determining Subject Matter Eligibility for Process Claims in View of *Bilski v. Kappos* (July 27, 2010).

²² Indeed, as the Office has indicated that it is developing additional guidance on § 101, a moratorium would be even more appropriate.

²³ Petition for a Writ of Certiorari at i, *Association for Molecular Pathology v. U.S. Patent and Trademark Office*, 653 F.3d 1329 (Fed. Cir. 2011), *cert. granted*, (U.S. Mar. 26, 2012) (No. 11-725).

concerns, please do not hesitate to contact Gabe Rottman, Legislative Counsel/Policy Advisor, at 202-675-2325 or grottman@dcaclu.org.

Very truly yours,



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