



December 20, 2012

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United States Patent and Trademark Office  
Mail Stop External Affairs  
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Alexandria, VA 22313-1450

**Re: Docket No. PTO-C-2012-0049;  
Notice to Public Roundtable on Genetic Diagnostic Testing**

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LIBERTIES UNION  
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ROBERT REMAR  
TREASURER

Dear Mr. Vishnubhakat:

We write in response to the United States Patent and Trademark Office's ("USPTO" or "the Office") notice of November 21, 2012, 77 Fed. Reg. 71,170 (Nov. 29, 2012) (the "Notice"), of a planned roundtable as part of the USPTO's efforts to fulfill its mandate under § 27 of the Leahy-Smith America Invents Act ("AIA"), Pub. L. 112-29, 125 Stat. 284 (2011), which charged the Office with preparing a study on genetic diagnostic testing.

The American Civil Liberties Union ("ACLU") is not seeking to share commentary for the January 10, 2013, roundtable, but we do urge the Office *to delay the proceeding* until the Supreme Court issues its ruling in *Association for Molecular Pathology v. United States Patent & Trademark Office*, 689 F.3d 1303 (Fed. Cir. 2012), *cert. granted*, *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 81 U.S.L.W. 3199 (U.S. Nov. 30, 2012) (No. 2010-1406) ("*Myriad*"). The planned roundtable—prompted as it was by earlier order of remand in *Myriad*, 132 S. Ct. 1794 (2012), and the Court's decision in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* ("*Mayo*"), 132 S. Ct. 1289 (2012)—would be premature as several questions raised for comment in the Notice cannot be answered before, and may be mooted by, the ultimate decision in *Myriad*.

The ACLU has a direct interest in the Office's study, especially with respect to the mandate in § 27 of the AIA to examine the "impact that current exclusive licensing and patents on genetic testing activity has on the practice of medicine, including but not limited to: the interpretation of testing results and performance of testing procedures." We are counsel of record in *Myriad*, and have appeared before the Supreme Court as amicus curiae in both *Mayo* and *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008), *aff'd*, 129 S. Ct. 3218 (2010). We frequently advocate in courts, Congress, the federal agencies and the states on matters at the intersection of intellectual property, scientific freedom and the First Amendment.

Importantly, the Notice was published before the USPTO was aware that certiorari would be granted in *Myriad* (the Court agreed to hear the case the day after the Notice was published in the Federal Register). While we fully appreciate the Office's efforts to gather as extensive a record as possible, the Office's rationale for delaying the report to Congress beyond the statutory deadline counsels strongly in favor of waiting for the decision in *Myriad*.<sup>1</sup> The complexity that will surely be added by a decision in *Myriad* addressing the patentability of human genes must be addressed in the final report, and must be explored in an event like the roundtable.

Further, the ACLU—as counsel of record in *Myriad*—is currently using its limited resources dedicated to these issues to full capacity, and will have difficulty fully engaging with the USPTO on this study. Numerous other organizations with interest and expertise in these issues have likewise been placed under significant strain by the deadline for submission of amici briefs in *Myriad*, which overlaps with the deadline for submission of commentary in the roundtable.

For all of these reasons, as well as the Office's prudential interest in limiting the number of formal proceedings in its preparation of the report, we urge you to delay the planned roundtable until after the Supreme Court has issued its final decision in *Myriad*.

Please do not hesitate to contact Gabe Rottman, legislative counsel/policy advisor in the ACLU's Washington Legislative Office, at 202-675-2325 or [grottman@dcaclu.org](mailto:grottman@dcaclu.org) with any questions or comments.

Sincerely,



Laura W. Murphy  
Director, Washington Legislative Office



Gabriel Rottman  
Legislative Counsel/Policy Advisor

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<sup>1</sup> As the Department of Commerce stated in its August 28, 2012, letter to the House and Senate Judiciary Committees: “[g]iven the complexity and diversity of the opinions, comments, and suggestions provided by interested parties, and the important policy considerations involved, we believe that further review, discussion, and analysis are required before a final report can be submitted to Congress.”