



June 15, 2011

Chairman David Dreier
Committee on Rules
U.S. House of Representatives
H-312 The Capitol
Washington, D.C. 20515

Chairman Lamar Smith
Committee on the Judiciary
U.S. House of Representatives
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Washington, DC 20515

Ranking Member Louise Slaughter
Committee on Rules
U.S. House of Representatives
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Ranking Member John Conyers
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TREASURER

RE: **ACLU Opposes Inclusion of Flawed Second Opinion Testing Language in Manager's Amendment to H.R. 1249, the America Invents Act**

Dear Chairman Dreier, Chairman Smith, Ranking Member Slaughter, and Ranking Member Conyers:

The American Civil Liberties Union (ACLU) is writing in opposition to the effort to include in the Manager's Amendment to H.R. 1249 language that is intended to provide for relief from patent liability for those who conduct second opinion genetic testing. Such testing is often barred by the issuance of gene patents. The proposed language would fail to block all patent holder objections to such testing, fails to address the many other limitations on scientific research arising out of the issuance of such patents, and risks allowing gene patent holders to argue that Congress implicitly endorses the validity of such patents. The ACLU is our nation's largest and oldest organization dedicated to the principles of liberty and justice enshrined in the U. S. Constitution and consists of over half a million members, countless additional activists and supporters, and 53 affiliates nationwide. We urge you to remove the relevant language from the Manager's Amendment, currently set forth in Section 27 of the '*Amendment to H.R. 1249, as Reported Offered by Mr. Smith of Texas*' and to refrain from including a vote on the '*Amendment to Manager's Amendment to H.R. 1249, as Reported Offered by Ms. Wasserman Schultz of Florida*' in the rule governing the floor debate on the America Invents Act.

The Supreme Court decided in 1980 that natural phenomena, products of nature, and laws of nature are not patentable.¹ As a result, a gene should be no more patentable than blood, or a kidney, or any other part of the human body, regardless of its size or complexity, and regardless of whether it has been removed from the body. This concept was upheld just last year in federal district court in a challenge to the patentability of two genes associated with breast and ovarian cancer (BRCA1 and BRCA2) in a case brought by breast cancer and women's health groups, individual patients, geneticists and scientific associations representing approximately 150,000 researchers, pathologists and laboratory professionals.² While we heartily support the goal of the amendment – to provide patients with more medical options – this amendment would be ineffective in achieving that result while increasing the risk that patent holders would claim the amendment provides support for their continued monopolistic practices.

According to the National Cancer Institute, over 200,000 Americans are diagnosed each year with breast or ovarian cancer. Many thousands more are diagnosed with the many other diseases – such as Alzheimer's disease, muscular dystrophy, and colon cancer – that are correlated with the 20% of human genes on which patents have been wrongfully issued. The amendment in question would not only fail to resolve second opinion testing issues, but it would not address the many problems with gene patents, including the inhibitions on research, treatment, and scientific progress. A real solution would not only allow for second opinion testing, but allow hospitals and laboratories to develop and offer testing in the first instance.

We have associated ourselves with advocates from across the political spectrum in opposition to this amendment. Attached below is a coalition letter expressing the opposition of patients and their advocates, health providers, scientific organizations, environmental activists, and Christian organizations. Some, like the Southern Baptist Convention, base their opposition in their belief that patenting human genetic material wrests ownership from God and makes a commodity of human biological material. Others oppose based upon notions of individual control over one's own person. Still others focus on the core intent of the American patent system as envisioned in the Constitution. But we are united in our opposition to the proposed amendment. We are also aware of the strong opposition of other important organizations like the American Medical Association, as expressed in their letter dated June 14, 2011, to the Chairman and Ranking Member of the Judiciary Committee.

¹ *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

² *Association for Molecular Pathology, et al. v U. S. Patent and Trademark Office, et al.*, 09 – CIV – 515 (S.D.N.Y. Mar. 29, 2010). The case is on appeal to the Federal Circuit, where the Department of Justice filed a brief in the pending lawsuit opposing the issuance of gene patents and arguing that they unlawfully cover products of nature.

We urge you to eliminate Section 27 from the proposed Manager's Amendment and to take such steps as are necessary to withhold the proposed amendment of Representative Wasserman Schultz from the debate on the bill on the House floor. To do otherwise would be to create unintended harms to patients, medical professionals, and genetic researchers.

Sincerely,



Laura W. Murphy
Director, Washington Legislative Office



Michael W. Macleod-Ball
Chief Legislative and Policy Counsel

cc: Speaker John Boehner
Majority Leader Eric Cantor,
Minority Leader Nancy Pelosi,
Minority Whip Steny Hoyer,
Representative Debbie Wasserman Schultz
Members of the Rules Committee
Members of the Judiciary Committee

June 15, 2011

U. S. House of Representatives
Washington, DC 20515

RE: **Oppose Wasserman Schultz Genetic Diagnostic Testing Amendment to H. R. 1249, the America Invents Act**

Dear Member of Congress:

The undersigned organizations representing the full breadth of the political spectrum are writing in opposition to the proposed Wasserman Schultz amendment titled '*Permitting Second Opinions in Certain Genetic Diagnostic Testing*' to H. R. 1249, the America Invents Act. We urge you to oppose the inclusion of its provisions in the bill, whether as part of the manager's amendment or as a stand alone amendment.

This amendment was intended to enable test developers to provide testing that confirms, or provides a second opinion on, genetic tests. Currently, patents on human genes present a barrier to second opinion genetic testing because patent holders don't license their patents to other labs, thereby stopping those labs from examining, testing, and working with patented genes. But the amendment does not achieve its objective of overcoming patent barriers to second opinion testing. Instead, the amendment would:

- Allow gene patent holders to continue to challenge such second opinion testing;
- Ignore the many harms that result from gene patents, including the restrictions they impose on scientists and physicians engaged in genetic research and clinical work and on the medical options available to patients with life threatening diseases; and
- Allow gene patent holders to argue that Congress has implicitly endorsed the validity of gene patents.

For these reasons, we urge you to vote 'NO' on the Wasserman Schultz second opinion testing amendment to H. R. 1249, the America Invents Act, when it comes up for a vote on the floor of the House this week.

Gene patents have been a source of great controversy, because they impose monopolies on products of nature, not true inventions. The Supreme Court decided in 1980 that natural phenomena, products of nature, and laws of nature are not patentable.³ As a result, a gene should be no more patentable than blood, or a kidney, or any other part of the human body, regardless of its size or complexity, and regardless of whether it has been removed from the body. This concept was upheld just last year in federal district court in a challenge to the patentability of two genes associated with breast and ovarian cancer (BRCA1 and BRCA2) in a case brought on behalf of breast cancer and women's health groups, individual patients, geneticists and scientific associations representing approximately

³ Diamond v. Chakrabarty, 447 U.S. 303 (1980).

150,000 researchers, pathologists and laboratory professionals.⁴ An appeal of that decision is now pending before the U. S. Federal Circuit, where the case was argued in early April 2011.

Gene patents give ownership and sole control over the fundamental building blocks of life, limiting the ability of scientists and physicians to use those building blocks to discover new, effective and affordable tests and treatments for a wide variety of diseases and conditions. Representative Wasserman Schultz's Amendment No. ____ laudably is aimed at curbing the restrictions on certain tests – those done for the purpose of obtaining second opinions. But the language of the amendment continues to allow the gene patent holder to bar second opinion testing involving an 'article of manufacture', a 'patented composition of matter', or the 'practice of a patented process'. Typical patents are defined so broadly that these exceptions could allow monopolistic gene patent holders to continue to restrict second opinion testing.

Moreover, the harms created by gene patents extend far beyond the barriers presented to second opinion testing, and any legislative proposal should address these as a whole. Gene patents limit the availability of and access to testing in the first instance, impede the development of new and different types of tests, and chill genetic research because scientists fear accusations of patent infringement and liability. Economist Joseph Stiglitz and geneticist John Sulston, both Nobel Prize winners, oppose gene patents because unlike patents on tests or drugs, monopolies on genes cannot be "invented around" – genes are the basis for the follow-on scientific work.⁵

While the undersigned groups believe that this amendment does not express any congressional view supporting gene patents, the mere adoption of this amendment could put at issue whether or not Congress has implicitly endorsed the validity of patents relating to genetic material. Since the 1980's, the Patent and Trademark Office (PTO) has approved of patents on human genes; yet, the federal government has recently shifted its position. The Department of Justice filed a brief in the pending lawsuit, arguing that gene patents approved by the PTO unlawfully cover products of nature. By adopting a law that contemplates exceptions to infringements of patents relating to genetic testing, the holders of gene patents will be tempted to argue that Congress is implicitly endorsing the basic validity of those patents.

Those at risk of or coping with breast cancer are tremendously concerned about access to genetic testing and have long advocated for a solution to the second opinion testing problem. But the head of a leading advocacy organization, Karuna Jaggar, Executive Director of Breast Cancer Action, opposes the amendment. "Breast Cancer Action is extremely concerned that the amendment will not address the needs of breast cancer patients and instead have an unintended, harmful impact. We do not believe that this

⁴ Association for Molecular Pathology, et al. v U. S. Patent and Trademark Office, et al., 09 – CIV – 515 (S.D.N.Y. Mar. 29, 2010).

⁵ Stiglitz, Joseph, and Sulston, John, "The Case Against Gene Patents", Wall Street Journal (Apr. 16, 2010).

amendment will sufficiently solve the issue of second opinion testing, while jeopardizing an appropriate solution to the underlying gene patent problems.”

The undersigned organizations representing medical groups, testing organizations, women’s advocacy groups, religious groups, and patent reform groups agree. The second opinion testing amendment is directed at a worthy target, but misses the mark. The amendment will not assure the availability of second opinion testing and it unnecessarily raises the question of whether natural phenomena, products of nature, and laws of nature can be monopolized for the benefit of a single patent holder.

We urge you to oppose the inclusion of the Wasserman Schultz second opinion testing in H. R. 1249 – whether as part of the manager’s amendment or as a standalone amendment - when it comes to the House floor this week. For information or comment, please contact Michael W. Macleod-Ball, ACLU Legislative Chief of Staff, at 202-675-2309 or mmacleod@dcaclu.org.

Sincerely,

American Civil Liberties Union

Breast Cancer Action

Center for Genetics and Society

Family Research Council Action

Friends of the Earth

International Center for Technology Assessment

National Women’s Health Network

Our Bodies Ourselves

Southern Baptist Ethics & Religious Liberty Commission

United Methodist Church-General Board of Church and Society