RESPONSE TO ‘PERVASIVE SEQUENCE PATENTS COVER THE ENTIRE HUMAN GENOME’

Shine Tu, West Virginia University College of Law; Christopher M. Holman, University of Missouri Kansas City School of Law; Adam Mossoff, George Mason University School of Law; Ted M. Sichelman, University of San Diego School of Law; Michael Risch, Villanova University School of Law; Jorge L. Contreras, American University Washington College of Law; Yaniv Heled, Georgia State University College of Law; Gregory Dolin, University of Baltimore School of Law; Lee Petherbridge, Loyola Law School Los Angeles

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Response to ‘pervasive sequence patents cover the entire human genome’

Shine Tu1*, Christopher Holman2, Adam Mossoff3, Ted Sichelman4, Michael Risch5, Jorge L Conteras6, Yaniv Heled7, Greg Dolin8 and Lee Petherbridge9

See related Correspondence by Rosenfeld and Mason, http://genomemedicine.com/content/5/3/27 and related letter by Rosenfeld and Mason, http://genomemedicine.com/content/6/2/15

Abstract
A response to Pervasive sequence patents cover the entire human genome by J Rosenfeld and C Mason. Genome Med 2013, 5:27.

Letter to the editor
In the article by Jeffrey Rosenfeld and Christopher Mason published in Genome Medicine [1], significant misstatements were made, because the authors did not sufficiently review the claims - which define the legal scope of a patent - in the patents they analyzed. The authors contend that ‘41% of the genes in the human genome have been claimed’ in US patents. Additionally, they suggest that claims to shorter sequences, specifically 15mers, in a patent held by Myriad Genetics (a litigant in the recent Supreme Court case involving the patentability of genes [2]) cover 91.5% of human genes. Their article has received wide attention in the press and industry (for example, in CNBC [3], Fox News [4] and CBS News [5]), and formed the basis for opinion articles by the authors in the Washington Post [6] and the Huffington Post [7].

We do not question the authors’ assertion [1] that as k-mers become shorter, the likelihood that those k-mers appear in some gene increases substantially. However, the article does not accurately reflect the law behind gene patenting, because by failing to specifically analyze the claims of these patents, it overestimates the share of the human genome that is ‘covered’ by US patents. As an initial matter, unlike most articles in Genome Medicine, Rosenfeld and Mason’s article [1] purports to make legal - rather than purely scientific - assertions. Our criticisms do not depend on our viewpoint as patent lawyers or as patent law professors. As we describe below, the authors [1] make important legal assertions that are either misleading or simply incorrect.

More specifically, Rosenfeld and Mason [1] did not apply the legal standards required for patent infringement and, in turn, misinterpreted the scope of the CAMBIA patent sequence database [8] when performing their analysis. In order to arrive at a legitimate conclusion as to what subject matter is ‘covered’ by a patent claim, it is absolutely necessary to read and interpret every single limitation or element in the patent claim. The patent claim defines the patented invention, and infringement can occur only when every element of a claim is met by the accused product or process. Rosenfeld and Mason [1] identified patents that mention DNA sequences, but then fail to review the other terms and limitations required by the claims. Based on our review of some of these claims, they almost all included additional limitations and some simply mention the gene sequence without even making the sequence a limitation in the first place. For example, one patent they identify as ‘covering’ DNA sequences corresponding to human genes also requires testing on a bovine subject. But they ignore the required step of bovine testing when analyzing whether their claim covers gene sequences. In fact, because this claim requires testing, it is not a ‘composition of matter’ claim at all and cannot independently cover gene sequences.

The article by Rosenfeld and Mason [1] made an assumption that just because a patent mentions a gene sequence in a patent claim, any use or research of this gene would result in patent infringement. This is not the case. To directly infringe a claim that is directed to a composition of matter (such as DNA) that comprises elements 1, 2 and 3, one needs to make a composition that includes at least elements 1, 2 and 3. If only element 1 is present, then there is no direct infringement of the
A manual review of patent claims to determine whether DNA sequences mentioned within the claims are in fact within the scope of the claims is more than feasible. First, one would only need to review the 3,945 patents that were matched from the CCDS gene sequence database [13] and the CAMBIA patent database [8] (not tens of thousands of patent claims). In fact, Graff et al. [14] show that there are only 11,868 gene patents, with 5,936 patents directed to humans. Second, one would only need to focus on the claims (usually only one to three pages at the end of a patent), and not necessarily read the entire patent. Finally, one could limit the analysis to only composition of matter claims. To do this quick first pass type of review, it took one of us (ST) less than 1 hour to review approximately 60 patents. Accordingly, for 3,000 to 4,000 patents, roughly 60 hours of work would be required - far under the amount of time spent preparing a typical article appearing in this journal. Interestingly, in a recent article, Jefferson et al. [15] describe tools for the CAMBIA database that begin to address this very issue.

We realize that Rosenfeld and Mason [1] are not patent lawyers. The field of patent law is one that can be both confusing and complex. However, we do not believe that readers could plausibly interpret the Rosenfeld and Mason [1] article as only making a statistical argument about coverage and not legal interpretations about patent law. Indeed, Rosenfeld and Mason [1] rely on their results to propose that ‘the Supreme Court and Congress should limit the patenting of existing nucleotide sequences because of their broad scope and non-specificity in the human genome.’

We note that none of the above necessarily reflects on the position of the authors [1] in the ongoing debate regarding the patentability of ‘gene patents’. Rather, we all believe that this vital debate should be tethered to legal reality. Also, since the publication of Rosenfeld and Mason [1], the US Supreme Court has issued an opinion regarding gene patents [2]. Specifically, the Court has drawn a line between isolated DNA (not patentable subject matter) and cDNA (patentable subject matter). According to the Court, ‘[the patentee] did not create or alter either the genetic information encoded [in the genes] or the genetic structure of the DNA. [The patentee] found an important and useful gene, but groundbreaking, innovative, or even brilliant discovery does not by itself satisfy the [statutory patentable subject matter requirement].’ However, the Court also ruled that cDNA is not a ‘product of nature,’ and is thus patent-eligible [2].

It is well within our expertise as patent law professors to rebut such arguments. Additionally, we have the expertise to understand the science, as all but two of us have first degrees in biology or medicine and four of us have PhDs in biological subjects or MDs. Put simply, Rosenfeld and Mason [1] use their scientific results to
make a legal argument, and that legal argument is based on an incorrect view of the law. So it is to these legal conclusions, and not their scientific results, that we object. Specifically, the claims of the patent define the legal boundaries and the inventor’s exclusionary rights. Accordingly, it is legally insignificant that the short nucleotide sequences statistically can be found in much of the human genome, unless many patent claims solely cover these short nucleotide sequences. Rosenfeld and Mason [1] have shown nothing of the sort, and our initial review of their patents indicates entirely otherwise.

Additional file

Additional file 1: Table S1. A brief analysis of the 58 patents referenced in Additional file 2 of the Rosenfeld and Mason article [1]. Analysis only includes review of the independent claims of the patent, and also a brief description of the elements necessary for patent infringement are given.

Competing interests

ST, CH, AM, JC and GD have written amicus briefs relevant to this publication. Amicus briefs are legal briefs written by someone who is not party to the lawsuit but who petitions the court to file a brief in the action because that person has a strong interest in the subject matter.

Author details

1West Virginia University College of Law, PO Box 6130, Morgantown, WV 26506, USA. 2University of Missouri-Kansas City School of Law, 500 East 52nd Street, Kansas City, MO 64110, USA. 3Center for the Protection of Intellectual Property, George Mason Law School, 3301 Fairfax Drive, Arlington, VA 22201, USA. 4University of San Diego School of Law, 5998 Alcala Park, San Diego, CA 92110, USA. 5Villanova University School of Law, 299 N. Spring Mill Rd, Villanova, PA 19085, USA. 6American University Washington College of Law, 4801 Massachusetts AvenueNW, Washington, DC 20016, USA. 7Georgia State University College of Law, 140 Decatur Street, Atlanta, GA 30303, USA, 8Center for Medicine and Law, University of Baltimore School of Law, 1420 North Charles Street, Baltimore, MD 21201, USA. 9Loyola Law School, 919 Albany Street, Los Angeles, CA 90015, USA.

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12. 35 USC § 157(a)(3).

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