

Will Gene Patents Impede Whole Genome Sequencing?: Deconstructing the Myth That 20% of the Human Genome Is Patented

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A 2005 Science article by Jensen and Murray is widely cited for the proposition that 20% of human genes are patented, and has led to a pervasive assumption that thousands of human genes cannot be used, studied or even "looked at" by researchers and healthcare providers without infringing a gene patent. Many have voiced concern that this perceived thicket of gene patents will impede the implementation of next-generation genetic technologies, particularly personal whole genome sequencing (WGS). In fact, Jensen and Murray only showed that, with respect to 20% of human genes known at the time they conducted their study, either (1) the DNA sequence of the gene, or (2) the amino acid sequence encoded by the gene, was mentioned in a US patent claim. The myth that 20% of human genes are "patented" has taken root because too many have incorrectly inferred that the mere "mention" of a gene in a patent claim precludes all uses of the gene. To better understand the actual implications of Jensen and Murray's findings, I analyzed the claims from a random sampling of 533 of the 4270 patents identified in their article as "gene patents." I found that, under any reasonable interpretation, 140 of the 533 patents would not be infringed by any form of genetic testing. The remaining 393 patents include claims with respect to which I cannot rule out the possibility that at least some form of genetic testing would be found infringing. These claims fall into two categories - products claims directed to polynucleotides (e.g., DNA molecules), and method claims. The language used in these claims is extremely heterogeneous, and it is impossible to predict with any certainty exactly how broadly a court would interpret their scope if they were ever asserted in litigation, but to varying degrees a majority of these patents would appear not to be infringed by at least some, perhaps all, forms of genetic testing. In particular, few (if any) of these patents would appear likely to be infringed by some next-generation WGS technologies, particularly those that do not require DNA amplification. In short, there is absolutely no basis to infer from the Jensen & Murray article that personal WGS, and other multiplex genetic diagnostic testing technologies, would result in the infringement of a large number of human gene patents. To the contrary, it appears that a vast majority of these patents were drafted in a manner that would not encompass WGS.