

The Impact of Human Gene Patents on Innovation and Access: A Survey of Human Gene Patent Litigation

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In 2005 the highly influential journal *Science* reported that one-fifth of human genes are patented. This figure has been widely cited and at times over-interpreted. For example, a popular science fiction author warns the public that their bodies are "owned" by someone else. Members of Congress have introduced a bill that would essentially seek to ban the patenting of DNA. The motivation for this bill, as expressed in an accompanying press release, is based in part upon a perception that 1/5 of our genes are owned by somebody else, that these owners can do whatever they want with these genes, and that there is "nothing that we can do to stop them" (presumably short of banning the patenting of DNA). While clearly many US patents have issued that reference human genetic sequences, the actual scope of exclusivity varies dramatically from claim-to-claim as dictated by the actual claim language. Many patents restrict only some very narrow use of the genetic sequence, others are much broader - none cover actual human genes as they exist in their native state. And it should go without saying that none confer actual ownership of human beings or allow the patent owner to do "whatever it wants" with a person's genes. In light of the hyperbole and high interest currently surrounding human gene patents, and in an attempt to assess the true impact of these patents, I conducted a search to identify and analyze all instances where a patent relating to a human gene was asserted in a lawsuit. The results suggest that the impact of human gene patents has been felt primarily in the context of biotechnology-derived protein therapeutics, i.e., biologics, the most important fruit of the biotechnology revolution. The impact on genetic testing and access to research tools has been relatively modest, with some notable exceptions. This paper considers a variety of facets of human gene patent litigation. For example, it assesses the extent to which patent thicket and patent troll concerns manifest themselves in the context of human gene patents, and considers the role of universities and non-profits. It also considers the susceptibility of human gene patents to geographic and/or technical avoidance, e.g., by design-around or off-shoring. Critics of human gene patents point to their potential to exclude, but this paper assesses the extent to which this negative effect, shared by all patents, is balanced by positive incentive effects. The paper concludes by questioning the current focus on DNA and human genes, and suggests some alternative policy prescriptions.