

Who Owns You? The Corporate Gold Rush to Patent Your Genes

By: David Koepsell

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While the practice of obtaining patents on living organisms is not a novel concept, the current race to patent human genes has presented our society with a very controversial trend.¹ The United States Patent and Trademark Office (PTO) has taken the position that human genes and gene fragments are patentable subject matter.² They supported this position by pointing to US Patent 141,072 that was filed by Louis Pasteur in 1873 for an isolated yeast organism and argued that the patent covers the gene in an isolated form, and is therefore not its natural state.³ In *Who Owns You? The Corporate Gold Rush to Patent Your Genes*, David Koepsell⁴ explores public policy arguments as well as the philosophical, ethical, and economic implications of allowing this type of property right in gene sequences. Koepsell argues objects that fit into intellectual property law are supposed to be “man-made objects, intentionally produced,” and gene patents that consist of isolating the gene sequence should not meet the patent requirements of novel, useful, and non-obvious inventions.⁵

¹ *Diamond v Chakrabarty*, 447 U.S. 303 (1980). Supreme Court held that “a live, human-made microorganism is patentable subject matter.”

² David Koepsell, *Who Owns You? The Corporate Gold Rush to Patent Your Genes*, (Wiley-Blackwell, 2009) at 90.

³ *Id* at 90-91.

⁴ Koepsell is an author, philosopher, and attorney who obtained his law degree from the University of Buffalo. He is also the author of *The Ontology of Cyberspace: Philosophy, Law, and the Future* (2000). He currently teaches at the Delft University of Technology and lives in the Netherlands.

⁵ See 35 USC §§100-05 (2000); see also Koepsell *supra* note 2 at 91.

Since the landmark Supreme Court decision in *Chakrabarty* to issue a patent for an oil-dissolving bacterium, genes and other biological resources have been subject to intellectual property rights.⁶ The first gene patent was issued to Regents of the University of California in 1982 for constructing a bacterium that contained the plasmid that expressed the gene for chronic somatomammotropin.⁷ Currently twenty percent of human genes have been patented by Universities, private research firms, and pharmaceutical companies. This behavior prompted the debate as to whether or not the PTO and US intellectual property law should issue patents on gene sequences.⁸

In *Who Owns You? The Corporate Gold Rush to Patent Your Genes*, Koepsell seeks to break down the issues in order to better frame the debate involving ethics, genes, and property. He begins by explaining basic molecular biology functions of DNA and genes to make sure the reader has a sufficient grasp on the role of genes in the development of each individual in order to understand the implications of human gene patents. Koepsell discusses the social and legal importance of individuality, and how owning genes mocks individuality and equality. Next, an introduction to property law and intellectual property is offered, which highlights various cases that influenced patent law regarding human genes. Eventually he questions whether genes appropriately fall within the category of intellectual property. Koepsell then offers a comparison of treating genes as common property that is available for everyone to use, similar to how radio spectra are treated. A final pragmatic argument is made to draw attention to the economic concerns for smaller biotech companies in the current patent system. Koepsell suggests that

⁶ *Chakrabarty*, *supra* note 1 at 303, *see also* Human Genome Project Fact Sheet, *available at* http://www.ornl.gov/sci/techresources/Human_Genome/publicat/hgnfactsheet.pdf.

⁷ *See* Gene Patents and Global Competition Issues, *available at* <http://www.genengnews.com/articles/chitem.aspx?aid=1163&chid=0> (last visited Jan. 1, 2006).

⁸ *See* Who Owns the Genetic Code, *available at* <http://academic.udayton.edu/health/05bioethics/00ammons.htm> (last visited April 5, 2000); *see also* Kyle Jensen and Fiona Murray, *Intellectual Property Landscape of the Human Genome*, 310 *SCIENCE* 239 (14 Oct. 2005).

patented genes may threaten research advancements because some researchers and smaller companies might not be able to afford the royalty fee, or may be deterred by the threat of litigation. The purpose of patent law is to encourage innovation and reward creativity, however exclusive licensing of gene patents seems to threaten diagnostic advancements by limiting the researchers that can access certain gene sequences. Koepsell argues that the practice of patenting human genes threatens genetic research, privacy rights, and human dignity, which is why the current legal policy should be reformed.

Unfortunately, Koepsell makes some errors throughout his book that challenge the validity of his argument that gene patenting is a threat to science and patent law. For example, when discussing the molecular background of DNA, Koepsell uses the term “amino acids” (which make up proteins) in place of “nucleotides” when discussing the four base pairs that compose a strand of DNA.⁹ He also confuses some basic principles of patent law when he argues that isolating a gene sequence is merely a “discovery” and not an “invention,” even though both are included in the definitions section of the United States Code regarding patents.¹⁰ Koepsell also inappropriately references the California case *Moore v Regents of the University of California*¹¹, suggesting that the case influenced the advancement of patents to include human genes. The scope of gene patents was not at issue in *Moore*, and the fact that it was a state case further demonstrates Koepsell’s misreading since state law has no jurisdiction over patent law because it is regulated by federal courts.

⁹ Koepsell, *supra* note 2 at 20, 49.

¹⁰ 35 USC §100 (2000). The term “invention” means invention or discovery. *See also* Koepsell, *supra* note 2 at 91.

¹¹ *See Moore v Regents of the University of California*, 51 Cal. 3d. 120 (1990) (case dealt with issue of property rights in one’s own body parts. The court ruled that the plaintiff did not have any property rights in his discarded cells or any profits made from the commercialization of the developed cell line. The court did find that the treating physician had an obligation to reveal his financial interests, and that he failed to disclose those circumstances to the plaintiff).

While Koepsell offers several important criticisms regarding the patentability of human genes from an ethical perspective, the fact that his arguments are based on assumptions and legal interpretations that are not quite accurate casts some doubt on the legitimacy of his statements. His misunderstanding of patent law and the effects of human gene patents results in Koepsell taking an alarmist position that is mistaken and overly dramatic. He makes several science fiction analogies, comparing humans to artificially created androids, and including movie references like *Gattaca*, suggesting that these outrageous exploitations of humans could become real through gene patents. He poses unrealistic possibilities such as paying royalties for having children as a result of companies having patent rights of human gene sequences, making the issues completely fantastic and far-fetched.

Instead of grasping at exaggerated and speculative arguments, developing statements grounded in genuine legal questions and existing scientific concerns would have proven more persuasive. For example, the standard used by the court to distinguish patentable products from non-patentable products is the distinction between “products of nature, whether living or not, and human-made inventions.”¹² Human genes are a product of nature. But scientists argue that since the natural sequence of the gene is altered by removing the non-coding intron sequences, a complementary DNA (“cDNA”) product is created that is not found naturally in the cell.¹³ The isolated sequence is therefore man-made and patentable.¹⁴ Yet Koepsell never explains the distinction courts make between man-made discoveries, which are patentable, and those that involve discovery of naturally occurring products, which are not patentable. Instead he chooses to create an issue that involves interpreting the isolation of human gene sequences as discovery

¹² *Chakrabarty*, *supra* note 1 at 313.

¹³ See Seldon Krimsky, *The Profit of Scientific Discovery and Its Normative Implications*, 75 Chi.-Kent L. Rev. 15, 26 (1999).

¹⁴ *Id.*

of natural products, stating that “The only thing the inventor has done is to point out, as if on a map, where the gene lies in nature.”¹⁵ While this is a good analogy that gene sequencing might be compared to, it fails to address the claim scientists make for considering isolated genes as patentable, man-made inventions. Removing introns from the gene sequence and arguing it is no longer a natural product is different from the discovery issue Koepsell creates. Scientists assert that they do more than just point out the location of a gene sequence. They modify the sequence. However removing the introns from a gene sequence and labeling it a man-made invention is similar to pruning a fruit tree, throwing away the inedible fruit, and then labeling the trimmed tree or final ripe produce as man-made, patentable products. This is the legal issue that must be discussed and explored, not whether an isolated human gene sequence qualifies as an invention or a discovery.

One of the better arguments presented by Koepsell is that DNA and genes should be categorized as commons by necessity. Similar to how air and radio waves are treated because their containment is impossible, the control of genes is also difficult given “1 their presence in reproducing individuals, 2 the fact that they exist across species, and 3 that they evolve without any input by human intention.”¹⁶ Koepsell further explains that “Commons that exist by logical necessity as described above are simply unencloseable, although we may choose to define limits to their use and regulate to preserve them.”¹⁷ Treating DNA and genes as commons by necessity could help define the legal, practical, and moral boundaries associated with their use that would better serve the public and benefit research.

¹⁵ Koepsell, *supra* note 2 at 92.

¹⁶ Koepsell, *supra* note 2 at 133.

¹⁷ Koepsell, *supra* note 2 at 133.

Koepsell's position regarding the abandonment of human gene patents is substantial. Unfortunately, it was damaged through his misunderstanding of patent law and the weak arguments that were formulated as a result of the confusion. By advocating for a more narrow interpretation of man-made discoveries, or focusing the analysis more on alternative solutions such as genes being treated as common property, the message for legal modifications would have been stronger.

Despite these weaknesses, *Who Owns You? The Corporate Gold Rush to Patent Your Genes* successfully explores the ethical controversy of human gene patents, prompting very important questions and encouraging a much needed debate. Koepsell's reservations involving the effects of gene patents and research involving genetic diseases is a legitimate concern, and one that may in the future trigger legislative action. This is a book for those who enjoy exploring legal topics from a perspective based largely on science fiction rather than focusing on practical legal issues and realistic policy concerns. While some may find his alarmist approach a little improbable, his philosophical and ethical concerns along with the pragmatic economic arguments against human gene patents may encourage further discussion or justification regarding the scope of gene patents.