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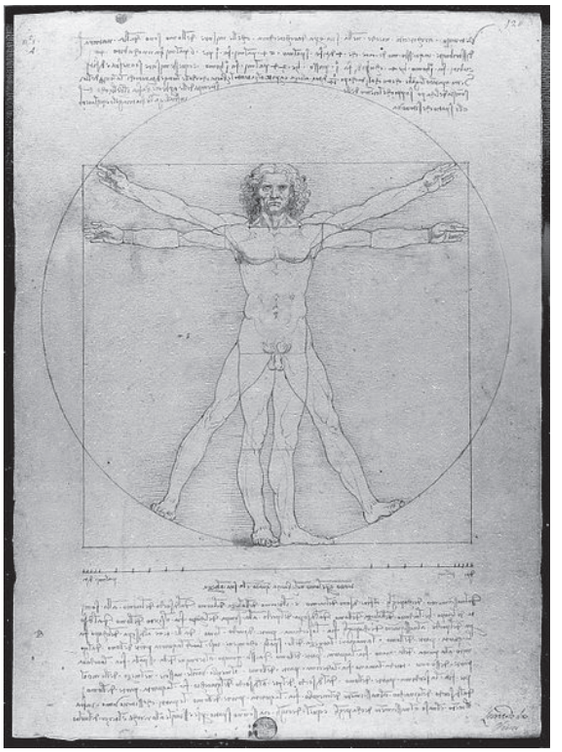
Patent Claims Directed to or Encompassing a Human Organism - Where Law, Morality, Ethics, and Religion Meet

by Robert Gunderman, PE and John Hammond, PE

Biotechnology and Human Dignity

While many areas of patent law are concrete and clear, neat and tidy, biotechnology patents are not. The rapid growth of biotechnology research pushes the limits of patent law, creating controversy, disagreement, and yes, court cases. The ability to patent life forms, organisms, and particularly human beings or parts of human beings is a topic that involves law, morality, ethics, and religion, and where they all meet there will certainly be controversy. Concerns that patenting living organisms violate the sanctity of life are primarily based on religious tenets and beliefs that are important and must be carefully considered. The notion of patenting parts of a human has received a great deal of opposition in recent years, and the controversy is far from over. Concerns over changes in the basic nature of humanity, creation of quasi-human life forms, a degradation of the value of human life, and the negativity associated with humans "playing God" are all very real and very problematic issues that must be addressed with each and every advance in the field of biotechnology and assertion of patent rights on the resulting inventions.

"Notwithstanding any other provision of law, no patent may issue on a claim directed to or encompassing a human organism."



What is Patentable?

So, with such a consequential perspective on the topic of patenting life forms, what really is patentable? Title 35 of the United States Code, Section 101, defines what is patentable by stating that "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."[1,2] This simple leading statute has been the subject of countless court cases that have molded and shaped the interpretation of "what is patentable" over the years.

Patenting Life Forms

The author of the original Patent Act of 1793, Thomas Jefferson, could never have envisioned that life forms would even be considered for patent protection. In fact, an 1889 tenet stated that you can't patent the trees of the forest or the plants of the earth. Of course the Plant Patent Act of 1930 changed all that by allowing new varieties of asexually produced plants that are the products of plant breeders to be patent eligible.[3] Then in 1972, in the famous case[1] of *Diamond v. Chakrabarty*, a biochemist at General Electric by the name of Anand Chakrabarty developed a genetically engineered bacterium that could break down crude oil. His patent application was rejected under 35 U.S.C. §101. He appealed and took his case all the way to the Supreme Court, which ultimately ruled in his favor by determining that "His claim is not to a hitherto unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter-a product of human ingenuity…" In 1981 he was issued U.S. Patent 4,259,444. From that point in time, life forms have been patentable to some degree, and many patents have issued that relate to *non-human* life forms.

Slavery and Other Forbidden Property Rights

A patent is a property right, and the condition where one human being is owned by another is considered slavery, and violates the 13th amendment to the Constitution. The United States Patent and Trademark Office has long upheld the policy that a claim encompassing a human being is not patentable. With the rapid growth of biotechnology, genetic engineering, and related fields, this policy and its relationship to 35 U.S.C. §101 and what is considered patentable seemed to need further definition by lawmakers. Congressman Dave Weldon M.D. (R-FL) in the early 00's advocated language to further codify the policy of the United States Patent and Trademark Office to not patent human organisms.

And Along Comes the America Invents Act

The efforts of Congressman Weldon and others resulted in Section 33(a) of the America Invents Act, which became law on September 16, 2011. The language of Section 33(a) of the America Invents Act simply reads as follows:

"Notwithstanding any other provision of law, no patent may issue on a claim directed to or encompassing a human organism."

In patent law, simple is not always best, and the brevity of Section 33(a) without further explanation will most certainly create controversy and court cases for years to come, with each new biotechnology invention creating the opportunity for court decisions and Patent Office actions to provide new interpretations of Section 33(a).

…And the Uncertainty it Creates

Two phrases in Section 33(a) are particularly vague and subject to interpretation: *"directed to"* and *"human organism."* Since neither phrase is used elsewhere or defined in the Patent Act, prosecutors and litigators must initially rely on the plain and ordinary meaning of each phrase. First and foremost is the dictionary definition of each phrase. For the phrase "directed to," Merriam Webster defines directed as "subject to supervision or regulation, having a positive or negative sense." Does this mean, for example, that a claim, perhaps a surgical tool for use on a human body, is "directed to"…a human organism? One would hope not, and while this is an extreme example, it points out the difficulties that will be encountered with the wording of Section 33(a).

Perhaps even more challenging is the phrase "human organism." At what point does a part of a human become a human organism? Is a human cell a human organism, or is a group of these cells required in order to be considered a human organism? The Merriam Webster Dictionary, for example, defines organism to be "1. an individual living thing 2. a system with many parts that depend on each other and work together." The Macmillan Dictionary defines organism to be "a living thing such as a person, animal or plant, especially an extremely small living thing." And Webster's Ninth New Collegiate Dictionary defines organism to be "a complex structure of interdependent and subordinate elements whose relations and properties are largely determined by their function in the whole."

It is safe to say that the language of Section 33(a) and related dictionary definitions do little to help clarify at what point a part of a human ceases to become an organism. Is only the whole human an organism, or are subcomponents such as organs and cells also organisms unto themselves? The answers to these questions have important implications in determining what is patentable, as these subcomponents of human beings are being increasingly used in biotechnology related inventions. Genes, DNA, cells, and other parts of a human being are becoming increasingly important in biotechnology inventions and their related patents. Better clarity and definition of section 33(a) will only come with time as court decisions mold and shape the definition of the rather vague language contained in Section 33(a).

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1. See **"The Limited Monopoly™" January 2008.**
2. See **"The Limited Monopoly™" January 2009.**
3. See **"The Limited Monopoly™" December 2009.**

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"Vitruvian Man," Leonardo da Vinci, 1490.