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## A Look At The Patentability Of 3-D Printed Human Organs

Law360, New York (May 28, 2013, 12:58 PM ET) -- It is well established that patentability of human organisms is a legal taboo. However, with the ongoing advances in science and technology, the line between patenting human and nonhuman living organisms continues to erode.

One area of science that has the potential to transgress the line of patenting human organisms is "bioprinting." The concept of bioprinting was born out of an intersection between 3-D printing, often used for creating 3-D models and manufacture of complex parts, and adaptation of inkjet printing technology to printing layers of living cells.

In short, bioprinters stack multiple layers of cells within a gel-based material to form functional living tissue. Depending upon the type of living cells being printed and printing geometry, various types of living tissue may be formed. For instance, scientists have already bioprinted functional 3-D human blood vessels, as well as human mini-livers a few millimeters in size. Therefore, bioprinting has a clear potential to generate entire human-sized living organs. While not exactly a Star Trek Enterprise replicator, this technology is conceptually related and is clearly poised to have a revolutionary impact on healthcare as we know it, including the fields of medical research and organ transplantation.

As with all pioneering fields, patent protection is of great importance to fully capitalize on the investment in the underlying research and development by deterring or at least slowing down competitors. With that in mind, we briefly explore some of the issues associated with claiming patent protection for artificially created living human tissue, including human organs manufactured by way of bioprinting.

While the patent office and Congress view patent claims encompassing a human organism as not being eligible for patent protection, patent applicants have been successful in obtaining protection for genetically engineered animals by narrowing the claim scope to "nonhuman" subjects. For instance, U.S. Patent No. 8,088,968 claims a "non-human mammal" with a particular genome composition where the nonhuman mammal is a mouse. A "tissue" of such nonhuman mammal is also separately claimed. However, would claiming a bioprinted collection of "human tissue" or a "human organ" run afoul of the prohibition of patenting a human organism?

Several arguments exist that bioprinted human organs and tissue should be eligible for patent protection. For instance, rather than being viewed as products of nature, bioprinted organs and tissue may be considered to be manmade living materials artificially arranged in accordance with a particular printing geometry that facilitates any naturally occurring cell behavior. This is not dissimilar to patents directed to implants, such as U.S. Pat. No. 8,394,141 that includes claims directed to an implant formed from "fibers of defatted, shredded, allogeneic human tissue" including a "tendon, fascia, ligament, or dermis" and further including a "growth factor" for inducing growth of various cell types.

Additionally, while patent claims including a human embryo have been rejected by the patent office under 35 U.S.C. Section 101 as being directed to a nonpatentable human organism, as well as being in violation of Section 33(a) of the Leahy-Smith America Invents Act, stand-alone bioprinted human organs and tissue should not be considered as encompassing a "human organism." Section 33 (a) of the AIA codifies the patent office policy that human organisms are not eligible for patent protection and states: "Notwithstanding any other provision of law, no patent may issue on a claim directed to or encompassing a human organism."

Undoubtedly, a body of caselaw will develop as to the interpretation of the terms "directed to or encompassing a human organism." However, even under the broadest reasonable interpretation used by the patent office, the notion that a claim reciting a bioprinted human liver or a bioprinted human bone is "directed to" or "encompasses" a human being is hard to fathom.

It should be further noted that the U.S. Supreme Court's upcoming decision on the patentability of isolated human genes in the *Association of Molecular Pathology v. Myriad Genetics Inc.* case may also shed additional light on patentability of manmade human tissue and organs. In the meantime, including the necessary supporting description into a patent application will preserve the applicant's rights to claim various aspects of inventions related to bioprinted human tissue and organs as this area of law develops.

In the end, the question of whether some collection of manmade human organs constitutes a human organism may be better left for the world of science fiction. In the words of Dr. Moreau: "These creatures of mine seemed strange and uncanny to you ... but to me, just after I make them, they seem to be indisputably human beings. It's afterwards, as I observe them, that the persuasion fades. First one animal trait, then another creeps to the surface and stares out at me. But I will conquer yet!"

--By Samuel Fifer and Dimitry Kapmar, Dentons

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