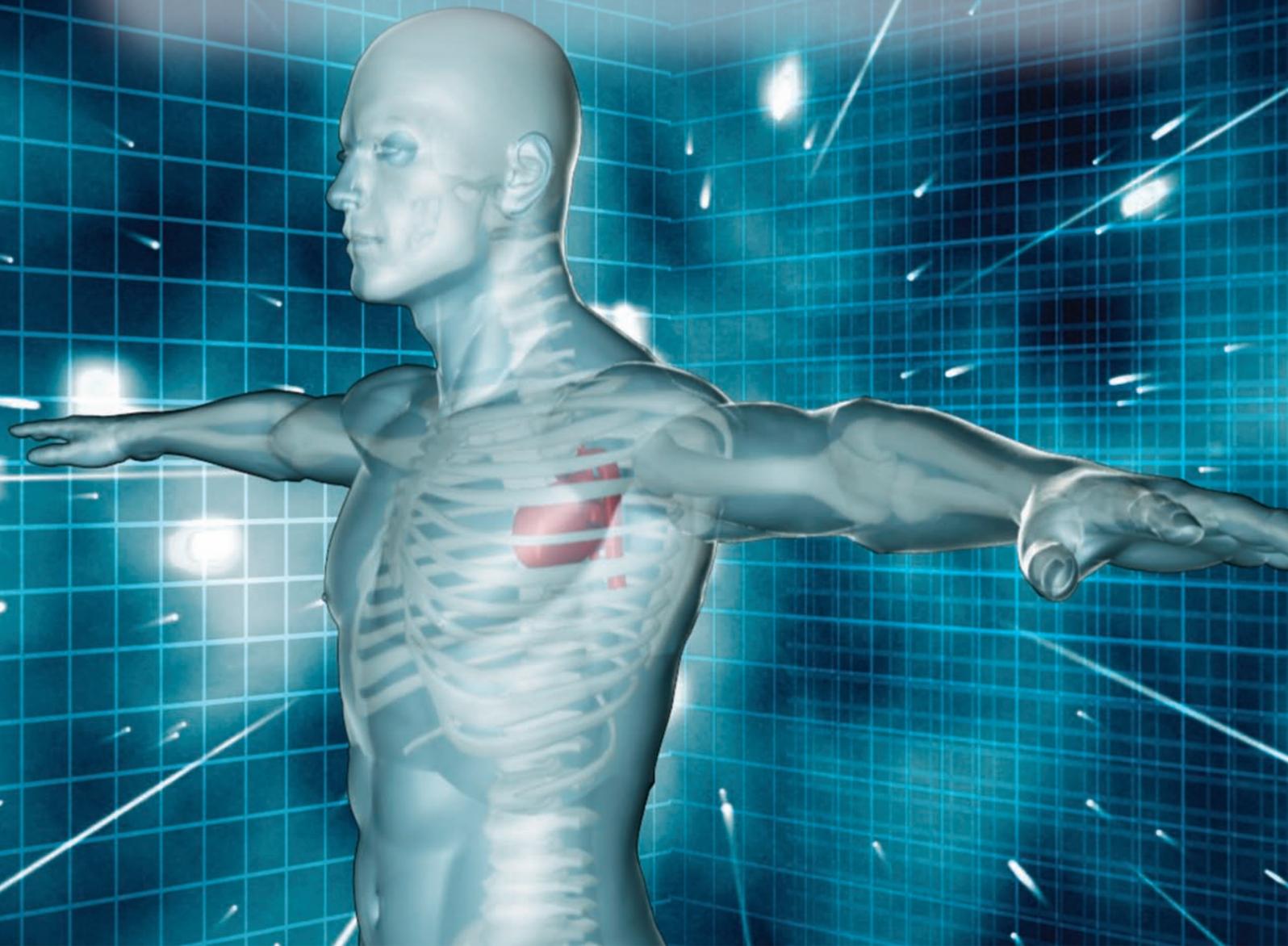


Today's GENERAL COUNSEL



Patent Eligibility of 3D Printed Organs Will Soon be an Issue

By Craig C. Martin and Sara Tonnie Horton

Biotech companies, technology companies and scientists are working on a breakthrough that could allow specialized 3D printers to create human organs, a process known as “bioprinting.”

Scientists already have printed blood vessels, a variety of organ tissues, and last year Princeton University scientists printed a functional ear. Should the scientists and companies who manufacture ears and blood

vessels be able to obtain patents on these objects even though they already exist in nature? The interplay between these new technologies and patent laws are unclear and ripe for examination by the courts.

Bioprinting is the process of creating human tissue and organs using a 3D printer. Bioprinted tissue and organs could be used for research, drug development and testing, and even at some point, organ transplants. The process works as follows (much simplified):

First, a computer model or scanned image of the tissue or organ is loaded into the 3D printer to create a blueprint of the object. Second, living cells are mixed with a gel to create bio-ink for the printer. The types of cells used for bio-ink, or combinations thereof, vary depending on the type of organ or tissue to be printed. Next, the printer deposits the bio-ink in thin layers through printing nozzles onto a platform to create the final product.

Following the printing of the tissue or organ, additional steps may be needed to solidify and incubate the printed tissue or organ.

PATENT ELIGIBILITY

The United States Code allows for patents on “any new and useful process, machine, manufacture, or composition of matter.” Human organisms and products of nature are not patent-eligible, but variations of naturally occurring organisms to create new organisms may be. (See the Supreme Court’s 2013 decision in *Association for Molecular Pathology v. Myriad Genetics, Inc.*, and a 1980 case, *Diamond v. Chakrabarty*.) Indeed, the U.S. Patent and Trademark Office has granted numerous patents for inventions related to human genes and naturally occurring phenomena. However, over

the last several years, the validity of these patents has come into question.

In *Myriad*, the Supreme Court decided whether a naturally occurring DNA segment could be patented. A research laboratory had obtained patents covering the precise location and sequence of certain genes. Mutations of those genes can increase the risk for breast and ovarian cancer. The genes are naturally occurring. However, their precise location was unknown before the invention *Myriad* patented.

Supreme Court held that cDNA was not a “product of nature” and thus was patent eligible. The Court’s reasoning in *Myriad* hints that whether the subject matter is an unknown but natural phenomenon, or a manufacture or composition of a matter that does not occur naturally, should be the touchstone of such decisions.

BIO-PRINTED ORGANS

With the advance of science in this area, and several companies

Scientists already have printed blood vessels, a variety of organ tissues and a functional ear.

Several years after the USPTO awarded patents covering these genes, petitioners brought suit seeking a declaration that the patents were invalid because they did not cover patent-eligible subject matter. The Supreme Court held that the isolated naturally occurring DNA segment was not patent eligible, reasoning that the research laboratory “did not create or alter any of the genetic information encoded in genes” and that “[t]he location and order of the nucleotides existed in nature” before the research laboratory found them.

The research laboratory also obtained a patent on complementary DNA (“cDNA”), which is synthetically created DNA. The

competing to perfect bioprinting of organs and tissue, the patentability of such objects is up for discussion.

Echoing the Court’s finding in *Myriad* regarding cDNA, proponents argue that bioprinted organs are not a product of nature but rather a product of human manufacture and innovation. While bioprinted organs may seek to replicate the design, shape and function of human organs, the composition and manufacture require highly scientific methods and precise machinery.

Furthermore, proponents of patents in general argue that patents spur innovation by rewarding inventors of new and useful products. Scientists and companies currently researching and creating the process

Would an application for a lab-created liver, which resembles and functions like a human liver, be denied?

to bioprint organs and tissue have spent considerable time, energy and resources to create technology that may one day transform the process of drug development and organ transplant. Proponents argue that they should be rewarded with patents for this work.

Opponents of the patents in Myriad argued that even synthetically created DNA should not be patentable, because it is not invented and not “markedly different” from what occurs in nature. Because bioprinted organs seek to replicate human organs, and even use human cells as building blocks, opponents may likewise argue that bioprinted organs are not markedly different from what occurs in nature, and in fact are designed to mimic human organs and therefore cannot be patentable.

Opponents also would likely argue

that patents covering this technology would stifle innovation and access to better medical treatments, because patent monopolies would foreclose future innovation and development of the bioprinting technology.

Both the process of creating a bioprinted organ or tissue and the composition of such organs and tissues may form the basis for future patent applications.

While it is clear that an application for a patent for a human liver should be denied, it’s not clear whether an application for a lab-created liver that resembles and functions like a human liver should be denied. It remains to be seen how the USPTO and courts will approach these issues. Patentability will likely rest on what the applicant seeks to patent – the method to create the bioprinted organ or tissue, the bioprinted substance, or the organ itself. ■



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