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PERSPECTIVE

Printed organs: patent eligible?

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Researchers have been toiling away for decades in an effort to move therapy from the two-dimensional cell culture to the three-dimensional construct realm. As with most innovation, the U.S. patent system has rewarded them for such efforts without much controversy, whether it was artificial livers, engineered articular cartilage, or a microfluidic organ-on-a-chip. Despite this significant progress, the impending arrival of 3-D printed organs cannot come soon enough to the approximately 121,000 people awaiting an organ transplant in the Unites States (according to United Network for Organ Sharing).

Briefly, 3-D bio-printers use established 3-D printing technology to deposit layered patterns of cells to produce a 3-D construct. For example, adult or embryonic stem cells can be layered with tissue components, such as collagen, until a desired 3-D tissue/organ is produced. In some instances, the 3-D printed tissue may additionally require incubation, or controlled cellular differentiation, to be complete. As the literature demonstrates, 3-D printed constructs have already been produced for skin, bone, blood vessels and ears.

While there is little debate that 3-D bio-printers and methods of bio-printing organs are patent eligible under 35 U.S.C. Section 101, 3-D printed organs present a unique challenge to patent laws simply because printed organs are increasingly (structurally and/or functionally) similar to their naturally occurring counterparts. The most pertinent law dealing with such issues is *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), as well as the recently implemented Leahy-Smith America Invents Act (AIA) Section 33.

In *Diamond*, the U.S. Supreme Court held that genetically engineered bacteria are patent-eligible subject matter for being man-made, and not naturally occurring. This line of reasoning was reinforced by the Supreme Court in *Association for Molecular Pathology v. Myriad*, 133 S. Ct. 2107 (2013), where the court stated that an isolated DNA fragment was not patent-eligible subject matter because it was not man made, irrespective of the significant human effort involved in isolating a DNA strand that would never otherwise exist in isolation. The test in Diamond is understood to state that, to be patent eligible, a manufacture or a composition of matter must be non-naturally occurring and a product of human ingenuity.

To this end, most patent practitioners consider current iterations of 3-D printed organs to meet both prongs of the Diamond test. In other words, 3-D printed organs are different enough from their naturally occurring versions (e.g., shape, cellular density/composition, artificial structural materials, etc.) to be considered non-naturally occurring, and the significant developmental work required to produce them illustrates ingenuity.

What is not addressed in *Diamond* is whether a 3-D printed organ that perfectly mimics a natural one, in structure and form, would be considered patent eligible. After all, while it is conceivable that 3-D engineered organs could be designed to outperform existing biology, it would nonetheless be a landmark achievement to achieve a "true copy," or an insignificantly different copy, an achievement most would certainly consider worthy of recognition and even patent protection. While it would appear that such a true copy would fail the first prong of the test in *Diamond*, the case never addressed the true copy scenario. Specifically, *Diamond* never addressed what would happen if Chakrabarty had engineered, from component parts, a naturally occurring bacteria. That said, in following the reasoning of the U.S. Court of Appeals for the Federal Circuit's decision in *In re Roslin Institute* (*Edinburgh*), one could argue that

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duplicate copies of tissue are patent ineligible.

In *Roslin*, the Federal Circuit stated that a clone which was the exact genetic copy of naturally existing sheep was not patent-eligible due to being genetically identical to her parent. However, that decision is distinguishable, in that the cloning method in *Roslin* involved somatic cell nuclear transfer, in which the nucleus of a somatic cell is removed and implanted into an enucleated oocyte, and thus, does not quite reflect the "from the grounds up" single cell/molecular component approach that is typical of 3-D organ printing approaches. Thus, *Roslin*'s genetic identity argument would likely only hold weight in a 3-D printed organ scenario if a patient's own cells were used to generate the organ for implantation into the patient. While a medically desirable approach, it is one that can likely be worked around.

As for the AIA, Section 33(a) states that "no patent may issue on a claim directed to or encompassing a human organism." Since the AIA provides no further detail, and there is virtually no case law addressing this statutory provision, the question as to whether 3-D printed organs encompass "a human organism" is for the courts to resolve in coming years. Looking to the legislative history of the AIA for guidance on the meaning of this provision, it includes the following statement: "[T]he U.S. Patent Office has already issued patents on genes, stems cells, animals with human genes, and a host of non-biologic products used by humans, but it has not issued patents on claims directed to human organisms, including human embryos and fetuses. My amendment would not affect the former, but would simply affirm the latter." Based on this limited insight, it would be unusual if a court considered any 3-D printed organ to be akin to a human organism. Conversely, it is also unclear what grouping of organs or other biological structures a court would consider rises to the level of being the equivalent of a human organism.

Given the uncertain legal climate on the issue of patent eligibility of 3-D printed organs, it seems like an inventor's/applicant's best bet is to continue to frame the invention in terms that steer clear from any notion of a naturally occurring composition of matter. Thus, use of terms or phrases such as "device" (e.g., "implantable device"), "engineered construct," or explicit recitation of any artificial materials such as gels and the like, are strongly suggested. And of course, patent protection is always available in the form of claims directed to the manufacturing apparatus/device and method of manufacturing a 3-D printed organ, as well as product-by-process claims.

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