

Patent Difficulties For 3-D Printed Medical Implants

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3-D printing (additive manufacturing) is revolutionizing manufacturing in ways that will change our economy and our lives.[1] For example, few realize that almost all in-ear hearing aids are now made by 3-D printing, with more than 10 million pairs sold.[2] 3-D printing raises unique intellectual property issues.[3] For example, 3-D printers eliminate barriers to entry in manufacturing because they enable anyone to make almost anything. People and companies that have always been customers can become competitors, making the products they formerly bought. And if those products are patented, detection and enforcement of patent infringement will often be impractical or impossible.[4]



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One application of 3-D printing that may someday have a profound impact on our lives is the development of 3-D printed surgical implants to replace damaged or malfunctioning organs and tissues.[5] Many printed implants can be made of synthetic biocompatible materials. Those implants have the significant advantage that they can be customized to fit an individual patient. Many kinds of 3-D printed implants are still experimental. Yet 3-D printed tracheal splints have already saved the lives of several infants.[6]

Particularly remarkable are methods that use 3-D printing to make structures from living cells (called “bioprinting”).[7] With the advent of bioprinting, living cells can be dispensed from a 3-D printer, layer by layer, onto a biologically compatible scaffolding to create three-dimensional viable tissue. Bioprinted implants may someday be constructed from the patient’s own cells, eliminating rejection. The dream is to eventually bioprint complete organs to fill the pressing need for organ transplants.

Claims to Methods Using Bioprinted Implants Must Overcome Immunity From 35 USC § 287(c)

Strong patent protection will be needed for novel 3-D printed medical implants and for methods of using them. Significant funding may be needed for clinical trials, obtaining U.S. Food and Drug Administration approval, and introduction into the market. Besides the intellectual property problems common to all 3-D printing, 3-D printed medical implants and bioprinted tissues and organs raise additional issues for protecting intellectual property.

The purpose of these implants, whether made of biocompatible materials or living cells, is to surgically implant them into the human body. Therefore, one would like to patent not only the printed materials, but also the methods of implanting them into the human body to treat a medical problem. However, although methods of surgical treatment can be patented, they are subject to special immunity under 35

USC § 287(c), which specifies that a medical practitioner's performance of an infringing medical activity is not subject to any penalties for infringement.[8] Immunity from penalties protects not only to the surgeon, but also "related health care entities," broadly defined to include any entity with which the medical practitioner has a professional affiliation under which the medical practitioner performs the medical activity, expressly including but not limited to nursing homes, hospitals, universities, medical schools, health maintenance organizations, group medical practices, and medical clinics.[9]

The purpose of § 287(c) was to protect individual physicians who treat patients and their sponsors from being sued for patent infringement. Congress originally considered simply making surgical procedures unpatentable, as is the law in many countries. But in response to concerns of the pharmaceutical, medical device, and biotechnology industries, the law was instead written to make such methods patentable but to absolve physicians and related health care entities from penalties when they perform those patented methods. *Emtel Inc. v. Lipidlabs Inc. et al.*, 583 F. Supp. 2d 811, 820-23 (2008) (legislative history). "The legislative history [shows] that section 287(c) was intended to protect physicians from infringement suits for the procedures they use to treat patients, while allowing patent protection for medical devices, biotechnology, or drugs and the methods of using them." *Id.* at 822.

To allow patent protection for medical devices, biotechnology and drugs, § 287(c) lists several situations in which penalties for infringement of the medical methods can still apply. Infringement penalties can apply if the infringement includes "(i) the use of a patented machine, manufacture, or composition of matter in violation of such patent, (ii) the practice of a patented use of a composition of matter in violation of such patent, or (iii) the practice of a process in violation of a biotechnology patent." § 287(c)(2)(A). Thus, if practicing the patented medical method involves uses a patented thing (machine, manufacture, or composition of matter),[10] then infringement can be enforced not only against the infringing use of the patented thing but also for practicing the patented medical method. Penalties can also result from activities directly related to commercial development of products and services regulated by the FDA, § 287(c)(3)[11], which means that penalties for infringement of a medical method patent can be brought against commercial competitors who develop infringing products or services.

Therefore, the key to patenting an enforceable method of medical treatment is for the method to use a patented thing. § 287(c)(2)(A),(3). Some tips for patenting such machines, manufactures and compositions of matter are discussed below. Note that the patented things used in the medical method need not be owned by the same patentee — they could instead be licensed.

One open question is what is a "biotechnology patent" that permits enforcement under § 287(c)(2)(A)(iii)? The meaning is not clear in the legislative history. In some statutes, biotechnology has been defined narrowly. For example, former 35 U.S.C. § 103(b)(3), which was eliminated from patent law in the America Invents Act, defined a "biotechnological process" as a process of genetically altering a single or multicelled organism or cell fusion procedures that express a specific protein.[12] Many bioprinted tissues or organs would not fit into this definition. On the other hand, the definition in 7 CFR 3415.2(d) (which provides definitions for the U.S. Department of Agriculture) is: "Biotechnology means any technique that uses living organisms (or parts of organisms) to make or modify products, to improve plants or animals, or to develop microorganisms for specific use. The development of materials that mimic molecular structures or functions of living systems is included." This broad definition could encompass most bioprinted tissues and organs. The scope of a "biotechnology patent" in § 287(c)(2)(A)(iii) will probably have to be determined in court.

Patenting 3-D Printed Implants

Implants made of biocompatible nonliving materials and bioprinted living tissues face different patent issues. Implants made of nonliving materials, as well as the biocompatible materials themselves and any devices needed to insert the implants, should be patentable under the same tests as all other machines, manufactures or compositions of matter. A problem that may eventually arise in this field may be increasing difficulty in proving nonobviousness under 35 U.S.C. § 103. Although groundbreaking today, making 3-D printed surgical implants may eventually face rejections asserting that because it was known to implant appropriate size devices made by other methods, it would have been obvious to make a similar device by 3-D printing and use it for the same purpose.

The U.S. Patent and Trademark Office's "Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103 in View of the Supreme Court Decision in *KSR International Co. v. Teleflex Inc.*," 72 Fed. Reg. 57526 (Oct. 10, 2007), lists several possible rationales for finding claims to be obvious that might be applied to substitution of a 3D printed surgical implant for prior art implants. *Id.* at 57529. For example, Rationale D is "Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results." *Id.* at 57531-32. This development would be analogous to how it is now generally considered obvious to merely replace devices controlled mechanically with devices controlled using computers. To prepare for the advent of such rejections, inventors of 3-D printed medical devices should be alert for objective evidence of nonobviousness ("secondary conditions") that can be evidence of nonobviousness.[13] It seems likely that many 3-D printed surgical implants could have unexpected beneficial results compared to the prior art, failure of others, acclaim in the field, commercial success, and other attributes recognized by courts as objective evidence of nonobviousness.

On the other hand, bioprinted living materials may have less difficulty with obviousness rejections because of their complexity and unpredictability. Many of the goals in this field have not yet been accomplished, and thus there is a lack a reasonable expectation of success, which is indicative of nonobviousness. But as a result of recent U.S. Supreme Court decisions, living compositions of matter may come to be viewed as ineligible for patenting under 35 U.S.C. § 101. Some bioprinted structures are clearly different from naturally occurring ones (e.g. a structure of living cells built on a non-naturally occurring substrate). Nevertheless, as bioprinted tissues and organs come to closely approximate their biological models, they might be rejected under § 101 as being merely copies of naturally occurring tissues or organs. The fact that they are manmade may not overcome this rejection. For example, in *In re Roslin Institute (Edinburgh)*, 750 F.3d 1333 (Fed. Cir. 2014), cloned sheep were held to be unpatentable as being identical copies of naturally occurring parent sheep, even though the clones exist only due to actions by the people who clone the sheep. It would be ironic if inventions that are the pinnacle of inventive bioprinting are held to be unpatentable because they are too much like their naturally occurring models.

One tool for patenting both nonliving and living 3-D printed surgical implants could be claiming them as a product-by-process, in this case, a thing made by a 3-D printing process. Product-by-process claims have vulnerabilities, because they are exceptions to the rule that patent claims are interpreted the same way for infringement and validity. They can be infringed only by something made by the specific process recited in the claim.[14] Thus, infringement of product-by-process claims can often be avoided by designing around the process used to make the product. Yet product-by-process claims can be invalidated as anticipated or obvious by a product made using an entirely different process than that recited in the claim.[15] Nevertheless, a valid product-by-process claim could satisfy the requirement for a patented thing that permits penalizing infringement of method claims under § 287(c)(2)(A).

Conclusion

New developments of 3-D printed surgical implants and bioprinted tissues are announced almost weekly. Intellectual property attorneys will be very busy finding ways to protect this rapidly developing technology.

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[1] John Hornick, 3D Printing Will Rock the World, CreateSpace Publishing, 2015.

[2] Hearing aid is the most successful 3D printed product you've never heard of.
www.inside3dp.com/successful-3d-printed-product-world/

[3] J. Hornick, 3D Printing and IP Rights: The Elephant in the Room, Santa Clara Law Review, 55(4), 801 (2015); another cite needed

[4] Id, [Hornick, Santa Clara L. Rev. 55,] 803-807.

[5] No Donor Required: 5 Body Parts You Can Make With 3-D Printers (Forbes, June 17, 2015)
<http://www.forbes.com/sites/robertszczerba/2015/06/17/no-donor-required-5-body-parts-you-can-make-with-3-d-printers-2/#231466da4a3b>

[6] Doctors Use 3-D Printing To Help A Baby Breathe, <http://www.npr.org/sections/health-shots/2014/03/17/289042381/doctors-use-3-d-printing-to-help-a-baby-breathe>; 3-D printed windpipe gives infant breath of life, <http://www.nature.com/news/3-d-printed-windpipe-gives-infant-breath-of-life-1.13085>

[7] S.V. Murphy and A. Atala, 3D Bioprinting of tissues and organs, Nature Biotechnology 32, 773–785 (2014); <http://www.cnn.com/2014/04/03/tech/innovation/3-d-printing-human-organs/> ;

[8] 35 USC § 287(c)(1). “With respect to a medical practitioner’s performance of a medical activity that constitutes an infringement under section 271(a) or (b), the provisions of sections 281, 283, 284, and 285 shall not apply against the medical practitioner or against a related health care entity with respect to such medical activity.”

[9] Id., § 287(c)(2)(C)..

[10] 35 USC § 101.

[11] More fully, § 287(c)(3) specifies that the immunity of § 287(c) “does not apply to the activities of any person, or employee or agent of such person (regardless of whether such person is a tax exempt organization under section 501(c) of the Internal Revenue Code), who is engaged in the commercial development, manufacture, sale, importation, or distribution of a machine, manufacture, or composition of matter or the provision of pharmacy or clinical laboratory services (other than clinical

laboratory services provided in a physician's office), where such activities are:

(A) directly related to the commercial development, manufacture, sale, importation, or distribution of a machine, manufacture, or composition of matter or the provision of pharmacy or clinical laboratory services (other than clinical laboratory services provided in a physician's office), and

(B) regulated under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, or the Clinical Laboratories Improvement Act.

[12] The full definition in 35 U.S.C. § 103(b) was "(3) For purposes of paragraph (1), the term 'biotechnological process' means-

(A) a process of genetically altering or otherwise inducing a single- or multi-celled organism to-(i) express an exogenous nucleotide sequence, (ii) inhibit, eliminate, augment, or alter expression of an endogenous nucleotide sequence, or (iii) express a specific physiological characteristic not naturally associated with said organism;

(B) cell fusion procedures yielding a cell line that expresses a specific protein, such as a monoclonal antibody; and (C) a method of using a product produced by a process defined by subparagraph (A) or (B), or a combination of subparagraphs (A) and (B).

[13] *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966); *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983) ("[E]vidence rising out of the so-called 'secondary considerations' must always when present be considered en route to a determination of obviousness.").

[14] *Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282, 1293 (Fed. Cir. 2009).

[15] *Amgen Inc. v. F. Hoffman-La Roche Ltd.*, 580 F.3d 1340, 1370 n 14 (Fed. Cir. 2009).
