

Chapter 6

Law Issues and 3D Printing

ABSTRACT

Revolution in 3D bioprinting advancing so quickly. Our special interest is focused on 3D bio printing, the printing of mammalian or human body parts. Very close to this term is cloneprint. The 3D printing living tissues is real and may be widely available in the near future. This emerging technology has generated controversies about its regulation. Another equally important issue is whether bioprinting is patentable. The U.S. Patent and Trademark Office (Patent Office) has already granted some bioprinting patents and many more applications that pending on a patent. This chapter highlighting these issues that can be part of our future.

INTRODUCTION

Since 2012, we have witnessed extraordinary growth in the legal practice at the intersection of law and 3D printing. Paven Mohatra observes —a gold rush underway as applicants sprint to the U.S. Patent and Trademark Office to stake claims on 3D printing techniques and systems. The USPTO has granted 3,500 patents relating to 3D printing since 2003. Mohatra concludes, —[a]s these applications are processed—and approved—the number of patent lawsuits is likely to rise. (Mohatra, 2014)

In 2014, the Federal Circuit decided its first 3D printing case. (DSM DESOTECH INC. v. 3D SYSTEMS CORP., 2014) In 2015, the Food and Drug Administration (FDA) has been busy thinking through how to regulate 3D printed medical devices. Gartner speculates a global debate in 2016 for

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whether to regulate bioprinting or ban it. The technology of 3D bioprinting (the medical application of 3D printing to produce living tissue and organs) is advancing so quickly that it will spark a major ethical debate. The rapid emergence of this technology will also create major challenges in relation to intellectual property (IP) theft. Gartner predicts that by 2018, 3D printing will result in the loss of at least \$100 billion per year in IP globally. (Janesa Rivera, ROb van der Meulen, 2014) Academics also went into similar discussion around the world.

BACKGROUND

3D printers resemble the Star Trek Replicator¹—a machine that can constitute any physical matter out of thin air. 3D printers can print out anything, from a lithium-ion micro battery (Ke Sun at all, 2013) to a human kidney, and can print in materials like plastic, metal, ceramic, cement, wood, food, and human cells.

Soon, the 3D printer will be just another home appliance. —A world in which everyone has advanced 3D printers at home or available in a public facility is a world in which manufactured goods no longer have to be produced in bulk and are no longer scarce, (Lemley, 2015) says Stanford Law professor Mark A. Lemley.

Our special interest is focused on 3D bio printing, the printing of mammalian or human body parts. Very close to this term is cloneprint. All of these mentioned facts attract attention of law scholars. Currently there is no official publication outlet for 3D printing law. Computer software and wireless technologies currently dominate the patent litigation market. There remain many unexplored questions about 3D printing and its subcategories. Here is list of useful articles related to this matter reader can find in the paper of Jasper Tran. (Tran, 2015)

Patenting Bioprinting

(Alas, naturally occurring genes are not patentable.) This question raises recently in prosecution on Supreme Court of the United States on October 2012, between parties Association for Molecular Pathology et al. versus Myriad Genetics, Inc., et al. (States, 2012)

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