The Challenges Surrounding Patenting 3-D Bioprinted Organ and Tissue Technology

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In this hoganlovells.com interview, New York-based partner Arlene Chow talks about the emergence of 3-D bioprinting and the ability of innovators in this space to patent organ and tissue printing technology.

“There is a tension between phenomenal innovation and the ability for scientists to adequately protect their innovations,” Chow explained. “The whole point of patents is to encourage people to innovate. After investing time and money and then disclosing details of their invention to the world in a patent — as opposed to maintaining it as a trade secret — the payback is an exclusive term such that others can be prevented from doing the same activities unless they pay a royalty. And yet, under the current patent regime, such innovation, even if associated with an issued patent, may be vulnerable to a later unpatentability challenge” in the courts.

Why is 3-D printing considered to be a disruptive technology?

Chow: With 3-D printing, people can print a lot of things using materials they can easily obtain. It’s a different form of printing called additive manufacturing. It’s basically layers of material that are laid down and built up until a 3-D object is obtained. It’s like building a structure out of Legos. You are building with small increment pieces until you get your final structure. And you are not wasting materials — you are using materials on an as-needed basis to make your final structure. It is both revolutionary and readily accessible.

Individuals can use this method to make things at low cost as opposed to purchasing products created by large-scale manufacturers. People are using this disruptive technology to build everything from medical devices like hearing aids to automobile parts. 3-D printing is disrupting all sorts of industries because individuals can sidestep the standard supply chain and just make what they need in the privacy of their homes.

What will 3-D bioprinting enable life sciences companies to do?

Chow: Bioprinting is a specialized form of 3-D printing that is even more revolutionary and cutting edge. With bioprinting, you are using an individual’s own cells to print replacement tissues and organs. Let’s say you have damaged tissue or a damaged organ. In the past you might have to rely on grafts from other areas of your body in order to repair yourself. Or if you were in a life threatening situation, you would have to wait for an organ transplant. Now with 3-D bioprinting, based on a patient’s own cells, you can build new tissue or a new organ three dimensionally as a

solution.

There is a frequently cited example of the dramatic impact that 3-D printing has on the life sciences. With 3-D bioprinting, you don't have organ rejection because — in essence — you're building something new based on a patient's own cells. Organ transplant rejection is a significant problem. According to the American Transplant Foundation, more than 120,000 people are in dire need of a lifesaving organ transplant and many of them die waiting. 3-D bioprinting can sidestep all of that. It has the amazing potential to dramatically save lives and improve quality of life.

What impact could the America Invents Act have on the ability to patent bioprinting?

Chow: The U.S. Supreme Court has weighed in on what is or is not patent eligible in the life sciences space. The most well-known of these cases is Association for *Molecular Pathology vs. Myriad Genetics, Inc.* — often called the gene patenting case. In *Myriad*, the Supreme Court held that a naturally isolated DNA fragment is not patent eligible subject matter. In reaching this decision, it was really important to the Supreme Court that a patent capture something that is the result of human ingenuity and non-naturally occurring.

I think that a number of patents would meet that requirement in the 3-D bioprinting space, but there's a wrinkle to it. The Leahy-Smith America Invents Act (AIA) dramatically revamped patent law. There's a provision in the AIA that says it is forbidden to issue patents "directed to or encompassing a human organism". This particular provision in the AIA hasn't been litigated yet. But the whole point of bioprinting is to replicate and approximate a naturally occurring human organism. And that could run afoul of the AIA provision.

Many do not want a dominant entity or entities with a portfolio of patents in the 3-D bioprinting space because there are so many amazing potential, life-saving applications for bioprinting. My guess is that this is going to be a highly contested area for patent litigation. What can or cannot be patented in the bioprinting space? What types of patent claims can you rely on in order to exclude others from doing the same thing or receive a royalty?

What does this mean for the players in the bioprinting space?

Chow: If you are at the forefront of bioprinting and investing a lot of time and money to ultimately achieve a method for making a replica organ or tissue that will save millions of lives, you would certainly hope to patent such innovation. Yet any patent claims in this area are vulnerable to challenge based on this particular provision in the America Invents Act.

I don't think bioprinting is as vulnerable to a patentability challenge based on the Supreme Court's laws based on *Myriad*. Under *Myriad*, there is a compelling argument that bioprinting epitomizes human ingenuity. Bioprinted products are not just purely human nature.

What impact could the *In re Roslin* cloning case have on the ability to patent bioprinting?

Chow: There was a federal circuit case — *In re Roslin Institute* — where cloned sheep were found to be unpatentable because they were identical copies of naturally occurring parent sheep. There are a lot of parallels between cloning and bioprinting. Of course, you can only clone sheep because of human ingenuity and human manipulation. And yet, the courts have already found — at least in the context of cloning sheep — that you can't patent them. It follows that bioprinting is vulnerable to such an unpatentability challenge.

That just underscores the concern that as bioprinting gets closer and closer to replicating the actual organ or naturally occurring tissue, that you will run afoul — at least in some court's eyes — of trying to patent something that's not eligible for patent.

About Arlene Chow

Arlene Chow is an IP partner in our New York office focusing on life sciences patent disputes and due diligence. She frames patent litigation matters from the perspective of the judge or the jury at the outset in order to achieve the best solutions for clients. Leveraging her lead trial attorney and biochemistry experience, she dives deeply into the relevant science and underlying facts before extracting key case themes for development with the case record. She loves engaging with the in-house and external experts on the science, and then simplifying that highly technical information in a way that is easy to digest.

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