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Panel discusses legal, ethical concerns of 3D printing

Since the start of the 21st century there has been large growth in the sales of 3D printers. The technology, which The Economist has termed "a third industrial revolution," is now being used to create a number of products that we interact with on a daily basis, such as clothes, cups, jewelry, food, medical devices and weapons.

Legal and ethical concerns have accompanied the rise of 3D printing, and a Friday panel at the ABA Annual Meeting sponsored by the Section of Science and Technology Law—"3D Printing: An Interactive Look at its Utility to Medicine and its Attractiveness to Pirates and Terrorists"—focused on some of them.

Michael Drues, Ph.D., president of Vascular Sciences in Grafton, Mass., has worked for and consulted with leading medical device, pharmaceutical and biotechnology companies. Drues also works on a regular basis for the U.S. Food and Drug Administration, allowing him to "see it from both sides," he says. He addressed the challenges that 3D medicines and medical devices pose for regulatory agencies.

In an overview of 3D printing and how it relates to his specialty, helping companies bring new and innovative medical products to market, Drues said, "3D printing gets a lot of press today, but it's been under development for three decades. And as they say in Boston, the most wicked cool stuff is yet to come," adding that we are "getting closer and closer" to printing actual living tissue.

"What about using living tissue for how we conduct clinical drug trials?" Drues asked. "Why not print a human liver and use that to test the drug?"

Indeed, 3D printing technology offers the advantage of making individual, specifically tailored parts on demand. The medical industry has taken advantage of 3D printing's ability to make unique objects that might otherwise be tough to build using traditional methods.

The FDA currently treats 3D-printed devices the same way it treats conventionally made medical devices. The agency evaluates all devices, including any that utilize 3D printing technology for safety and effectiveness.

Panelist Sonali P. Gunawardhana, of counsel at Wiley Rein in Washington, D.C., and a former FDA attorney, offered advice for lawyers in related regulatory fields: "Although a number of 3D printed-medical devices have received 510(k) clearance through the existing regulatory pathway, the FDA believes novel technologies in development will require new regulatory considerations. Learn about how the FDA intends to navigate the challenges of innovative technology, including addressing safety issues as they pertain to mechanical properties, biocompatibility and the interactive design of 3D medical devices."

Two FDA laboratories are looking into ways 3D printing could affect the way medical devices are manufactured in the future. The Functional Performance and Device Use Laboratory uses computer-modeling methods to determine how tweaks to a medical product's design could affect its safety and performance in various patient populations.

The Laboratory for Solid Mechanics focuses on how different printing methods affect the strength and durability of the materials used to make the devices. The findings will help the FDA develop standards and set parameters for scale, materials and other critical aspects that contribute to product safety and innovation.

Despite these efforts, technology is quickly outpacing regulation. Gunawardhana termed the FDA a reactive agency because it does not have the funding to be proactive.

Beyond medical devices, the creation of everyday objects, many of which are modeled from existing models, raises several trademark and copyright concerns. In one example last year, cited in background materials for the program, Shapeways, a marketplace for user-designed 3D-printed objects, was doing strong business selling user-created figurines based on the popular Final Fantasy VII video game – until the game creator sent a take-down notice that resulted in immediate compliance. The blog Best 3D Printer quotes the figurine creator Joaquin Baldwin on the take down: "[It's] standard procedure," he said, "just like a video in YouTube regulating copyrighted song can be pulled down."

A partner at Sughrue Mion in Washington, D.C., panelist Leigh Ann Lindquist, is confident that the challenges of regulating 3D printing can be met: "I don't think we should be scared of this new technology. We shouldn't think that because people don't have to buy a Louis Vuitton bag, they can make their own, that there won't be any way for Louis Vuitton to protect its trademarks. Trademark and copyright lawyers should be able to come up with ways to protect such clients."

Lindquist pointed out that trademark is a broader protection than copyright, and that a company such as Gucci has both trademark and copyright protections, as well as patent protections. She said that the law is still undeveloped regarding trademark and copyright in relation to 3D printing, and she could find no pending cases in the area.

Panelist Anthony Vicari, a research associate at Lux Research, Inc., focused his presentation on the technology behind 3D printing. Vicari pointed out that low-end 3D printers for the consumer market sell for a few hundred dollars but that printer manufacturers are selling the materials cartridges for their machines at high markups, and that Amazon has launched a 3D printing store.