INTELLECTUAL PROPERTY

3-D PRINTING: MANUFACTURING, DISRUPTED

When it comes to 3-D printing, much of the excitement revolves around the amazing potential of the machine to build almost anything one layer at a time. In health care, that means drugs, medical devices, tissue, even hearts or lungs.

But much of the promise—and peril—of 3-D printing stems from the way it could upend the manufacturing process. And that change could have major implications for how companies in this space manage intellectual property, product liability, and cybersecurity.

Traditionally, products are built and distributed by the same company that designs them or by a handful of factories with close relationships with that company. The model that 3-D printing is moving toward—known as distributed manufacturing—is very different.

In the near future, many medical devices will be made not in factories but in hundreds or thousands of hospitals or doctors' offices on their own 3-D printers. Here's how that might work: A doctor would send details about a patient to a device's maker, which would customize a design file and send it to the printer, which would "print" the device for the doctor to implant.

These devices will be personalized to an unprecedented degree and be printable on demand. This should make them cheaper, safer, more effective, and timelier than ever—if everything goes as planned.

But what if something is wrong with the printer, the software, or the materials the printer uses to make the device? What if the doctor, or a technician, fails to catch a manufacturing defect prior to implantation? What if a hacker intercepts the design file, steals the personal data, and modifies the design? What if the hacker uploads the design to the internet, so anyone with a 3-D printer could attempt to build the device with no training or experience? If any of these occur, lives could be at stake. And who would be responsible?

Distributed manufacturing is poised to disrupt a world where legal and regulatory frameworks have been built around the assumption of a close or identical relationship between designers and makers.

"So much control is being relinquished," says Deborah Yellin, a partner in Crowell & Moring's Intellectual Property Group. "I think you'll see companies moving away from making things and toward saying, 'Here are our instructions, and if you don't follow them, you'll be responsible.'"

HERE COME THE FEDS

Into this fray jumped the U.S. Food and Drug Administration, which has already approved more than 100 medical devices made using 3-D printing. In the past, Yellin notes, the agency could shut down a manufacturing facility if it suspected a problem with a drug or device. In the future, tracking and fixing problems may require a very different approach.

In December 2017, the agency released guidance for technical considerations for 3-D-printed medical devices. The document provides some guidelines for ensuring quality and safety across the production process, from design through printing and testing. Eventually, Yellin says, the FDA may also release guidance for bioprinting or 3-D printing of pharmaceuticals.

With its own 3-D-printing lab in-house, the FDA appears determined to keep up with the pace of technology. But there are many issues yet to be resolved, Yellin says. How will the agency regulate nontraditional manufacturing sites such as hospitals or doctors' offices? How will it regulate the printers, the "inks," or the design files? What about the IP covering the printers, "inks," and design files? Patents may cover the hardware and software. And some aspects of the production process may be trade secrets. Enforcement of IP will be a big concern.

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collaborate with industry to develop new regulations," Yellin says. "More change is coming, and those active in the medical 3-D printing community should consider communicating with the FDA early and often to advocate for the best regulations possible."

STOP, THIEVES

For a sense of what could go wrong in the new world of 3-D manufacturing, consider the so-called Four Thieves Vinegar Collective, which has posted blueprints for a 3-D-printed replica of a widely used allergy injection device and a 3-D-printed "lab" that can supposedly produce homemade versions of other popular drugs. The collective claims to be democratizing medical treatment, but experts and the FDA have warned that DIY drug making could be deadly.

Design files for drugs or devices are vulnerable to piracy just as music or video files are today, and drug or device makers may someday face a challenge similar to the one faced by entertainment companies starting in the 1990s. Unlike a leaked song, however, a leaked drug design file could ultimately result in injury or even death.

With value chains more broadly dispersed, companies will need to take stronger measures to ensure that intellectual property does not "leak" and that product quality is maintained. Yellin provides some guidelines:

- Register for copyright (for design files) as well as patents (for other innovations) whenever possible.
- Keep careful records of use and ownership during the R&D process.
- Make strategic use of trade secrets. One way to make a stolen design file impossible to use is to keep details such as materials confidential.
- Monitor the internet to ensure that design files are not being leaked.
- Many companies may shift to licensing out their manufacturing and marketing. These firms will require "very stringent licensing agreements with very strict instructions and indemnities" to ensure that inferior products are not marketed under their names, Yellin says.

3-D printing and distributed manufacturing could disrupt the drug and device industries. New opportunities await companies that can adapt their business model and work within the new legal and regulatory landscape.

STOP, COLLABORATE, PRINT

Before 3-D printing can reshape the world of manufacturing, it needs to work through some key challenges.

One is ownership of essential technologies. The major players in smartphone technology have spent years and billions of dollars in epic litigation battles over patent royalties and damages. The major players in 3-D printing are determined to avoid these conflicts, says John Gibson, a partner in Crowell & Moring's Antitrust Group and chair of the firm's 3-D Printing Digital Transformation Working Group.

Gibson advises HP, the world's leading 3-D-printer maker, on regulatory and standards issues. HP is a founding member of the 3MF Consortium, which is developing a modern, universal 3-D printing file format. The format will allow design applications to send full-fidelity 3-D models to virtually any printer or application. All consortium members have pledged to make the standard open-source or royalty-free. "To build this new ecosystem unburdened by some of the substantial legal disputes afflicting other technology ecosystems and platforms, we wanted to solicit broad input before full development and adoption," Gibson says.

Another issue is the ease of making weapons on 3-D printers. The Texas group Defense Distributed has threatened to post digital blueprints for a 3-D-printed gun made of plastic parts that would evade a metal detector. Similar files may be available on underground sites.

The industry has begun collaborating on security efforts, Gibson says. One strategy is to design and share printer features that would prevent them from producing dangerous items. Gibson and other lawyers will advise to ensure that the collaboration takes place without triggering antitrust concerns.

The industry has also made overtures to the intelligence community about starting a dialogue so printer makers can learn more about—and be better equipped to address—threats for making 3-D-printable weaponry.

"We wanted to have a different way of thinking when setting up this ecosystem," Gibson says. "Consumers, designers, materials suppliers, OEMs, and printer makers all win if we talk to each other ahead of time and figure out what's best for the world, not just for each individual company."