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The intriguing new legal questions raised by 3D printing

by Maya M. Eckstein

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It is not an understatement to say that additive manufacturing — commonly referred to as 3D printing — is taking over the world. If you are not yet familiar with 3D printing, you will be soon, likely because your company will incorporate 3D printing into its manufacturing process, or you or your company will (knowingly or unknowingly) purchase something produced by a 3D printer. Some have referred to 3D printing as the harbinger of the "third industrial revolution." See "A third industrial revolution," The Economist, 2012-04-21 (http://www.economist.com/node/21552901).

Many legal issues surrounding 3D printing, though, remain unanswered. Who owns the IP? Who has liability? What regulations apply? These and many other legal questions abound.

What is 3D Printing?

Generally, 3D printing turns a 3D digital model created on a computer or with a scanner into a physical object, letting users "print" almost anything. 3D printing is an additive process, fusing materials, layer upon layer, with heat, chemicals, light, electron beams, or adhesives.

How is 3D printing being used?

3D printing's popularity is on the rise and, with the development of 3D ink pens and desktop 3D printers, it is soon to become a household concept. It is much more than a novelty. There are numerous examples of 3D printing's growing ubiquity:

- GE Aviation plans to introduce in 2016 the first 3D printed parts for aircraft engines. The company predicts it will produce more than 100,000 parts using 3D printing by 2020.
- Prosthetic and orthotic device manufacturers are using 3D printers to produce standard implants, as well as surgical guides for a range of procedures, including total knee, total hip, and shoulder replacements.
- The FDA approved in August 2015 the first 3D printed drug product, a prescription drug used in the treatment of epilepsy.
- New Balance is now manufacturing and offering for sale a running shoe with a 3D printed midsole.

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What legal issues does 3D printing implicate?

3D printing is a disruptive technology with far-reaching implications for manufacturers, retailers, consumers, intellectual property owners, and others. While 3D printing allows manufacturers to make complex designs, rapid prototypes, and final parts in new and different ways, it also allows almost anyone to re-create any existing product and make, use, or distribute it without permission from its original creator.

The technology brings with it a host of new legal questions surrounding intellectual property, product liability, regulatory (such as FDA), and other practice areas. Below, we present a sampling of those legal questions. In coming posts, we will address each with more depth.

Intellectual property issue in the mix

Users and manufacturers of 3D printers and 3D printed objects will encounter issues involving patents, trademarks, copyright, and other IP rights, whether their own or owned by others. Notably, the Gartner Group predicts that 3D printing will result in the global loss of at least $100 billion per year in intellectual property by 2018. Gartner Reveals Top Predictions for IT Organizations and Users for 2014 and Beyond, (Oct. 8, 2013), http://www.gartner.com/newsroom/id/2603215.

Consider that companies that previously purchased replacement parts could print them themselves with 3D printers. Similarly, consumers seeking replacement parts for home appliances and plumbing — or seeking finished consumer goods — could print them themselves. Each of these situations raise issues of at least patent, trademark, and copyright infringement.

Moreover, the growth of 3D printing will make product blueprints extremely valuable. Yet, they also could become easily accessible or copied once loaded to the web or provided to a specific customer. This raises issues of at least patent and copyright infringement.

Yet, what good is an IP right if the power to enforce it is meager? The “democratization” of manufacturing through 3D printing means rights holders often will not know when others are printing copies of their products, making infringement difficult to identify. And, even when it is identifiable, rights holders will need to determine whether to pursue consumers who infringe, as well as corporations who infringe, in an effort to protect their IP. In many instances, enforcement may be futile.

Products liability

Defects in printed products or injuries resulting from printed products is likely to result in products liability litigation. Manufacturers of 3D printers, chemicals and other materials used to print 3D printed products, and 3D printed products, as well as suppliers of software for the production of 3D printed products, all are likely targets for litigation. But who is liable? Where should a suit be brought? And under which law?

Consider this fact pattern: Someone in India uploads a file for the printing of a product; a company in China accesses it, modifies it, and offers the modified file for sale on its website; a consumer in the United States purchases the modified file, 3D prints it at a local store that prints from customer files, and then is injured by the product.

Who can sue whom? Where can they sue? What law will apply? Will strict liability apply and, if so, to whom? Is the file used to print the product even a “product” to which certain tort liability applies? Or is it an intangible? Or is it a “good” governed by the UCC? These and numerous other questions abound.

The FDA weighs in

The FDA recently approved the first 3D printed drug. Moreover, several medical device makers are manufacturing prosthetics using 3D printing. And the FDA has approved the use of a limited number of 3D printed devices under its Emergency Use Pathway, including a 3D manufactured tracheal splint for use on a newborn needing an anatomically-specific splint to address a disorder that made it difficult to breath.

The printing of medications, prosthetics, cosmetics and foodstuffs raises numerous FDA issues. Indeed, the FDA conducted its own research into 3D printing to obtain the knowledge and experience needed to assess the safety, effectiveness, quality and performance of FDA-regulated products developed with 3D printing. Additionally, it currently is developing a policy for regulating the commercial use of products developed with 3D printing. Policies also will be developed for the 3D printing of medical devices by non-traditional entities, such as hospitals, rather than the entity that sponsored the device for FDA approval.

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3D printing is an exciting technology that is likely to change manufacturing as we know it. It brings with it, though, numerous legal challenges. We will look at some of those challenges in our upcoming posts.

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