What General Counsel Must Know About 3D Printing

How Providers Can Address the Legalities of 3D Printing

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The recent breakthroughs of 3D printing can read like a science fiction novel, especially in the medical field. Many are calling 3D printing the "third industrial revolution." In 3D printing, a computer sends the software containing a product design to one or more printers, which builds the product, layer by layer, from many kinds of materials, including plastics, metals, drugs, paints and even human tissue. In the medical field, researchers and scientists are using 3D printing to create medical equipment, prosthetics, synthetic skin, medical models, dental implants, skeletal reconstruction, tissue and organ replacement, heart valves and a variety of other body parts. Surgical teams are using exact replicas of a person's heart to perform a practice surgery before operating on a patient. In August, the FDA approved the first 3D-printed pharmaceutical. The drug, which Aprecia Pharmaceuticals has named Spritam, is for treating patients with epilepsy. Aprecia Pharmaceuticals' ZipDose® Technology utilizes 3D printing that overlays multiple layers of powdered medication on top of one another until the correct dosage is reached. This type of technology can lead to easier-to-take medication that is individualized in nature with precise dosages based on a patient's needs. When there is quick growth in an industry and advances in technology, there are multiple legal aspects that a company developing and using this technology needs to consider.

One of the biggest legal issues that a company needs to keep in mind as it contemplates the use of 3D printing technology are intellectual property rights. Intellectual property and ownership thereof is a particularly important, but potentially confusing, issue. A company needs to (1) understand how it can use third party intellectual property and any restrictions on such use, and (2) ensure that it is properly protecting its own intellectual property. 3D printing may involve patents, trademarks, copyrights and trade secrets, with the majority of intellectual property rights qualifying as patentable inventions or copyrights.

A copyright is a form of protection provided by the laws of the United States for "original works of authorship," including, architectural, pictorial, graphic, sculptural, and audiovisual creations.

Copyright protection does not extend to any idea, procedure, process, system, title, principle, or discovery. Copyrights will cover the printed product, the software used by a designer to create the product and print the product, any software used to create and any documentation and related materials. Although a company does not have to immediately file for a copyright registration, the copyright registration process can take a long time, so we recommend filing for a registration earlier rather than later, in order to more easily assert copyright infringement and increase the amount of potential damages.

A patent is a form of exclusive protection of an invention provided by the laws of the United States for a limited period of time. Unlike a copyright registration, that a company can file even after it learns about an infringer, a company must file a patent application within twelve months of publically disclosing a product or process. We recommend having an intellectual property policy that includes an internal procedure for reviewing inventions and filing timely patent applications. As technology changes and your company's use of that technology changes, we recommend reviewing your company's intellectual property policy and adapt it where necessary.

There are multiple parties both externally and internally that can claim intellectual property rights in a 3D-printed product or design. Externally, the parties to consider include manufacturers of the 3D printers, scanners and digital blueprint designers, product manufacturers and designers, customers, and distributors. A company should review its agreements with external parties to understand its rights to use the 3D-printed products. Contractually, a company may unintentionally assign intellectual property rights to a third party. Internally, a company needs to consider those employees or independent contractors that are working on a project for the company. A company should make sure that all independent contractors have an agreement that assigns all intellectual property to a hiring company. It is also important to have employees assign intellectual property rights to their employer. As long as independent contractors and employees have assignment language in their contracts, then the company will own any intellectual property created on the company's behalf.

In addition to the potential pitfalls related to intellectual property, depending on what 3D products a company is using or producing, the Food and Drug Administration (FDA) may regulate the products. Applicable 3D products that the FDA regulates include prescription and over-the-counter pharmaceutical drugs, dietary supplements, medical devices, electromagnetic radiation emitting devices (ERED) and veterinary products. If a company is using 3D printing for any of these types of products, then it

will need to go through the FDA approval process. We recommend consulting an FDA regulation expert in the specific field (i.e. medical devices or pharmaceuticals) to aid you in the FDA review process.

There are also potential product liability and product safety and warranty issues that can arise based on use or sale of 3D-printed products. Product liability is a method for holding manufacturer's and commercial enterprises accountable for the risk that they impose on a consumer. Depending on the field of use of the 3D-printed products, the product liability and safety issues will vary. A company's product liability may depend on if the company is the producer of the 3D-printed product or is the designer of the 3D-printed product. In any agreement between companies, the companies should determine what company is responsible for the design of the product and the production and quality of the product. In addition, we recommend that any company using 3D printing for any reason should notify its insurance carrier to ensure that it has proper coverage.

There are still many unanswered legal and regulatory questions related to 3D printing. It will likely be some time and a few legal battles before any of these questions are definitively answered.

Source: "General Counsel Agenda, Fourth Quarter, 2015," The Advisory Board Company, December 18, 2015, available at: https://www.advisory.com/research/health-care-law-roundtable/members/white-papers/2015/general-counsel-agenda-q4.