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Is Our Legal System Ready for the Evolution of 3D Printing Technology?

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Our prediction about the challenge to our long-held notions of product liability law posed by 3D printing (a/k/a stereotactic lithography) appears to be coming true. Many are of the opinion that the occasional use of a 3D printer – even one that produces a defective product – would not give rise to strict product liability. Typically, the commercial sellers of products, and not the hobbyist, are at risk. Others have questioned the potential liability of one whose design is used by the 3D printer inasmuch as her intellectual property is generally not considered a tangible "product" that could give rise to strict liability. So, who is left – the manufacturer of the 3D printer hardware? Perhaps, but how is its liability any different than the manufacturer of a press brake that was used to create an allegedly defective widget? How is the standing of the 3D printer manufacturer any different than the manufacturer of an oven that allegedly baked "defective" food products?

What if I used a 3D printer to make an exact replica of Michelangelo's *Pieta* to display in my museum in the States and thereby make travel to Rome unnecessary to "experience" the Renaissance masterpiece? Have I broken some kind of law? What if I use my left running shoe to replicate and replace my lost right running shoe? Have I violated the manufacturer's patent? As 3D printing becomes more accessible to the consumer given technological advances and decreased costs, product manufacturers and their insurers and lawyers – as well as those dealing with intellectual property and constitutional law – will need to deal with these interesting questions.

Growth in the Industry

Meanwhile, the 3D printing industry continues to take off. Although some individual "3D" stocks have taken a hit during the past year, by one estimate the industry overall grew at a compound annual rate of over 30 percent from 2012 to 2014 and is now a $4 billion segment of the economy. It is expected to surpass $20 billion in sales by 2020.

Much of this projected growth will undoubtedly take place in the medical devices field, which has already seen the development of a number of 3D-printed medical products, particularly in the orthopedic and dental fields. 3D-printed medical products have even extended into implantable devices such as spinal columns or segments. The drive to create these devices extends well beyond the traditional medical manufacturing sphere, as evidenced by the story of 17-year-old Frank Nguyen, a student from Toronto's Ryerson University. As part of a summer school project, Nguyen used 3D printing to design and manufacture a heart monitor for his ailing mother to wear on her wrist. The monitor, which he named the "HelpWear HeartWatch," tracks his mother's heart rate and is capable of sending a text message to alert a caregiver in the event she experiences an abnormal heart rate that continues through a series of re-checks conducted by the watch.

3D-printed drugs are also making their way to the marketplace. An Ohio-based pharmaceutical manufacturer recently announced that the FDA had approved 3D printing of its anti-epilepsy drug. The use of 3D printing has allowed this manufacturer to increase the content of the active ingredient in

each tablet, while decreasing tablet size and making the tablet easier for patients to swallow. Given this recent development, we expect other manufacturers to follow suit and secure the FDA's approval for their own 3D-printed drugs in the near future.

3D Printing and the Law

These impressive strides forward in 3D printing technology are certain to have ramifications in the legal field. The coming years will determine how manufacturers, lawyers and regulators sort out the interesting legal problems presented by this emerging technology. Hopefully, the legal industry can do so in a way that does not hinder continued innovation.

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