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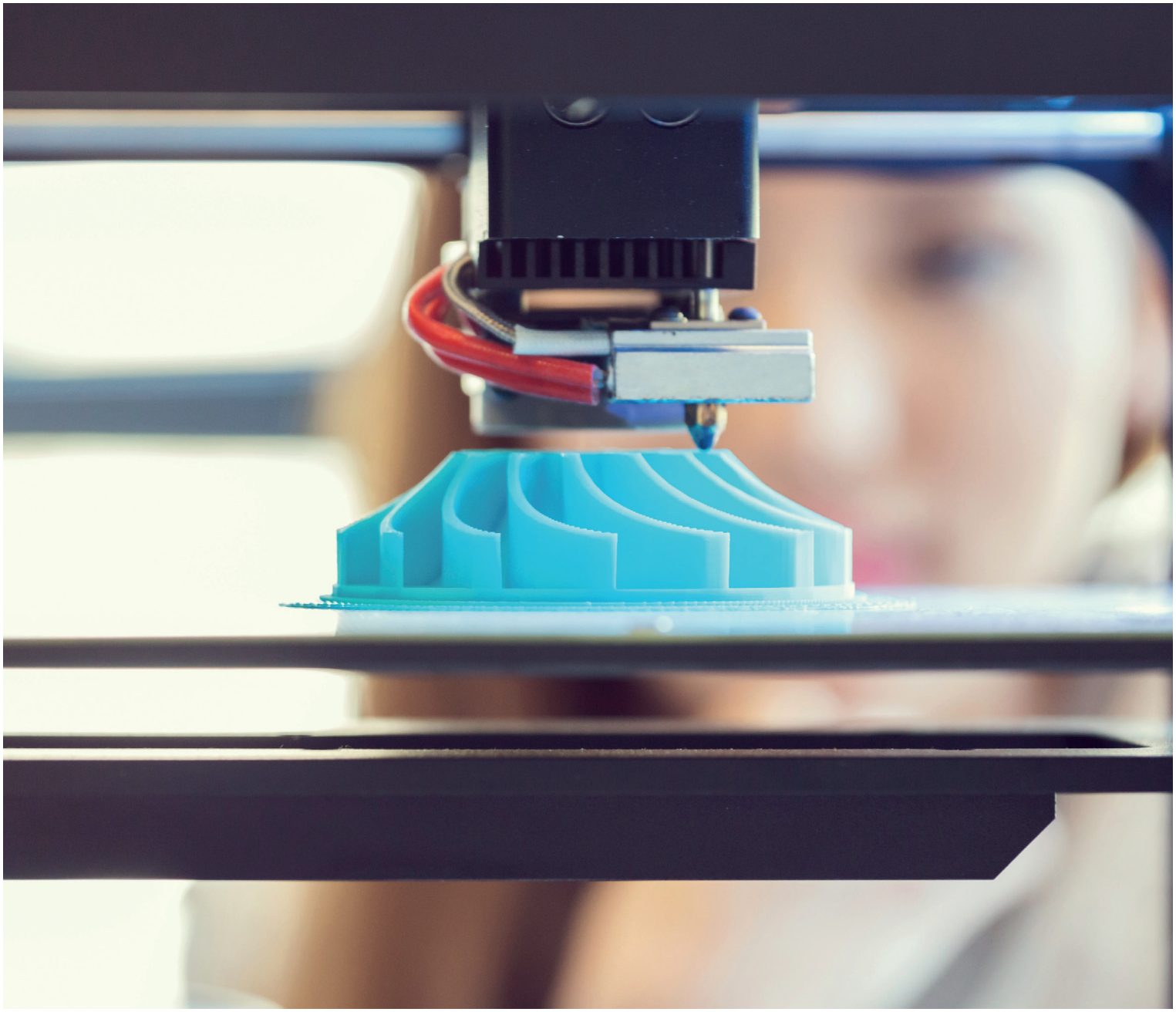
The disruptive technology of 3D printing: Could it disrupt your business risk?



A mother creates a special football-themed cookie cutter for her son in the 3D store at an online retailer. Doctors build a customized prosthetic arm for a 7-year-old girl using 3D technology. The FDA approved a 3D printed prescription pill for consumer use. Right in his small office, a dentist manufactures a crown during a patient's appointment. In New York, a designer develops a limited edition of jewelry created on a 3D printer. Research hospitals print live brain tissue to study various brain disorders, like schizophrenia and Alzheimer's disease.

Clearly, 3D technology is not just for industrial engineers or science hobbyists anymore. The 3D printing industry is radically changing the business and personal lives of millions of people, and will do so for decades. Per Wohlers Report 2014, the 3D industry is expected to quadruple in the next four years, growing from $3 billion in 2013 to over $12 billion by 2018.[1]

The speed, efficiencies and customization that 3D printing offers is projected to have far-reaching effects on the global economy, changing the way we all create, distribute and use products.

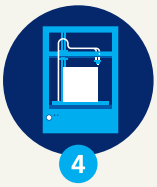
HOW IT WORKS

3D printing (additive manufacturing) starts with a digital "recipe" that is developed using software and then sent to the printer for the sequential layering process:

1 Computer Aided Design system software creates a 3D design of product

2 Final design is converted to an electronic format readable by the 3D printer

3 Materials that will become the 3D object are manually or automatically loaded into the 3D printer



4 Printer receives electronic file of the object

5 Object is automatically dispensed or removed by hand

6 Product is refined into precise shape

7 3D printed object may be further refined using traditional secondary operations

3D: Additive, disruptive, creative

For centuries, traditional manufacturing has been a subtractive process whereby an object is shaped by removing material through cutting, edging, sawing and drilling. 3D technology uses the completely opposite approach — material is added layer by layer to produce the object. This sequential layering — or additive manufacturing — can be used anywhere in the product lifecycle, from pre-production (rapid prototyping) to full-scale production (rapid manufacturing), in addition to tooling applications and post-production customization. Additive manufacturing techniques offer a higher degree of creative flexibility, allowing the use of multiple materials in the course of construction, as well as the ability to print multiple colors and color combinations simultaneously.

But it's not the process of 3D printing that is the real disruption. It's the fact that anyone can buy and use a 3D printer to create food, clothing, human bones, product parts, seemingly anything in one's imagination. It is radically changing how products are being made in virtually all industries — architecture, consumer products, construction, industrial design, automotive, aerospace, food, engineering, biotechnology and fashion. Retailers are installing 3D systems in their stores allowing consumers to create their own products. Even small, affordable 3D printers are being sold for home use. In essence, everyone can be a manufacturer today, creating and selling a variety of products in the marketplace and without the type of safety and regulatory oversight that is imbedded in traditional manufacturing.

Benefits: Global, local and personal

3D printing will likely have a positive impact on global and local manufacturing by potentially increasing product speed-to-market, improving health care, reducing environmental waste, and transforming how we maintain our homes, among many others.

For businesses, faster product development cycles may occur through the rapid prototyping made possible by 3D printing. As the technology systems become cheaper, the cost of entry into markets should decline, allowing highly niche businesses to develop. Because of the customization benefit of 3D technology, companies will focus on customer-centered design and feedback, making their products more desirable in the marketplace.

Some products are profitable but have a limited market, making it not worth the investment in expensive tooling. 3D printing is an ideal solution for this type of short-run production. It also makes sense when demand is uncertain. Instead of spending money up front for tooling, a business can make a few products on the 3D printer to test the market.

The health and medical industries are also exploring the use of 3D printing (or "bioprinting") to produce living tissue for organ replacement, including the liver and eyes. Some researchers believe this technology will allow 100 percent of the cells to live instead of the 50 to 80 percent that typically survive using current technology.[2] 3D printing is also being used today to create bone material for hip and jaw replacements.

On the environmental front, 3D printing can help lessen the waste and carbon footprint that typically comes with traditional manufacturing. Some of the environmental benefits of 3D printing include:

- Fewer wasted materials, as only the raw materials needed to create the object—be it plastic filament, metal powder or carbon fiber are used
- Potentially longer product life spans as individual parts can be replaced using 3D printing, making a significant impact on our disposable lifestyle
- Less transport fuel as 3D printing production and assembly can be local with only raw materials being shipped instead of the entire product
- Fewer unsold products that end up in landfills

For consumers, they can now buy a home 3D printer for about the same price of a laptop computer, and create home accessories, toys and even baked goods to whatever shape, size, and color they want. 3D technology will also help consumers save time, energy and cost by allowing them to print and make replacement parts for products right at home rather than ordering and waiting for them to be shipped.

Challenges: Unprotected, untested, unregulated

The use of 3D printing in industry is evolving so quickly that manufacturers, product managers, suppliers, regulators and consumers are all challenged to keep on top of the technology and the implications it brings to the overall economy, specific industries and the relationship between buyer and seller.

A vast majority of the current digital software recipes are unpatented, allowing them to be copied and sold by anyone. Expensive designer objects can also be reverse-engineered and sold at a cheaper price. For product managers, this can mean an increased opportunity for counterfeit products to enter the marketplace.

Supply chain management is another challenge for manufacturers using 3D technology. The purchase of different types of materials is likely necessary, requiring manufacturers to perform the appropriate due diligence on new suppliers and in-house testing of materials. Additional attention may need to be paid to the handling of raw materials and quality control systems during the manufacturing process itself.

Inevitably, a defective product could come out of a 3D printer. Determining who is liable for the defect will be an issue since there are many participants involved in the production—printer manufacturer, software designer, materials supplier, distributor and retailer. To date, we are not aware of any case law regarding 3D printed product liability, so this is unchartered territory for users.

Perhaps most concerning is the lack of regulatory oversight for 3D printing since much of it will take place outside of a traditional mass production factory, and not subject to inspection from agencies such as OSHA, FDA, FAA and the EPA. Regulators currently are studying how 3D printed products will perform over time, the consistency of their quality, and the types and safety of materials used with this technology.

Complicated production, complicated risks

The potential for 3D technology to improve our lives is exciting. Some liken it to the "next industrial revolution." But as history shows, there is often a downside to a rapid introduction and adoption of a new process that can result in economic, environmental and even human loss.

Just as the 3D process itself is a multiple layering of materials, there is also the potential for a multiple layering of risks. This is a much more complicated production scenario than the business and manufacturing world typically encounters. Anyone participating in the process is wise to assess the multiple potential risks both for today as well as potentially unknown risks that will continue to evolve.

> "3D technology is an additive manufacturing process — material is added layer by layer to produce the object."

A comprehensive review of potential risk scenarios should include among other things:

- **Business interruption:**
  3D printing technology requires more energy than is required in traditional manufacturing. If the power goes out, backup generators may not be able to support the process that could result in production disruption. In addition, your supply chain could be an added risk if you have not assessed it thoroughly.

- **Contractual risk:**
  The process requires a multitude of participants (producer of printer materials, software developer, printer manufacturer, retailer, etc.). A defective product could result in any of these participants being held accountable. This type of potential liability should be reviewed at a contractual level.

- **Intellectual property:**
  There is an increase in the risk of design theft as the underlying software file can be easily used to produce counterfeit products. The current intellectual property legislation does not explicitly regulate 3D printing.

- **Manufacturing materials:**
  The process may require materials such as plastics and nanofibers that are new to a manufacturer. Contaminated, defective, or incorrect materials may result in a faulty product. The materials used may create an overall greater potential liability exposure than those presented by the 3D printer itself.

- **Product liability:**
  3D printer manufacturers sell printers and supplies for a range of applications, unlike a traditional industrial machine manufacturer that may produce machines for one application. The 3D printer manufacturer is selling equipment that could be used to create solid objects, medical products, clothes, food and other finished products with different exposures to loss.

- **Quality & reputation risk:**
  A counterfeit product produced and sold under a company's name can result in reputation risks. In addition, an aggressive salesperson may overstate 3D capabilities, and any inaccuracy in marketing claims may lead to breach of warranty issues.

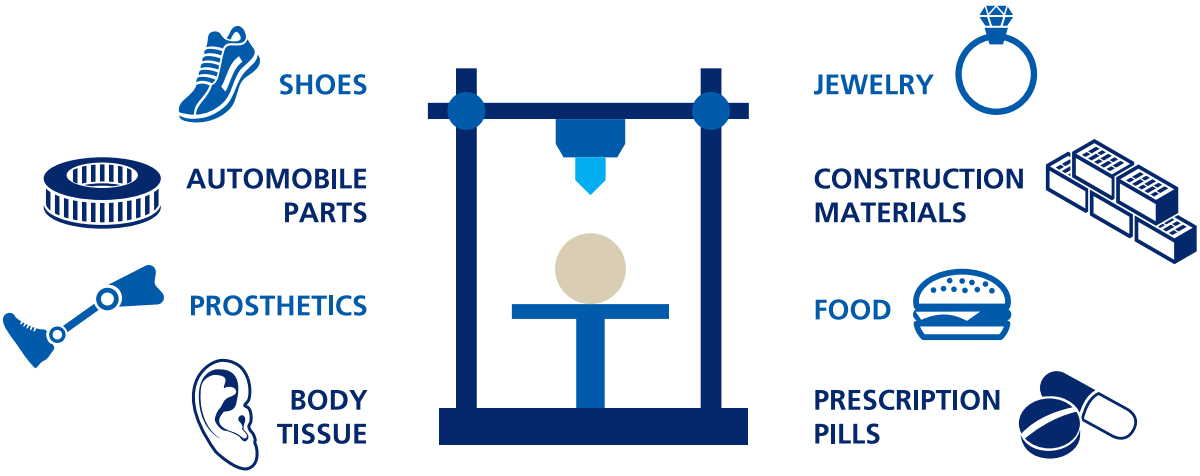
- **Security and privacy:**
  3D technology is a digital manufacturing process that means there is a higher risk for hackers to steal information or sabotage the process. This exploitation of intellectual property could disrupt sales and revenue.

- **Workers' compensation:**
  New materials in the 3D process such as powdered metals like chromium and formaldehyde presents exposures to workers. High heat sources used in the process and toxic fumes that are being emitted from melting and decomposition of materials could also be sources of worker health issues and claims.

Move ahead, look ahead

3D technology is moving so fast that the rush to seize this business opportunity may cause manufacturers to overlook the potential risks found in the multiple applications of this process. As mentioned, the use of 3D technology is still so nascent that we are not aware of any case law concerning it. Therefore, understanding how a loss will be defined in a court of law is still unclear. A manufacturer should work closely with its risk advisors, including legal counsel and insurance brokers, to keep anticipating any future risks that could spoil the rewards of this new technology.

OBJECTS CURRENTLY BEING 3D PRINTED FOR ACTUAL USE



Manufacturers increase their risks of counterfeit

As manufacturers find more applications with 3D printing, they also have to be conscious of the counterfeiting risks involved in their designs. 3D printing is a perfect solution for end-of-product-life replacement parts. For instance, these 3D printed parts can extend the life of even 20-plus year-old automobiles or farm equipment. What would happen if someone created an inferior version? How will this impact your product development lifecycle management?

Mass production is also possible with 3D technology because of the introduction of large-scale printers and new technologies that are producing parts faster. Electronics, toys, and automotive parts are some of the mass produced items that are a natural fit for 3D technology. It's no surprise that China recently announced it has created the world's largest 3D printer in order to stay competitive in terms of manufacturing speed and cost.

Hospitals take on the risks of manufacturers

The medical industry is rapidly adopting 3D printing with products such as hearing aids and knee implants being manufactured using this technology. It is also holding great promise for the work being done in hospitals and research laboratories, where physicians are using 3D printing in personalized situations such as creating and replacing a trachea or fitting patients with more affordable prosthetics. Bioengineers are replicating brain tumors for surgeons to study prior to a procedure and sections of the brain damaged by Alzheimer's for researchers in that field. Use of 3D technology by hospitals and doctors to manufacture these types of medical devices or create new organ tissue could shift their risk landscape. Instead of relying on professional liability insurance alone, health care professionals may need to consider product liability, directors and officers (D&O) and other types of protection in their new role as manufacturers, not just practitioners.

As technology evolves, so do potential risks

For manufacturers of 3D printing hardware, product liability coverage is just the same as if they were manufacturing any other type of product. But in this age of the Internet of Things, where everything is connected digitally in order to run, manufacturers may not be thinking about their exposure to software issues needed to run their printer. A traditional piece of hardware typically does not need maintenance more than once a quarter. With the sophisticated type of software used for 3D printing, the piece of complementary hardware may require constant 24/7 attention, especially with the constant threat of hackers seeking to steal the digital recipe. As the hardware "host" of the software, a manufacturer now may need to consider risk transfer techniques more typical of a software manufacturer, such as security and privacy to cover intellectual property theft, errors and omissions (E&O) to handle any software malfunctions that result in problems with the printer function, and business interruption if enough energy is not available to run the equipment for any significant length of time.

Construction faces changes in the way structures are built

The construction industry has not changed that much in the last 100 years; however 3D printing could make some drastic changes in this industry in the near future. Concrete, for example, changes when it is 3D printed—the super-sized printers use a special concrete and composite mixture that renders a thicker product, which allows for it to be self-supporting while it sets. The 3D printer has the capability of creating hollow concrete structures as well, using less material and reducing overall costs, and possibly changing the way designers and architects plan the actual structure.

References

1 Wohlers Report 2014®. Wohler Associates, 2014. Web. 25 Sept. 2015.

2 Houston Methodist. (2014, February 10). New live-cell printing technology works like ancient Chinese woodblocking. ScienceDaily. Retrieved September 21, 2015 from www.sciencedaily.com/releases/2014/02/140210161116.htm

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