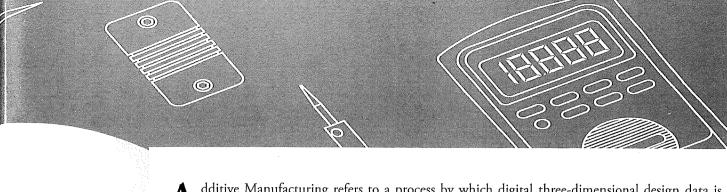
WHY LAWYERS SHOULD CAR by Bob Lambrechts



Additive Manufacturing refers to a process by which digital three-dimensional design data is used to build up a component in layers by depositing material. The term "3D printing" is increasingly used as a synonym for Additive Manufacturing. Instead of milling a workpiece from a solid block, for example, 3D printing builds up components layer by layer using materials such as metals, plastics, composites, pharmaceuticals and even human tissue.

As with any advance in technology, 3D printing gives rise to myriad legal issues. How, for example, will intellectual property rights be enforced if anyone with a 3D printer can create replicas of objects, such as sculptures and patented devices? Do 3D printed guns run afoul of U.S. federal law that prohibits firearms that are not detectable by walk-through metal detectors? And who will be held liable if objects created with 3D printing technology are distributed to consumers and other users, and those objects turn out to be defective and unreasonably dangerous? This article will provide an overview of a few of the major business sectors that are being impacted by 3D printing and the legal implications of this new technology.

BACKGROUND ON THE TECHNOLOGY

In August 1984, Charles Hull, co-founder and chief technical officer of 3D Systems (at that time, in Valencia, California), applied for a U.S. patent titled Apparatus for Production of Three-Dimensional Objects by Stereolithography, which was granted in March 1986.¹ Hull's 1986 patent describes a process of photo-hardening a series of cross sections using a computer-controlled beam of light. Stereolithography utilizes an acrylic-based material known as a photopolymer. Expose the liquid photopolymer to an ultra-violet laser beam, and the polymer instantly changes phase to a solid piece of plastic making it possible to fabricate complex parts, layer by layer, in a fraction of the time it would normally take.

3D printing uses a machine to turn digital blueprints into physical objects.² For 3D printing, physical objects reside in digital form in .amf³ format, or the older and more widely used .stl⁴ format. These files "can be thought of as the object equivalent of a .pdf file—they are universally printable by 3D printers and allow objects to be transferred digitally around the world."⁵

As noted above, the 3D printing process starts with a digital file. The computer aided design ("CAD") file may be created with a CAD program on a computer, producing a virtual 3D model of an object. The CAD design process replaces the need for prototypes allowing a designer to create a model, freely manipulate a design, and save it as a file. In the alternative, a 3D scanner can create a CAD design by scanning an existing object. Regardless of which process is used to create it, once a CAD design exists it can be distributed like any other computer file.

Until 2009 3D printing was mostly limited to industrial uses, but then the patent for fused deposition modeling, one of the most common 3D printing technologies expired.⁸ As more and more manufacturers have entered the 3D market, what once cost hundreds of thousands of dollars suddenly became available for a few thousand dollars, and the consumer 3D printing market took off in 2009.⁹ Three-dimensional printer sales have been growing ever since, and as 3D printing patents continue to expire, more innovations can be expected in the years to come. It is estimated that over 455,000 3D printing units were shipped in 2016 and that 6.7 million units will be shipped globally in 2020.¹⁰ The 3D printing industry has seen a remarkable 21 percent growth as the industry is expected to exceed \$7.3 billion in revenues in 2018.¹¹

Traditional manufacturers make the same standardized product to put on the market, but 3D printing allows products to be tailored to meet an individual's specific needs, tastes, and measurements. ¹² 3D printing is making unparalleled advancements in industries including healthcare, automobiles,



aviation, construction and even firearms.¹³ The impact of 3D printing in each of these five sectors is discussed below in greater detail to give context to the advances and challenges this technology is bringing forth.



AVIATION INDUSTRY

The aviation industry in Kansas employs over 77,000, roughly 4.1 percent of all jobs in Kansas, and the industry has an economic impact of \$17.1 billion. Aircraft design and construction is changing rapidly and to maintain leadership, Kansas industry must invest in innovation. 3D printing's suitability for complex parts, short production runs, weight reduction, and fewer tooling changes are reducing costs and turnaround times. 3D printing has enabled aviation companies to create complex components previously impossible with traditional techniques. The capabilities of 3D printing fosters innovation while reducing costs and turnaround times in a complex, highly-regulated environment.

Because of the limited number of parts fabricated in an aviation production run, the aviation industry is a prime candidate to benefit from 3D printing. The technology provides companies with the flexibility to print specific parts for short production runs without the substantial cost of tooling changes. While 3D printing has entered the aviation industry focusing on smaller-scale parts, it is possible that entire aerospace frames could be 3D printed in the future. This advancement is already underway in drones, such as the SoleonAgro. ¹⁷ Intended for biological pest control in agriculture, the drone was developed using 3D printing for rapid prototyping, testing, and design verification to reduce the cost of product development. ¹⁸

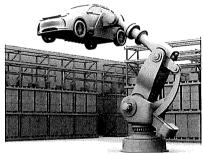
There are challenges to further implementing 3D printing in the aviation industry. Aircraft components often need to be certified to meet rigorous standards and must undergo a First Article Inspection which is a design and design history verification and a formal method of providing a reported measurement for a given manufacturing process. ¹⁹ A First Article Inspection Report (FAIR) requires among other criteria, printer and third-party material qualification. The FAIR evaluation

requirements, not only applicable to 3D printing, consist of comparing supplier and purchaser results by measuring the properties and the geometry of an initial sample item against given specifications, such as a drawing. ²⁰ The rationale for this comprehensive testing of aircraft components is the need to meticulously document a process control methodology and the need to verify the stringent federal requirements for delivering a new product within such a heavily regulated space.

The FAA has understandably expressed concerns with 3D printing to include the potential for material defects in 3D printed parts which could lead to a part lacking in airworthiness; the unknown mechanical properties of metal 3D printed parts; a lack of understanding as to "failure modes" and their connection to key production parameters for 3D printed parts; and the susceptibility of 3D printed parts to environmental conditions.²¹ Likely only with the passage of time and the amassing of performance data will the FAA come to acknowledge the acceptability of 3D printing technology.

AUTOMOTIVE

3D printing is no stranger to the automotive industry when it comes to both prototypes as well as finished parts. Among others, many Formula 1 racing teams have been using 3D printing for proto-

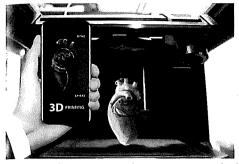


typing, testing and ultimately, creating custom car parts that are used in competitive races.²²

3D printing also has the potential to revolutionize the auto repair industry, making it easier to obtain spare parts. 3D printing technology also allows automakers to affordably customize vehicles and develop stronger, more efficient, lightweight designs. It can simplify both complex and small production, enabling manufacturers to print a single component on demand. One machine can support unlimited product lines. Before long, local auto shops may be able to print parts for repairs. In fact, for years Jay Leno has relied on a sophisticated scanner and 3D printer to replace obsolete parts in his collection of antique cars. ²⁴

HEALTH CARE

It is a good bet that no industry has embraced or benefited more from advances in 3D printing technology than the healthcare industry. The FDA has reviewed over 100 medical devices currently on the market that were made with 3D printers, ²⁵ including orthopedic and cranial implants, surgical instruments, dental restorations, and prosthetics. Many of these products are customized to fit each patient. The FDA has also granted emergency exemptions for devices not yet approved.



In 2012, the FDA granted an emergency exemption for the implant of a 3D-printed trachea into a sixweek-old infant.²⁶ A year later, the FDA again granted an emergency ex-

emption for a man to have 3D-printed plates replace 75 percent of his skull.²⁷ Analysts from iData Research estimate that the 3D-printed trauma device market will be worth \$8 billion by 2020.²⁸

Pharmaceutical companies are using 3D printing technology to develop medications and the FDA has approved the first drug produced on a 3D printer. In 2015, the FDA approved Spritam[®], a drug for treatment of epilepsy.²⁹ The FDA website provides that "tailoring size, drug release profile and dosage form shape can be particularly useful for special populations with unique or changing medical needs."30 In addition, the FDA provides that "children, for instance, may need special or smaller doses beyond what is conventionally available, or they may need unique dosage forms other than the standard pill, which can be difficult to swallow."31 Due to certain illnesses or resulting from taking multiple medications older adults may have various physiological or metabolic conditions which may require alterations in doses or dosage forms and it may be possible to combine certain medications into one "polypill" using 3D designs and 3D printing processes. 32 The FDA further provides that "3D printing of drugs offers these and other advantages because modifying a 3D digital design to control the performance of a drug product is easier than modifying physical equipment or process.33

3D-bioprinting is the utilization of 3D printing to combine cells, growth factors, and biomaterials to fabricate biomedical parts that maximally imitate natural tissue characteristics. Bioprinting can produce living tissue, bone, blood vessels, and potentially, whole organs for use in medical procedures, training and testing.³⁴ Bioprinted tissue may be a game changer for developing and testing how new drugs affect human cells.³⁵ Although bioprinting is in the early stages of development, it shows immense promise for medical treatment, with the end goal of 3D printing of replacement organs.³⁶

CONSTRUCTION INDUSTRY

The 3D printing boom has reached the construction industry and will certainly impact the way construction projects are managed. 3D printers developed for the construction industry operate very similarly to robots. The 3D printer is not just printing a roof brace or a door frame that will later be installed by construction workers, although that capability certainly ex-

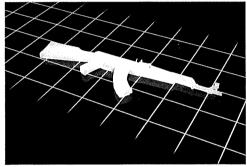
ists, it is effectively installing the printed component in-place.

The rise of 3D printers will translate into fewer workers on construction sites, as printers will be automated and largely autonomous. Projects will be completed faster, as 3D printers become more capable of working at all hours, and will not require overtime pay. Exemplary of this transition are the concrete-injection 3D printers developed by WinSun Decoration Design Engineering, in China. These printers have the capacity to print small houses, including walls and roofs, at a pace of up to 10 in a twenty-four-hour period.³⁷

Experts predict that 3D printing can cut the cost of building materials by 60 percent and reduce manpower requirements 50-80 percent. 38 3D-printing also significantly reduces the amount of waste material created in production and 3D-printing offers new opportunities to accelerate delivery and reduce risk. By operating 24/7 and by reducing onsite mishaps, 3D printers can reduce construction times by as much as 50-70 percent. 39

FIREARMS

3D printers can even create firearms. Until a late August 2018 ruling by Federal District Court Judge Robert Lasnick to ex-



tend a temporary restraining order against Defense Distributed, ⁴⁰ plans outlining how to make 3D guns were widely available on the internet at file sharing websites like Github. ⁴¹ Federal law mandates the licensing of individuals and companies engaged in the business of selling firearms. ⁴² The typical finished firearm has a unique serial number, which is engraved in several places on the gun, that must be registered with the government. ⁴³ A 3D printed gun is virtually untraceable and contains no serial number. A 3D-printed gun requires no background check, no mental health disclosures and no age restrictions.

The Undetectable Firearms Act of 1988, however, makes it illegal to manufacture, import, sell, ship, deliver, possess, transfer, or receive any firearm with less than 3.7 oz (105 g) of metal content or with major components that do not generate an accurate image before standard airport imaging technology.⁴⁴ This law was renewed in 2013 for another ten years.⁴⁵ On April 6, 2017, Representative Ruben Khuen from Nevada introduced H.R. 2033 titled the Undetectable Firearms Modernization Act.⁴⁶ The bill sought to amend the Undetectable Firearms Act to "revise what are prohibited firearms to include any firearm: (1) that, after removal of all parts other than major components is not as detectable by walk-through metal detectors as the Security Exemplar (an object fabricated

for the testing and calibration of metal detectors); or (2) any major component of which, if subjected to inspection by the types of detection devices commonly used at airports for security screening, would not generate an image that accurately depicts the shape of the component."47 The Undetectable Firearms Modernization Act if passed would ban all undetectable weapons. Crucial functional components must be made of detectable metal. The legislation, if passed, would make a working, fully 3D printed gun essentially impossible to legally produce. As of November 2018, H.R. 2033 has not passed the House.

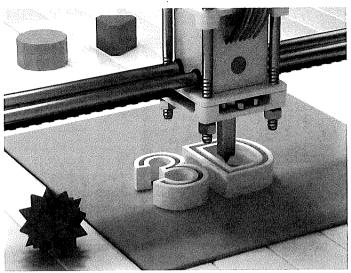
Although the current state of desktop 3D printing doesn't necessarily allow high-quality firearms to be manufactured at home, this could change as the technology advances. For instance, as metal 3D printing capabilities advance, the ability to create higher-grade weapons could grow. 48 While it is purportedly easy to produce a plastic firearm with the proper 3D files and desktop printer, the typical homemade 3D printed gun is not as functionally reliable as one might anticipate. 49 Police testing has shown that a 3D printed gun is as much a danger to the user as it is to the intended target. 50 A firearm produced with ABS51 material could break apart or even potentially explode in the hands of the user when fired.⁵² Softer PLA⁵³ will likely cause the parts to bend or deform after firing. While most plastic 3D printed guns are made using ABS, chances are only a single shot will be able to be fired before the plastic experiences stress fractures.⁵⁴ Nonetheless, efforts are underway to develop a gun that can be 3D printed in carbon fiber, a material that has a higher strength-to-weight ratio than aluminum.55

LEGAL IMPLICATIONS

Copyright Issues

3D printing creates copyright issues for many players in industry. Traditional manufacturers of products may wish to protect against infringement by 3D printed products, as well as those who wish to use 3D printing to manufacture new products. Subject matter that is eligible for copyright protection is afforded only to "original works of authorship fixed in a tangible medium of expression."56 Copyright protection is also expressly reserved only to aesthetically separable portions of a work, and does not extend to a work's functional features.⁵⁷ It is unlikely that a common object such as a cup or a plate is protectable under the copyright statute unless there is some ornamentation that is aesthetically separable from the object. Consequently, copyrightable subject matter likely does not exist for a 3D printed version of a basic cup or plate but may for those same objects with some level of ornamentation.

A copyright attaches to a computer program's human-readable source code and screen displays, but not its basic functions, because the source code and displays contain expressive



content.58 The creator of a copyrightable CAD file has the sole right to sell or share the file. If someone else obtained a copy of the file and made it available for download without permission, the downloader would be infringing the creator's exclusive right to distribute copies of the work. If the downloader made changes to the CAD file to improve or build on the existing design, he could be infringing the copyright owner's right to create derivative works.

There are two ways to create digital design files: (1) scanning, and (2) as discussed immediately above, creating (programming) a computer design file. While there is currently limited case law, scans of useful objects have not warranted independent copyright protection. The justification for this is that "scans are not sufficiently 'original' to qualify for copyright protection."59 A useful object created in CAD software, however, may warrant protection if independent artistic elements are added to the otherwise useful object via the CAD process.

Therefore, websites aggregating CAD files for download and use in personal 3D printers may be liable for making copyrighted designs available for download (copying) by users of 3D printers. 60 The copyright statute defines a copyright infringer as anyone "who violates any of the exclusive rights of the copyright owner."61 Copyright owners can use the procedures outlined by the Digital Millennium Copyright Act (DMCA)62 to have infringing files removed such as by filing take-down notices.63

While the legal framework for addressing 3D printing is rapidly advancing, some manufacturers are pursuing measures to protect their 3D printed goods from others. One option is to encrypt the 3D model so that it is difficult to copy.⁶⁴ Another option is to embed QR codes, barcodes, or other microstructures to reveal and verify the part's origins. 65 There are; however, limits to what can be imaged from the product if the source code for the 3D model is unavailable. If the microstructures⁶⁶ cannot be accurately imaged, they will not be included as part of the copy. Importantly, customs agents at the border, an intermediate seller, or the customer themselves must be able to recognize and authenticate the microstructures.

There are benefits to this form of intellectual property protection. One such benefit is that copyright is automatic and attaches at the time of the creation of the work.⁶⁷ In addition, the Berne Convention on International Copyrights provides protection throughout most of the world.⁶⁸ While 3D printing has greatly expanded the capacity for infringement and counterfeiting it has also expanded licensing opportunities. Copyright protection can often be obtained faster than patent protection, lasts much longer, and is obtainable at a lower cost. Whereas patent infringement damages must be separately proven at trial, copyright damages are statutory and the copyright owner may recover statutory damages of an amount between \$750 and \$30,000, or up to \$150,000 if the infringement was willful.⁶⁹

To that end, intellectual property owners should evaluate any copyrights they own in their products, including creative artistic works, useful objects (which may include separable protectable design elements), and the electronic files and source code underlying the works. Going a step further, those seeking to protect useful articles should consider adding design elements to useful articles, such as a raised emblem or ornamentation, to create an additional layer of intellectual property protection.

Trade Dress and Trademarks

With the increased risk of trademark and trade dress infringement through 3D printing, it will become increasingly important to file applications for trademark and trade dress registrations as soon as the manufacturer has an intent to use the mark or trade dress, and before the manufacturer begins to use the marks. Manufacturers will ideally want their trademark applications accepted and the marks registered promptly to discourage would-be infringers from placing the mark onto unauthorized 3D printed products, advertising, or packaging.

For any brand management strategy, it is important to understand how to protect a brand in light of new technological developments. There are strategies companies can employ to protect their brand assets in this rapidly evolving environment. As discussed above, useful articles are not protectable under U.S. copyright laws. As a result, goods that are printed without brand authorization, while possibly infringing patent rights, may not infringe any copyright or trademark rights unless they contain a separate copyrightable design element or a registered or recognizable signifier of the brand itself. The simplest way to include a brand signifier is to include a registered trademark on the product at issue.

Including a trademark on a product, however, comes with its own limitation, as it only protects the use of the mark itself and does not protect the design or appearance of the item on which the trademark is printed. To address this loophole, brand owners should also consider utilizing trade dress to identify their products. This type of branding is particularly useful when it is not easy, or not preferable, to place product logos and other marks on the products themselves. It also means that brands can claim trademark protection outside of pure unauthorized use of their "marks."

Historically, trade dress referred only to the way a product was dressed up to go to market with a label, package display card and similar package elements. The modern view of trade dress is much more expansive than the traditional view. Now, trade dress is defined as a product's total image or overall appearance and may include features such as size, shape, color, texture, graphics or even certain sales techniques. That dress is a complex composite of features and "[t]he law of unfair competition in respect to trade dress requires that all of the features be considered together, not separately. Thus, a party may claim protection for a unique combination of features, even though all of the features, individually, may have been used previously by others. An important aspect of the trade dress right is that it goes on indefinitely while utility and design patents expire.

Patents

Patent office statistics reveal the 5-year growth rate for published patent applications for 3D printing grew at a compound annual rate of 35 percent from 2013 to 2017.⁷³ The only technology with a higher 5-year growth rate was e-Cigarettes at 45 percent.⁷⁴ Machine learning took third place at 34 percent and autonomous vehicles came in fourth and had a 27 percent compound annual growth rate.⁷⁵ The enterprises with the greatest number of 3D printing published applications for 2017 are General Electric with 89 applications, Xerox with 78 applications and Boeing with 50 applications.⁷⁶ This information is included purely to convey that this technology is advancing rapidly and is seen as a critical technology sector by some of the largest manufacturing companies in the world.

Each 3D printed copy of an invention is a lost potential sale to the patent holder. But, to sue for infringement, the patent owner would need to be aware that someone is using a 3D printer to make the patented invention. And that is a very challenging prospect since these printers are widely dispersed across households and businesses. Alternatively, patent owners could go after the people facilitating the infringement. The Patent Act permits a patent holder to sue parties who induce others to infringe.⁷⁷ Potential inducers of patent infringement could be the sellers of the 3D printers, someone providing CAD files of the patented device, or websites that sell or share various CAD files that instruct the 3D printer to make the patented invention.

As a practical matter, the electronic files required for 3D printing are often easily converted to drawings for inclusion with design patent applications. A design patent protects only the appearance of the article and not structural or utilitarian features. Design patents can be drafted inexpensively and can generally be prosecuted to allowance and issuance within about a year of filing. Utility patents, which are directed to an invention or discovery of a new and useful machine, manufacture, composition of matter, or process typically require years before allowance and issuance. Many industries are already utilizing design patents to cover replacement parts that can easily be made with 3D printing to protect the market for original equipment manufacturers. Design patents are useful to keep up with the pace of innovation and quickly acquire intellectual property rights.

Utility patents should be considered when evaluating how to protect functional aspects of additive manufacturing and the resulting products. Inventors may obtain utility patents for new, non-obvious, and useful inventions that are functional or structural aspects of a technology. After the filing of a patent application at the U.S. Patent and Trademark Office, several years can pass before a patent is issued. Inventors of 3D printable designs may want to consider expediting this process by paying an extra fee to the USPTO at the time of filing the patent application to request "Track One" prioritized examination of the application.⁷⁸ Doing so enables the patent application to receive a final decision regarding patentability from the USPTO within 12 months.

Trade Secrets

The Defend Trade Secrets Act of 2016 provides trade secret owners with a private, federal, and civil cause of action to assert claims for misappropriation of trade secrets.⁷⁹ The Kansas Uniform Trade Secrets Act provides similar protections to the holder of a trade secret in the state of Kansas. 80 A trade secret is confidential, commercially valuable information that provides its owner with an ongoing competitive advantage. In order for a trade secret to remain protected, a business must take steps to maintain it. In other words, it must restrict access, it must guard against its disclosure and it must not be publicly available.

Once information is published in a patent, for example, it can no longer be the subject of a trade secret. Thus, when deciding whether to pursue a patent, some consideration should be given to maintaining the information as a trade secret. For example, a process that cannot be reversed-engineered lends itself to trade secret protection. Once a trade secret becomes public, even if by unlawful means, it is no longer a trade secret.

For 3D printing purposes, source code or blueprint designs kept as a trade secret provide manufacturers with the ability to assert a claim for misappropriation of trade secrets against the owners of websites that host 3D model data.

Food and Drug Administration Guidance

In December 2017, the Food and Drug Administration issued final guidance applicable to prescription drugs and medical devices manufactured with 3D printing technology.81 The guidance suggests extensive device testing for 3D printed products and internal checks to prevent the operator from exceeding pre-established device specifications. 82 It also recommends that users archive device files in standardized 3D specific formats and that they document materials used extensively.83

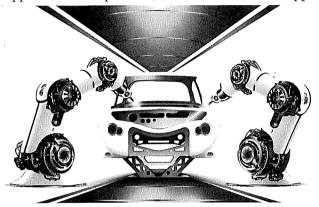
The FDA guidance provides technical considerations that should be addressed as part of fulfilling Quality System requirements for a regulated device made in whole or in part by 3D printing. These recommendations are particularly helpful for patient-matched device designers and manufacturers, or manufacturers that customize devices to match a patient's anatomy. The FDA guidance also recommends that designers and manufacturers compare the desired feature sizes of the finished printed product to the minimum possible feature sizes of individual 3D printing machines. In making this recommendation, the FDA cautions designers to ensure that the particular 3D printer being used is compatible with the design of the device.

For custom devices, the FDA guidance recommends that designers set clinically-relevant parameters within which a particular device design can be altered to fit a patient's anatomy without resulting in a change that would render the device defective. Consequently, when users other than the designers seek to customize a device, they will know what parts of the design can be customized, and what parts of the design cannot be reconfigured. The FDA guidance also notes that the designer of medical devices based on anatomical images should pay attention to image quality and resolution, any smoothing or image-processing algorithms that may alter the dimensions of the image, the rigidity of the anatomic features being imaged, and the clarity of the anatomic image. The objective would be to ensure that the original design of the device or product is not altered in such a way that renders it defective.

The FDA also notes that given that the 3D printing process can involve interaction between several different types of software, designers should maintain and archive standardized digital formats as a cautionary procedure to avoid design defects that might result from file conversions. The guidance provides that designers and manufacturers would be wise to extensively document all aspects of the 3D printing process, from identifying CAD image file formats, to describing the software validation process and to documenting all materials used in the 3D printing process. Medical device designers and manufacturers are at considerable risk in the product liability context, where plaintiffs may bring claims against multiple parties under a theory of joint and several liability.

Product Liability

Product liability law in the United States generally provides that one "engaged in the business of selling or otherwise distributing products who sells or distributes a defective product is subject to liability for harm to persons or property caused by the defect." Product liability principles are especially problematic in the 3D printing space because of the expansive supply chain. The parties involved in the 3D printing supply chain, any of whom might be implicated in the event of a potential product liability issue, include: (1) the manufacturer or supplier of the 3D printer; (2) the manufacturer or supplier



of the 3D printing material; (3) the printer owner; (4) the person who designed or sold the original object upon which a 3D printing design is based; (5) the person who created or shared the CAD blueprint of the object; (6) the person who created the object using the printer; and (7) the person who sold the 3D-printed object.

Consequently, problems with 3D-printed products can develop in many ways. For instance, the fundamental design of the product may be defective including when the original product upon which the design is based is defective or the design may be defectively rendered in the CAD data file. Even when the design and CAD rendering are free from defects, the 3D printer may be defective such that it fails properly to implement the design in creating the product. The printing material also may be defective in a manner that in turn produces a defective product. Alternatively, the 3D printer and/or printing material may be free from flaws, but result in a defect due to human error at various points in the printing process.

Under the basic rules of product liability law in most jurisdictions, manufacturers are strictly liable for defects in their products. This includes defects in design, manufacture, or warnings that render a product unreasonably dangerous for its intended use. Shapped in 1981, the Kansas Product Liability Act (KPLA) applies to all Kansas product liability claims regardless of the substantive theory of recovery. In most jurisdictions, if the product is misused by the consumer, the manufacturer is still liable so long as the misuse was foreseeable to the manufacturer. That means that manufacturers

must design, build, and develop warnings for their products that contemplate consumer behavior, even if that behavior includes using the product in ways the manufacturer did not intend. Plaintiffs, however, are likely to face at least two significant hurdles: first, whether the vendor is a product seller⁸⁷ subject to strict liability; and, second, whether the object is a "product" subject to product liability standards.

A casual user of a 3D printer is unlikely to be strictly liable for injuries caused by a defective 3D-printed product, even if she occasionally sells products. A routine vendor of 3Dprinted goods might very well be a "seller" within the meaning of the rule.89 One important question in the 3D printing arena is whether the computer aided design (CAD) rendering for a 3D-printed object is itself a product for the purposes of product liability. No case law was found which precisely ruled on this issue. However, courts have suggested that, as a rule, computer code used in 3D printing is not a product.90 Additionally, the CAD rendering arguably undergoes considerable change when it is converted into an object and is accordingly not likely a "product" itself.91 Another theory that might be available to a person injured by a 3D-printed product is to assert that the 3D printer caused her injury. This would require the litigant to establish that at the time the printer left the manufacturer, it was defective in design or manufacture or contained inadequate warnings, and that this defect ultimately caused the person's injuries.92

Construction Defect Liability

3D printers will undoubtedly expose contractors to liability and claims that would typically be attributed to human error. Instead of human workers building a structure, a 3D printer will fabricate the structure from a pre-generated plan that is uploaded to the printer. How the liability will be allocated when the finished structure is found to have flaws such as cracked walls, leaking components or missing structural members is the primary issue of concern. Depending upon if the 3D printer is owned by the contractor, is being leased or is owned by the subcontractor will be part of the assessment as to who can be found liable.

Printer malfunctions that result in construction flaws will result in the contractor's having warranty and indemnity claims against the manufacturer arising out of privity from purchasing or leasing the 3D printer. If the construction flaw was caused by a software malfunction, that could draw the developer into negligence and warranty claims for the reduced value of the project due to the defects introduced by the 3D printer. If there is a third party, serving as a subcontractor, loading digital files into the 3D printer, the subcontractor may also be liable if the defect was the result of improperly uploading those plans or faulty operation of the 3D printer.

The owner could arguably have claims against the manufacturer or software developer for economic loss, even in the

absence of direct privity. Kansas law permits a qualified thirdparty beneficiary plaintiff to enforce a contract expressly made for his or her benefit even though he or she was not a party to the transaction.93 When confronted with a construction defect caused by a 3D printer used by the contractor or one of its subcontractors, the owner will have an argument that the manufacturer of the printer or developer of the software should have been aware that a malfunction of its hardware or software would, in turn, impact the owner's property.

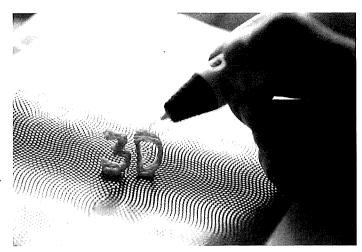
The growing availability and utilization of this emerging technology will also have an impact on material suppliers. If 3D printers are to be used on a construction project, designers and contractors should provide precise specifications for compatibility of the construction material such as concrete with the specific 3D printer. Certification of construction materials for use with specific printers will undoubtedly become more common place with material suppliers. Insufficient attention to detail on compatibility of specified materials with the 3D printer could open designers and material suppliers to liability for construction defects.

The International Building Code is a model building code developed by the International Code Council (ICC).94 It has been adopted for use as a base code standard by most jurisdictions in the United States and provides for different types of inspections that are necessary before the government certifies a structure for use and occupancy. Chapter 17 of the International Building Code requires special inspection by a qualified individual and in some cases structural observation by a registered design professional to verify proper assembly of structural components and the suitability of the installed materials. 95 The increased speed with which 3D printers can complete projects may be hampered by the current inspection requirements and inspection scheduling mandates.

An increased use of 3D printers at construction sites will likely require government agencies in charge of inspecting construction projects to adapt to the faster-paced construction offered. In the ideal scenario, governmental agencies would embrace the new technologies in the construction industry and, for example, invest in automated scanner drones that could inspect an automated 3D printer's work and, immediately thereafter, send the inspection's result to the governmental agency for certification. Such advances, however, may be difficult to achieve unless states, cities and counties make significant investments in infrastructure. As 3D printers/robots become more commonplace on construction projects, contractors should be mindful of including express warranty clauses in purchase and leasing contracts for 3D printers.

Conclusion

Just as with other cutting-edge technologies, such as block chain, artificial intelligence and autonomous vehicles, 3D printing is bound to disrupt society. This technology will pro-



vide greater manufacturing options which will only be limited by the imagination. 3D printing will facilitate rapid prototyping and increase manufacturing speed and likely reduce costs and the need for warehousing. In the not-too-distant future, one should expect to see customizable body parts and even organs produced with 3D printing. Some of the negative implications of 3D printing will be the need for fewer manufacturing jobs, the ease of counterfeiting parts for commercial or defense operations, the ability to disguise weapons in non-hazardous products and even that children could print dangerous items. While 3D printing will create opportunities for companies, it will also raise challenges especially concerning civil liability and intellectual property rights.



Bob Lambrechts is a partner with Lathrop Gage LLP in Overland Park where he practices patent and environmental law. He formerly served with the U.S. Environmental Protection Agency in the Clean Air Division and as a special assistant to the Region 7 Administrator. In addition to a law degree from St. Louis University, Mr. Lambrechts earned a Bachelor's and Master's Degree in Mechanical and

Aerospace Engineering from the University of Missouri at Columbia and prior to practicing law, he served as a robotics engineer with the Bendix Corporation in Kansas City. As avocations, Mr. Lambrechts served as an Engineering Duty Officer in the U.S. Navy Reserves for 28 years and as an adjunct faculty member for the Schools of Law and Engineering at the University of Missouri at Kansas City since 1993.

1. US Patent 4,575,330 titled Apparatus for production of three-dimensional objects by stereolithography, granted on March 11, 1986.

2. Michael Weinberg, It Will be Awesome if They Don't Screw it Up: 3D Printing, Intellectual Property, and the Fight Over the Next Great Disruptive Technology, Public Knowledge (Nov. 2010) [hereinafter Weinberg].

3. Additive manufacturing file format (AMF) is an open standard for describing objects for additive manufacturing processes. The official ISO/ASTM 52915:2016 standard is an XML-based format designed to allow any computer-aided design software to describe the shape and composition of any 3D object to be fabricated on any 3D printer. Unlike its predecessor STL format, AMF has native support for color, materials, lattices, and constellations.

4. STL (an abbreviation of "stereolithography") is a file format native

to the stereolithography CAD software created by 3D Systems. This file format is supported by many other software packages; it is widely used for 3D printing.

5. Michael Weinberg, What's the Deal With Copyright and 3D Printing? Institute for Emerging Innovation, 1 (Jan 2013), available at http://pub-

licknowledge.org/copyright-3Dprinting

6. What is 3D Printing & How Does 3D Printing Work? https://mec-

soft.com/3d-printing-explained/

- 7. Kalani Kirk Hausman and Richard Horne, How to Scan Objects for 3D Printing, https://www.dummies.com/computers/pcs/printers/how-to-scan-objects-for-3d-printing/
- 8. U.S. Patent No. 4,863,538 titled Method and apparatus for producing parts by selective sintering, filed October 17, 1986.
- 9. Filemon Schoffer, How expiring patents are ushering in the next generation of 3D printing; https://techcrunch.com/2016/05/15/how-expiring-patents-are-ushering-in-the-next-generation-of-3d-printing/

10. Global unit shipments of 3D printers from 2015 to 2020, Statista; https://www.statista.com/statistics/370297/worldwide-shipments-3d-

printers/

- 11. TJ McCue, Wohlers Report 2018: 3D Printer Industry Tops \$7 Billion, June 4, 2018 https://www.forbes.com/sites/tjmccue/2018/06/04/wohlers-report-2018-3d-printer-industry-rises-21-percent-to-over-7-billion/#35d966772d1a.
 - 12. Weinberg, supra note 2.

13. *Id*.

- 14. The Economic Impact of Civil Aviation on the U.S. Economy, Economic Impact of Civil Aviation by State, U.S. Department of Transportation, Federal Aviation Administration, September 2017, p. 20.
- 15. Bryan Crutchfield, 3D Printing's Impact on Aerospace, http://www.aerospacemanufacturinganddesign.com/article/3d-printings-impact-on-aerospace/, May 3, 2018.

16. Id.

17. Italian Drone company Soleon uses 3D printing to improve battery life of crop dusting UAV, https://www.3ders.org/articles/20170405-italian-drone-company-soleon-uses-3d-printing-to-improve-battery-life-of-crop-dusting-uav.html; April 5, 2017.

18. Id.

- 19. Aerospace Standard AS9102 is the North American aerospace standard for First Article Inspection Requirements.
- 20. Maegan Burkhart, *How First Article Inspection Helps Limit Defects in Mass Production*, August 22, 2018, https://www.intouch-quality.com/blog/first-article-means-mass-production-inspection
- 21. Is aerospace additive manufacturing ready for takeoff? Examining FAA attitudes towards 3D printing, Benedict, www.3ders.org, June 20, 2017, http://www.3ders.org/articles/20170620-is-aerospace-additive-manufacturing-ready-for-takeoff-examining-faa-attitudes-towards-3d-printing.html

22. Justin Cunningham, How 3D Printing is being used to develop F1 cars at the track, http://www.eurekamagazine.co.uk/design-engineering-features/interviews/how-3d-printing-is-being-used-to-develop-f1-cars-at-

the-track/165843/, December 5, 2017.

- 23. Vivek Srinivasan and Jarrod Bassan, Legal Edge Forum, 3D Printing and the Future of Manufacturing, https://leadingedgeforum.com/publication/3d-printing-and-the-future-of-manufacturing-2272/, January 21, 2013.
- 24. Jay Leno, Jay Leno's 3D Printer Replaces Rusty Old Parts, Popular Mechanics, https://www.popularmechanics.com/cars/a4354/4320759/, June 7, 2009.
- 25. U.S. Food & Drug Admin., Press Release, Statement by FDA Commissioner Scott Gottlieb, M.D., on FDA Ushering in New Era of 3D Printing of Medical Products; Provides Guidance to Manufacturers of Medical Devices, Dec. 4, 2017.
 - 26. 3D-Printed Windpipe Gives Infant Breath of Life, Marissa Fessen-

- den, https://www.scientificamerican.com/article/3D-printed-windpipe-gives-infant-breath-of-life/, September 1, 2013.
- 27. 3D-printed implant replaces 75 percent of patient's skull; https://www.cnet.com/news/3d-printed-implant-replaces-75-percent-of-patients-skull/. March 8, 2013.
- 28. World's First 3D-Printed Titanium Cranial Implant Cleared by FDA, Suzanne Hodsen, Med Device Online, February 9, 2016, www. meddeviceonline.com/doc/world-s-first-d-printed-titanium-cranial-implant-cleared-by-fda-0001
- 29. FDA Approved 3D Printed Drug Available in the US, https://www.forbes.com/sites/jenniferhicks/2016/03/22/fda-approved-3d-printed-drug-available-in-the-us/#540e55b3666b, March 22, 2016
- 30. Ahmed Zidan, Ph.D., CDER Researchers Explore the Promise and Potential of 3D Printed Pharmaceuticals, https://www.fda.gov/drugs/new-sevents/ucm588136.htm
 - 31. Id.
 - 32. Id.
 - 33. Id.
- 34. Melissa Little & Gordon Wallace, Printing the Future: 3D Bioprinters and Their Uses, Australian Academy of Science; https://www.science.org.au/curious/people-medicine/bioprinting
- 35. W. Peng et al., 3D Bioprinting for Drug Discovery and Development in Pharmaceutics, Acta Biomaterialia (May 2017).
- 36. Tim Lewis, Could 3D Printing Solve the Organ Transplant Shortage? The Guardian, July 30, 2017.
- 37. Legal Implications of 3D Printing in Construction Loom, Engineering News-Record; https://www.enr.com/articles/44798-legal-implications-of-3d-printing-in-construction-loom, Aldo E. Ibarra, June 18, 2018.
- 38. Selen Denonain, *How 3D printing is transforming the construction industry?* http://www.mbadmb.com/2018/04/04/how-3d-printing-transforms-the-construction-industry/

39. Id.

- 40. Defense Distributed is an online open-source hardware organization that develops digital schematics of firearms in CAD files, that may be downloaded from the Internet and used in 3D printing applications. On May 5, 2013, Defense Distributed made these printable STL files public, and within days the United States Department of State demanded they be removed from the Internet, citing a violation of the International Traffic in Arms Regulations.
- 41. Where to find 3D Printed Gun Files, Patrick Roberts, http://www.recoilweb.com/where-to-find-3d-printed-gun-files-140438.html; August 10, 2018.
 - 42. Gun Control Act of 1968, 18 USC § 44.
 - 43. See 27 CFR § 478.92.
 - 44. 18 U.S.C. § 922(p).
- 45. Albanesius, Chloe (2013-12-10). "Obama Signs Bill to Extend Ban on Plastic Guns | News & Opinion". PCMag.com; https://www.pcmag.com/article2/0,2817,2428186,00.asp
- 46. Congress.gov https://www.congress.gov/bill/115th-congress/house-bill/2033
 - 47. Id.
- 48. 2018 3D Printed Gun Report—All You Need to Know; https://all3dp.com/3d-printed-gun-firearm-weapon-parts/, Tyler Koslow, August 1, 2018 [hereinafter Koslow].
 - 49. Id.
 - 50. Id.
- 51. Acrylonitrile butadiene styrene (ABS) is a common thermoplastic polymer.
 - 52. Koslow, supra note 48.
- 53. Polylactide (PLA) is a biodegradable and bioactive thermoplastic aliphatic polyester derived from renewable resources, such as corn starch.
 - 54. Koslow, supra note 48.
 - 55. Andy Greenburg, Bill to Ban Undetectable 3D Printed Guns is Com-