A Disruptive Technology: How Will 3D Printing Alter the Products-Liability Landscape?

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If you believe the news, 3D printing (also known as additive manufacturing) will change virtually every aspect of your life in the next three to five years. News articles suggest that everything from your four-year-old's next favorite toy, to the prescription medicines that we take,[1] to the replacement parts needed for our cars will be 3D printed in the near future. Some have argued that 3D printing will impact manufacturing on the same scale that the personal computer affected the office environment. One open question, however, that companies must begin to evaluate is how corporate exposure and liability issues will evolve as products-liability lawsuits begin to surface involving 3D-printed products. This manuscript will explore the underpinnings of traditional products-liability law, describe what additive manufacturing is and how it disrupts the traditional paradigm, and then examine how the new technology could impact products-liability litigation.

Traditional Manufacturing and the Applicable Legal Paradigm

Products-liability law developed to address individuals who were injured by defects in (tangible)[2] products that were manufactured by a commercial[3] seller. The legal framework evolved at a time when product manufacturers tended to be large commercial enterprises, which were primarily responsible for the design and development of their products as well as their sale and distribution. This centralization of this activity supports an underlying premise of products-liability law that a "manufacturer" is most knowledgeable about the products that it sells and is in the best position to ensure that safe products reach the marketplace. Under such a paradigm, the imposition of strict liability theories on such manufacturers was deemed appropriate.

[1] The FDA has now approved a 3D printed prescription medicine, Spritam®, which is manufactured by Aprecia Pharmaceuticals and indicated to treat epilepsy. The manufacturer touts its use of a proprietary "ZipDose" 3D printing technology, which "prints" the medicine layer-by-layer and results in a pill that is more porous than traditional pills, allowing it to disintegrate more quickly in a patient's mouth.

[2] *See* Restatement (Third) of Torts: Prod. Liab. §19(a).

[3] *See* Restatement (Third) of Torts: Prod. Liab. §1 (indicating that to be subject to a products liability theory of recovery that a person or entity must be "engaged in the business of selling or otherwise distributing products." *But see id.*, at cmt. c. (providing that the liability does not apply to "noncommercial seller[s] or distributor[s]" nor to an "occasional or causal" sale).

Mass production is the second characteristic of traditional manufacturing upon which products-liability law is based. Historically, products were uniform, mass-produced, and based upon a single (or small set of) design(s) as captured in the manufacturing specifications. Liability theories evolved out of this paradigm. For example, the Restatement (Third) of Torts describes theories of recovery based upon whether a product deviates from a manufacturing specification (manufacturing defect), whether the risks associated with the product's design specifications exceed the benefits (design defect), and whether the product (as designed) requires a specific warning to be used in a safe manner (inadequate warning).

Additive manufacturing, however, has the potential to unmoor both of these underlying principles. The proliferation of 3D printing technology is likely to dispense with the historic, *de facto* requirement that a "manufacturer" be a large commercial entity that is also responsible for design and distribution activities. Likewise, the "mass production" paradigm will be replaced in time with the "mass customization" of products, given the lower costs and manufacturing flexibility that 3D-printing technology provides over traditional manufacturing. These fundamental changes inevitably will exert pressure on existing products-liability theories, but to better understand how the legal framework may change, it is first important to explore the new technology at issue.

What is Additive Manufacturing?

Additive Manufacturing (AM), also known as 3D printing or rapid prototyping, is defined by ASTM International (formerly known as the American Society for Testing and Materials) as the "process of joining materials to make parts from 3D model data, usually layer upon layer, as opposed to subtractive manufacturing and formative manufacturing methodologies."[4] The technology dates back to 1984, when Charles Hull, who later founded 3D Systems, Inc., patented a process described as "stereolithography" (solid imaging) using fluids and digital blueprints.

Additive manufacturing differs from the traditional manufacturing methods of subtractive manufacturing (e.g. milling, drilling or turning) and formative manufacturing (e.g. pressing, forging or stamping) as the part is "printed" in a machine from a digital model of the part layer by layer. The material that the part is manufactured from is built up, layer by layer, from the raw material by the printer, rather than starting the production process with a solid block of material which is cut and shaped to produce the final part.

[4] ISO/ASTM 52900:2015(E) Standard Terminology for Additive Manufacturing – General Principles – Terminology

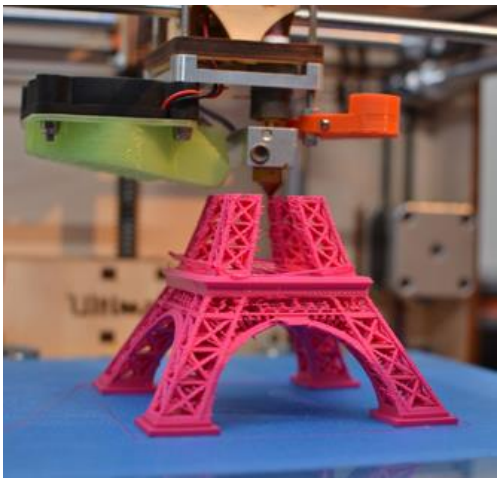

Figure – Half-complete 3D printout of Eiffel Tower model

The technology offers everybody the chance to become a "manufacturer," using either their own home 3D printer or one of many commercial entities offering 3D-printing services, such as UPS.[5] Parts can be printed from digital models created by the individual or from models downloaded from the internet. Some futurists predict that every house will soon have a 3D printer, displacing traditional factories and mass production entirely. Others have described the huge potential offered by this technology as "the next industrial revolution."

What Are the Benefits and Limitations?

There are many potential advantages to additive manufacturing; it allows designers to produce easily customizable parts, or parts that cannot be manufactured by other production methods. It has the potential to produce finished products, with multiple materials and moving pieces. Additive manufacturing allows production with no upfront cost due to manufacturing tooling. It also offers cost and time savings for prototype parts or smaller production runs. In terms of the potential, imagination is the limit!

However, additive manufacturing does have some disadvantages compared to traditional manufacturing methods. Currently, additive manufacturing processes may have slower build rates and are more expensive for mass production parts. Parts produced by additive manufacturing may have inferior or variable mechanical properties and are limited by the size of the available printer. Parts may require post processing (cleaning, for example), further procedures to improve material properties, improvements to surface finish or further machining. Additionally, in some industries, the regulatory approval pathways are currently undefined.

[5] *See* https://www.theupsstore.com/print/3d-printing.

How Does Additive Manufacturing Work?

The world of additive manufacturing is currently bogged down in a lexical quagmire, with many patented and trademarked processes. For legal and marketing reasons, individual manufacturers frequently use different terms for nearly identical processes. The standardization bodies, ASTM International and ISO (the International Organization for Standardization) have classified all additive manufacturing technologies into seven generic categories.[6,7] The basic principles, advantages and disadvantages of these seven categories are summarized in Appendix A.

Some basic, common steps apply to all additive manufacturing technologies. All 3D printers require a digital model (i.e., a digital blueprint) of the part to be produced. This model may be generated by reverse engineering, a process where an existing part can be 3D scanned to produce a digital model of the physical object.

Figure: Demonstrative of Commercially Available 3D Scanner[8]

The digital model created by the 3D scan can then be used to 3D print a duplicate part with the same dimensions as the original part (though not necessarily the same mechanical properties). Alternatively, websites exist with libraries of digital models of 3D parts that are available for free or paid download. The source of these models may be unknown individuals designing untried and untested parts, reverse engineered parts, or potentially pirated designs from OEMs (Original

[6] ISO/ASTM 52900:2015(E) Standard Terminology for Additive Manufacturing – General Principles – Terminology

[7] ISO 17296-2:2015 Additive manufacturing -- General principles -- Part 2: Overview of process categories and feedstock

[8] *See* http://www.engadget.com/2009/09/17/z-corporation-debuts-worlds-most-affordable-portable-3d-scann/

Equipment Manufacturer).[9] Digital models also can be generated using the traditional engineering design tools or from free software that allows unskilled individuals to design particular custom components or parts, for example children's toys.[10]

The digital model is then uploaded to the 3D printer, which typically builds up the finished part in successive layers until the whole part is completed. Printer feedstocks include powders, filaments, sheets, pastes, liquid photopolymers[11], or other liquids. Feedstock materials include metals, plastics, ceramics or even concrete. Today, it is possible with adequate processing and controls to print metal or plastic parts with comparable mechanical properties to similar parts made via traditional manufacturing processes.[12] It is even possible to print tissue, cells or whole organs in a process known as "bioprinting."

Challenges of Additive Manufacturing

In some applications and industries, additive manufacturing offers significant advantages over traditional manufacturing processes. It is likely that the use of additive manufacturing techniques will only become more widespread in the future. However, additive manufacturing does come with a specific set of challenges and potential problems that do not exist with traditional manufacturing processes.

3D printers have hundreds of variables that may potentially affect the mechanical and geometrical properties of the finished part. While many of these variables are controlled by the printer software and established by the printer manufacturer, there are still many quality critical factors under the control of the user.

For example, in the case of powder-bed fusion printing (one specific type of additive manufacturing that uses powder as the feed material which is then fused together layer by layer by a high powered laser beam), powder management is an important factor. Powder that is not consumed during the printing process is typically recycled and used for the next print. However, the powder has been reported to degrade over subsequent uses (for example, the morphology of the particles may change or the oxygen content increase resulting in changes in the mechanical properties over subsequent builds).[13] Further, if the 3D printer is used to print different materials, then care must be taken to prevent cross contamination of the powders. If all traces of the previous powder are not cleaned out of the printer, even a small amount of contamination can

[9] An OEM (Original Equipment Manufacturer) is a company that makes a part or subsystem that is used in another company's end product.
[10] The design and sale of such digital models raises unique products-liability questions that will be addressed later in this manuscript
[11] In this context, a photopolymer is a liquid that changes to a solid when exposed to light
[12] However, in many instances, the mechanical properties remain inferior.
[13] *See* http://www.lpwtechnology.com/cms/lpw-content/uploads/2016/02/LPW-Case-Study-05-E.pdf

cause structural defects in the subsequent parts.[14] Likewise, the mechanical properties of parts produced by powder bed fusion printing can vary depending on the precise location of the part in the 3D printer, the orientation of the part in the 3D printer, and even within the same part at different locations. This variation must be understood by the printer user, and allowed for in the design, specification and build plan of the parts. These material factors are far more important in additive manufacturing (where the bulk material is laid down layer by layer in the printer) than in traditional manufacturing processes (where certified material can be bought in bulk form from an external supplier).

Standardization

The development of consensus standards to support the additive manufacturing industry has been spearheaded by ASTM International and ISO. ASTM committee F42, formed in 2009, aims to address the requirements and issues across a wide range of additive manufacturing processes and applications by establishing a top level set of fundamental standards. To date, the committee has developed more than 11 standards, with an additional 20 standards currently under development. In the future, the committee plans to develop specialized standards, linked to the fundamental standards that will address a specific additive manufacturing process or technology. A list of the relevant ASTM standards can be found at the ASTM website[15]. Currently, ASTM standards cover areas such as the specifications for powder-bed fusion additive manufacturing with a range of materials and test methods for evaluating material properties of metal parts made via additive manufacturing.

Since 2011, ASTM has cooperated with ISO in the development of additive manufacturing standards to eliminate the duplication of efforts between the two organizations. Several joint standards have been developed, including "ISO/ASTM 52900, Standard Terminology for Additive Manufacturing Technologies." ISO technical committee ISO/TC 261 Additive Manufacturing has published 6 standards to date and has several more in development. ISO standards cover areas such as an overview of additive manufacturing process categories, and main characteristics and testing requirements. ISO is currently developing standards including requirements for purchased additive manufacturing parts and a guide for design for additive manufacturing. A list of the standards developed by ISO/TC261 can be found on the ISO website[16].

Other organizations are working to develop industry specific standards; for example SAE International (formerly known as the Society of Automotive Engineers) is working to develop and maintain Aerospace Material Specifications (AMS) and Aerospace Standards (AS) relating

[14] *See* http://www.lpwtechnology.com/cms/lpw-content/uploads/2016/02/LPW-Case-Study-01-E.pdf
[15] *See* http://www.astm.org/Standards/additive-manufacturing-technology-standards.html
[16] *See* www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_tc_browse.htm?commid=629086.

to areas such as materials, processes, post processing, inspection, testing and quality assurance.[17] FDA has issued a draft guidance document entitled "Technical Considerations for Additive Manufactured Devices."[18]

Current Applications of Additive Manufacturing and Potential Legal Implications

Automotive Industry

The automotive industries were early adopters of additive manufacturing technologies, especially for the manufacture of prototype parts (i.e., "rapid prototyping"). Ford Motor Company claims to have produced more than half a million prototype parts using additive manufacturing and "saved billions of dollars and millions of hours of work." [19] Rapid prototyping allows manufacturers to produce prototype parts directly from a digital model, without the time-consuming and expensive process of developing production tooling. Rapid-prototype parts range from plastic scale models that allow engineers and designers to visualize new designs, to real full-size parts that are used for laboratory testing or in development vehicles used for testing and validation.

Currently, the use of 3D-printed parts in mass-produced cars is limited by cost issues. While additive manufacturing significantly reduces the cost of manufacturing custom parts, it remains less cost effective than traditional manufacturing methods when employed to produce large numbers of identical parts. However, manufacturers of low volume super cars and racing cars have embraced the technology. Koenigsegg, the Swedish supercar manufacturer, has used additive manufacturing to produce the turbo charger for their latest production car. Additive manufacturing has allowed them to design a complex shape, which offers a performance advantage, and would be difficult to manufacture by traditional processes.[20] The internal moving parts of the Koenigsegg turbo charger are printed at the same time as the casing, saving on assembly operations.

Ultimately, additive manufacturing has the potential to revolutionize the supply chain for automotive spare parts. Currently, 3D scanners and computer-aided-design software are available that would allow individuals to reverse engineer and/or design custom parts for their cars. When combined with additive manufacturing technology, it is now possible to "manufacture" replacement car parts on site, rather than having to order parts from a traditional manufacturer.[21]

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[17] *See* https://www.sae.org/works/upcomingmeetingResources.do?eventGenNum=30001
[18] *See* www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/-UCM499809.pdf.
[19] *See* https://corporate.ford.com/innovation/building-in-the-automotive-sandbox.html
[20] *See* https://www.youtube.com/watch?v=DNedUZxP8NU
[21] *See* http://www.popularmechanics.com/cars/a4354/4320759/

Thus, in the future, it is possible that garages and parts centers will have 3D printers to print replacement parts – instead of ordering them from the existing supply chain. This also has the potential to allow dealers or garages to design and print customized parts and accessories for individual cars. The digital models of the parts may be licensed and provided by the OEM to their own dealers so that the parts will still be manufactured within a quality framework controlled by the OEM.

But this would raise questions about whether the sale or license of an ***intangible,*** digital blueprint for a part would expose an OEM to strict products liability.[22] While not in the context of 3D-printed products, existing jurisprudence reflects a hesitancy of courts to label digital files, software, and/or intangible thoughts and ideas as "products" for purposes of products liability law.[23] However, even the Restatement itself recognizes that there may be exceptions to the traditional requirement that "products" be tangible items. *See* Restatement (Third) of Torts: Prod. Liab. § 19(a) ("[o]ther items . . . are products when the context of their distribution and use is sufficiently analogous to the distribution and use of tangible personal property . . . ."). And this exception may ultimately swallow the rule if additive manufacturing results in the sort of supply-chain reconfiguration that is discussed here.

Additive manufacturing also results in the potential for non-franchised garages, parts centers, or individuals to print parts from digital models provided by generic aftermarket parts companies, and the "manufacture" of these parts may be subjected to varying levels of quality assurance. It also will be possible to print parts from pirated digital models, open source models, or reverse engineered models, all of which are completely untested and unregulated. Under such circumstances, it is certainly conceivable that a garage that 3D prints a car part will be deemed a "manufacturer" for purposes of strict products liability – even though the garage: (1) played no role in the design of the part, and (2) may have no understanding of science upon which the design of the part is premised.

[22] *See* Restatement (Third) of Torts: Prod. Liab. §19(a) (defining a "product" as "tangible personal property distributed commercially for use of consumption.")

[23] *See, e.g., U.S. v. Aleynikov*, 767 F.3d 71, 76-79 (2d. Cir. 2012) (concluding that computer source code was not a "product" within the meaning of the Economic Espionage Act but rather "purely intangible property embodied in a purely intangible format."); *Sanders v. Acclaim Entertainment, Inc.*, 188 F. Supp. 2d 1264, 1279 (D. Colo 2002) (finding intangible content in contained in video games are not "products" for purposes of strict products liability); *Gorran v. Atkins Nutritionals, Inc.*, 464 F. Supp. 2d 315, 324, *aff'd* 279 Fed. Appx. 40 (2d Cir. 2008) (same with respect to intangible ideas in books).

Aerospace Industry

Like the automotive industry, the aerospace industry has been a pioneer in the field of additive manufacture and makes extensive use of rapid prototyping for development and prototype parts. Recently, the U.S. Federal Aviation Administration (FAA) has certified the first part produced by additive manufacturing for use inside a GE jet engine.[24] Work is proceeding on the next generation of jet engines, which will include more additive manufactured parts. Additive manufactured parts are used elsewhere in aircraft, where they allow manufacturers to optimize the design of parts to save weight in ways not possible by traditional manufacturing methods.[25] NASA has demonstrated the capability to 3D print a tool on the International Space Station from a digital model transmitted from earth to the printer.[26] However, the FAA has identified specific concerns and challenges relating to additive manufacture that need to be addressed, including: a limited understanding of key manufacturing variables and failure mechanisms, lack of specifications and standards, lack of robust supply base of feedstock powder and a low barrier to entry for new (i.e. inexperienced) suppliers.[27] Such statements by a regulating body will, of course, be quoted verbatim by plaintiffs' lawyers should a 3D-printed, aerospace product become the subject of litigation.

Medical Device Industry

The medical industry is also exploring the use of additive manufacturing technologies. To date, there are dozens of medical devices approved or cleared by FDA that employ 3D printing technology, including spine implants,[28] foot and ankle replacement systems,[29] and hip implants.[30] However, there are specific considerations in this industry related to the regulatory framework which are elaborated upon in Appendix B.

While medical devices that have received regulatory clearance to date have been made using a variety of additive technologies covering a number of device types, they can generally be separated into implantable and non-implantable devices and devices that are patient matched or non-patient matched.[31]

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[24] *See* http://www.gereports.com/post/116402870270/the-faa-cleared-the-first-3d-printed-part-to-fly/
[25] *See* http://www.eos.info/eos_airbusgroupinnovationteam_aerospace_sustainability_study
[26] *See* http://www.nasa.gov/mission_pages/station/research/news/3Dratchet_wrench
[27] *See* http://www.nianet.org/ODM/ODM%20Wednesday%20presentations%20Final/7%20Kabbara%20On-Demand%20Workshop%20AM%20Presentation%2803-09-2016.pdf
[28] *See* Oxford Performance Materials, Inc.'s SpineFab® VBR implant system (http://www.oxfordpm.com/oxford-performance-materials-receives-fda-clearance-spinefab-vbr-implant-system).
[29] *See* Zimmer Biomet's Unite3D™ Bridge Fixation System (http://www.prnewswire.com/news-releases/zimmer-biomet-announces-fda-clearance-for-unite3d-bridge-fixation-system-300219104.html).
[30] *See* Smith & Nephew's REDAPT® Revision Acetabular Fully Porous Cup with CONCELOC® Technology (http://www.smith-nephew.com/news-and-media/media-releases/news/first-3d-printed-titanium-hip-implant/).
[31] M. Di Prima, J. Coburn, D. Hwang, J. Kelly, A. Khairuzzaman, L. Ricles, Additively manufactured medical products – the FDA perspective, 3D Printing in Medicine, 2 (2016) 1-6.

Non-Implantable Products

Patient-matched devices usually are customized using either medical imaging data or laser scans of individual the patient's anatomy to modify the geometry of the resulting device. Patient-matched custom cutting guides and drill templates are non-implantable products that are widely used in the orthopaedic industry. These are disposable products, used by surgeons during arthroplasty procedures to aid the surgeon in positioning bone cuts, and are derived by the manufacturer from computed tomography or magnetic resonance imaging scans of the patient. Their use can decrease surgical time, replace trays of reusable instruments, and are thought to reduce surgical errors during arthroplasty. However, opportunity for more widespread use of such customized surgical aids (particularly when provided by a medical device manufacturer), also will increase the opportunities for plaintiffs' attorneys to argue that the manufacturer is now an active participant in the surgical procedure, a role traditionally limited to the surgeon and his or her surgical team. This is another example of how the adoption of additive manufacturing technologies could conceivably impact the scope of legal exposure for product manufacturers.

Implantable Products

Another example of the trend to mass customization can be found in total knee replacements. ConforMIS currently offers patient-matched orthopaedic implants based on medical imaging data.[32] In this process, a CT scan of the knee is converted to a 3D model by mapping the articular surface of the joint. Additive manufacturing technology then is used to form an implant from cobalt-chromium alloy based on a patient's own CT scan.[33,34]

However, such mass customization of medical implants raises a host of unanswered legal queries. As mentioned, products-liability law is predicated on a mass-production environment. In that setting, manufacturing specifications typically are uniform, and thus, it is relatively straightforward to evaluate whether a product complies with its manufacturing specifications, such as in the context of a manufacturing-defect claim. Likewise, a risk/benefit analysis of an

[32] *See* http://www.conformis.com

[33] Although each implant is matched to an individual patient, this device was cleared for use under the 510(k) regulatory pathway. US Food and Drug Administration (FDA) has indicated that patient matched medical devices are not considered to be "custom" devices as defined by section 520(b)(2)(B) of the FD&C Act and therefore do not qualify for a custom device exemption from premarket notification. *See* M. Di Prima, J. Coburn, D. Hwang, J. Kelly, A. Khairuzzaman, L. Ricles, Additively manufactured medical products – the FDA perspective, 3D Printing in Medicine, 2 (2016) 1-6.

[34] As stated in the draft FDA guidance *(see Appendix B)*, "Patient-specific devices are, in general, ones in which ranges of different specifications have been approved or cleared to treat patient populations that can be studied clinically. Premarket submissions for such devices are sometimes referred to as "envelope" submissions because their approval or clearance covers the entire range of specifications data they contain to support. The final manufacturing of these devices can be delayed until physicians provide imaging data or other information to the manufacturer to finalize device specifications within cleared or approved ranges. As a result, such devices are specifically tailored to patients." *See* M. Di Prima, J. Coburn, D. Hwang, J. Kelly, A. Khairuzzaman, L. Ricles, Additively manufactured medical products – the FDA perspective, 3D Printing in Medicine, 2 (2016) 1-6.

overarching design (as defined by product specifications) is possible among a broad population of users to determine whether a particular design is "defective." But this sort of legal inquiry is complicated in the context of customized products.

For example, if a person that has received a customized implant ultimately requires a revision procedure, the implant manufacturer could face significant challenges if a design defect claim is asserted. The alternative-design/risk-utility test employed in most jurisdictions becomes weighted in the plaintiff's favor because:

(1) There are an infinite number of alterative designs available to the manufacturer using 3D printing technology;
(2) There is a reduced feasibility hurdle that weighs against the alternative design (because all designs may be possible to print using additive manufacturing);
(3) There is not a broader population of implant recipients available to demonstrate the principle that widespread benefits of the implant outweigh the particular risks that occurred for the plaintiff.

Moreover, Plaintiffs' lawyers will surely argue that the manufacturer failed to appropriately test their customized products. But it is impossible, practically speaking, for a manufacturer to test each of the theoretically unlimited product designs that are now available via additive manufacturing in the same manner in which a single design traditionally would have been tested during research and development.[35]

Conclusions

In theory, 3D printing has the potential to reduce an entire manufacturing facility into a single 3D printer that might range in size from a desk to a desktop. "Manufacturing" then becomes as easy as hitting a button from within computer-aided-design (CAD) software once the product has been digitally designed.

Ultimately, two aspects of additive manufacturing are likely to have the most significant impact on products-liability law: (1) the mass customization of products; and (2) the inevitable dissociation of product design, manufacturing, and sales.

As previously noted, products-liability law was formulated to address injuries to individuals resulting from ***mass-produced*** products. As such, the products-liability law framework that

[35] Similar complications exist when analyzing a "manufacturing defect" claim involving a customized, 3D-printed product. To begin, the manufacturing specifications themselves become murky. Are the "specifications" the digital model generated by the scanning software or perhaps the digital instructions to the 3D printer concerning how to actually print the implant? Likewise, evidentiary and spoliation issues begin to arise regarding whether a customized product manufacturer should have a duty to preserve files and software related to every customized product that it makes so that an injured party can evaluate whether a deviation from a manufacturing specification (whatever that is) actually occurred.

developed does not immediately lend itself to the analysis of injuries from custom-made items. Moreover, the fracture or dissociation of product design, manufacturing, and sales that is now more likely with the adoption of additive manufacturing will require a reanalysis of fundamental products-liability questions, such as: what is a product? (e.g., tangible item or digital model) and who is a manufacturer? (e.g., designer of digital model or owner of 3D printer that prints the item).

Unfortunately, the law lags technology, and the preceding issues have yet to be addressed by our courts. Our research reveals only one decision addressing liability for a 3D-printed product, the Invisalign orthodontic system. But the case focused on allegations of misrepresentations regarding the effectiveness of the system, as opposed to more product-oriented allegations of the sort that we have raised here. *See Buckley v. Align Technology, Inc.*, No. 5:13-CV-02812-EJD, 2015 WL 5698751, (N.D. Cal. Sept. 29, 2015).

Thus, while there is dearth of legal authority on the subject, there are nonetheless common-sense steps that corporate manufacturers and their outside legal counsel should keep in mind when venturing into these untested waters:

1. Consider the potential ramifications of new business ventures employing additive manufacturing, and evaluate whether the new venture could subject the company to a new type of exposure, such as strict product liability.
2. Reevaluate hold-harmless and indemnity agreements with vendors and component-part suppliers when additive manufacturing is being used by any entity in the supply chain.
3. Examine all types of corporate insurance to determine whether additive manufacturing is the subject of any exclusions or special treatment.
4. Ensure that company employees and engineers are monitoring regulatory and trade organization activities on the subject – and updating company practices and protocols accordingly.[36]

Additive manufacturing technology is exciting and likely to have an impact on industry and the associated legal landscape, but corporate manufacturers should monitor developments closely to ensure that potential legal implications are understood and exposure is minimized.

[36] For example, the FDA recently issued a guidance on the use of additive manufacturing with prescription medical devices entitled "Technical Considerations for Additive Manufactured Devices." Likewise, the American Society of Testing and Materials (ASTMi) held a symposium on the subject of additive manufacturing in May of 2016. ASTMi is actively exploring how to implement standards in the area, which will undoubtedly appear in litigation once disseminated.

Appendix A – Summary of Additive Manufacturing Processes

AM Process	Description	Advantages	Disadvantages	Typical Feedstock and Materials	Synonyms
Material Extrusion	A filament is melted as it passes through the heated print nozzle and is then deposited layer by layer onto the work piece.	• Filament can be standard engineering plastics. • Printers may be purchases for a few hundred dollars for small business / home use.	• Mechanical properties are anisotropic (i.e. parts are weaker in some directions than others). • Support structures required for some geometries. • Part surface will have a "stepped profile."	Filament or paste • Thermoplastics (e.g. ABS or PLA). • Structural ceramics • Concrete.	FDM – Fused Deposition Modelling PJP – Plastic Jet Printing FFM – Fused Filament Modelling MEM – Melted and Extruded Modelling FFF – Fused Filament Fabrication FDM – Fused Deposition Modelling
Vat Photo-polymerization	Computer controlled laser beam (or light source) selectively cures photopolymer in vat of liquid. The laser traces out each layer, then the build platform lowers and the object is built up layer by layer.	• Parts can be printed with good accuracy and good surface finish • Wide range of build materials are available	• Cost of resins higher than other build materials for other methods. • Feedstock is UV-active photopolymers and not standard materials. • Parts may not be durable over time. • Support structures required for some geometries.	Liquid photopolymer. • Compounds that simulate properties of ABS, PC, or rubber.	SL – Stereolithography SLA – StereoLithographic Apparatus
Material Jetting	Photopolymer is sprayed from print head and set with UV light from print head. Support structures are printed at the same time. The 3D shape is built up from successive layers.	• Good accuracy and surface finish • Multiple materials can be printed at the same time. • Multi-material and multi-colored parts can be printed.	• Feedstock is UV-active photopolymers and not standard materials. • Parts may not be durable over time. • Support structures required for some geometries.	Liquid photopolymer. • Compounds that simulate properties of ABS, PE, PC, or rubber. • Molten wax	MJP – Multijet Printing Polyjet modeling Multijet modeling, polyjetting Multijetting Jetted photopolymer DOD – Drop on demand
Binder Jetting	Thin layer of powder spread onto build platform and then print head selectively sprays liquid binding agent onto thin layer of powder particles. Platform is then lowered and the process repeated.	• Parts can be printed in full color • Technology is relatively fast and cheap • Parts can be post processed to improve mechanical properties • Often used to make casting patterns and molds • No support structures required	• Parts straight from the machine have limited mechanical properties and may be fragile • Excess powder must be removed during post processing for some applications	Powders and liquid adhesive / bonding agent • Ceramics, composites, metals, plastics or sand	

AM Process	Description	Advantages	Disadvantages	Typical Feedstock and Materials	Synonyms
Powder Bed Fusion	A layer thin layer of powder is spread over the build platform and is then melted or fused together by a laser or other high energy source. A new layer of powder is spread across the previous layer using a roller or scraper.	• Metal parts can be manufactured with high density and good mechanical properties • Plastic parts can be manufactured with good mechanical properties, but do not have the same mechanical and surface finish properties as injection molded parts • No support structures required	• Technology is slow and expensive compared to other technologies • Tolerances and surfaces finished are limited • Mechanical properties are not the same as their injection molded counterparts	Power • Thermoplastic polymers, metals, ceramics	LS – Laser Sintering LBM – Laser Beam Melting DLMS – Direct Metal Laser Sintering DMP - Direct Metal Printing SLM – Selective Laser Melting EBM – Electron Beam Melting EBAM - Electron Beam Additive Manufacturing SHS – Selective Heat Sintering SLS – Selective Laser Sintering
Directed Energy Deposition	Metal powder or wire is melted in a high power laser bean and deposited as molten build material. The process does not have to take place on a flat powder bed.	• Metal powder fed into print head can be continuously altered during the build, and can therefore fabricate objects with properties that cannot be obtained using traditional production methods • Parts can be used directly after printing as fully dense metal parts Method can be used to repair old parts as well as fabricating new parts	• Parts may require surface finishing	Wire or powder • Metals	LENS – Laser Engineered Net Printing
Sheet lamination	Object is built up from layers (sheets) of material bonded to the previous layer by adhesive backing or sprayed adhesive. The sheets of material are advanced onto the build platform and outline of layer cut with laser or blade.	• Cheap feedstock	• Large amounts of waste	Sheet Material • Paper, metal foil, polymers or composite sheets	LOM – Laminated Object Manufacturing UAM – Ultrasonic additive manufacturing

Appendix B - Special Considerations for Medical Devices

As a regulated industry, the potential uses of additive manufacturing raise many questions when applied to medical devices. Additive manufacturing has been used historically both as a design tool for rapid prototyping of new designs and to create physical models of unique patient anatomy to aid in surgical planning. With improvements in the ability to print structural materials from both polymeric and metallic materials, additive manufacturing has been rapidly adopted by the medical device industry for use in surgical instruments, surgical guides, dental implants, orthopaedic implants, prosthetics, hearing aids and porous tissue engineering scaffolds. However, as regulatory law lags the development of this technology, there is increasing regulatory uncertainty regarding the traditional role of a medical device manufacturer. This uncertainty may also result in new risks in products-liability litigation as compliance with FDA regulations and conformance with recognized consensus standards are often used to aid in the technical defense of FDA-regulated products.

A medical device is defined under Section 201(h) of the Food Drug and Cosmetic Act as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

- recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
- intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes."

Therefore the determination whether a device is FDA regulated is often driven by the intended use via claims in the labelling and promotional materials.

The degree of regulatory scrutiny that a manufacturer or distributor faces by FDA is determined based on the regulatory classification of the device. Devices are classified as Class I, II or III according to a risk assessment, which is based on the intended use of the device and the indication for use. Class I devices are considered lowest risk, while Class III devices are considered greatest risk. While most Class I and a few Class II devices are exempt from premarket regulatory oversight by FDA, most class II devices require a review process called Premarket Notification or 510(k) to demonstrate to FDA that the devices is substantially equivalent to a legally marketed predicate device. Novel or high risk devices must seek FDA approval through a more burdensome approach known as the Premarket Approval (PMA) process. Other, less common regulatory pathways include:

- *De Novo* for low risk devices for which there is no direct precedent
- *Humanitarian Device Exemption (HDE)* for devices intended to benefit patients in the treatment and diagnosis of diseases or conditions that affect (or are manifested in) fewer than 4000 individuals in the US per year
- *Investigation Device Exemption (IDE)* for devices that are the object of a clinical investigation
- *Product Development Protocol (PDP)* for class III devices using well established technology
- *Custom Device Exemption (CDE)* for devices created or modified in order to comply with the order of an individual physician or dentist, subject to certain restrictions

Although many Class I and a few Class II devices are exempt from premarket notification [510(k)] requirements, these devices are not exempt from other general controls. With the exception of a few exemptions, all medical devices must be manufactured under a quality assurance program, be suitable for the intended use, be adequately packaged and properly labeled, and have establishment registration and device listing forms on file with the FDA. The Quality System Regulation's current good manufacturing practice requirements are intended to ensure that finished medical devices are safe and effective and compliance with the Food, Drug & Cosmetic Act. Moving manufacturing away from established manufacturing sites and into the clinical setting will require consideration of these regulatory factors in order to maintain compliance with the existing Quality System Regulation.

The use of additive manufacturing for medical devices and the associated uncertainty of how the technology can affect the safety and effectiveness of products led to the creation of the Additive Manufacturing Working Group by FDA.[37] This workgroup held a public workshop in October of 2014 entitled "Additive Manufacturing of Medical Devices: An Interactive Discussion on the Technical Considerations of 3D Printing," to obtain input from stakeholders. Topics discussed included best practices for validation and verification, technical challenges, future use of bioprinting (3D printed tissue engineered biologics), and printing of pharmaceuticals. Details of this meeting, including minutes are available on the FDA website.[38] Following this meeting, an FDA draft guidance document was released entitled "Technical Considerations for Additive Manufactured Devices."[39] This draft guidance document represents, FDA's initial thinking on technical considerations specific to devices using additive manufacturing and broadly covers design and manufacturing and device testing considerations. This guidance document does not address point-of-care manufacturing or bioprinting. A separate guidance document is expected

[37] M. Di Prima, J. Coburn, D. Hwang, J. Kelly, A. Khairuzzaman, L. Ricles, Additively manufactured medical products – the FDA perspective, 3D Printing in Medicine, 2 (2016) 1-6.
[38] http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm397324.htm
[39] *See* www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/-UCM499809.pdf.

that will cover the agency's thinking on who the manufacturer is and where manufacture occurs when 3-D printing is used. It is noteworthy that FDA guidance acknowledges the specific technical challenges associated with additive manufacturing, FDA considers additive manufacturing as an enabling technology, like CNC (computer numerical control) machining.

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