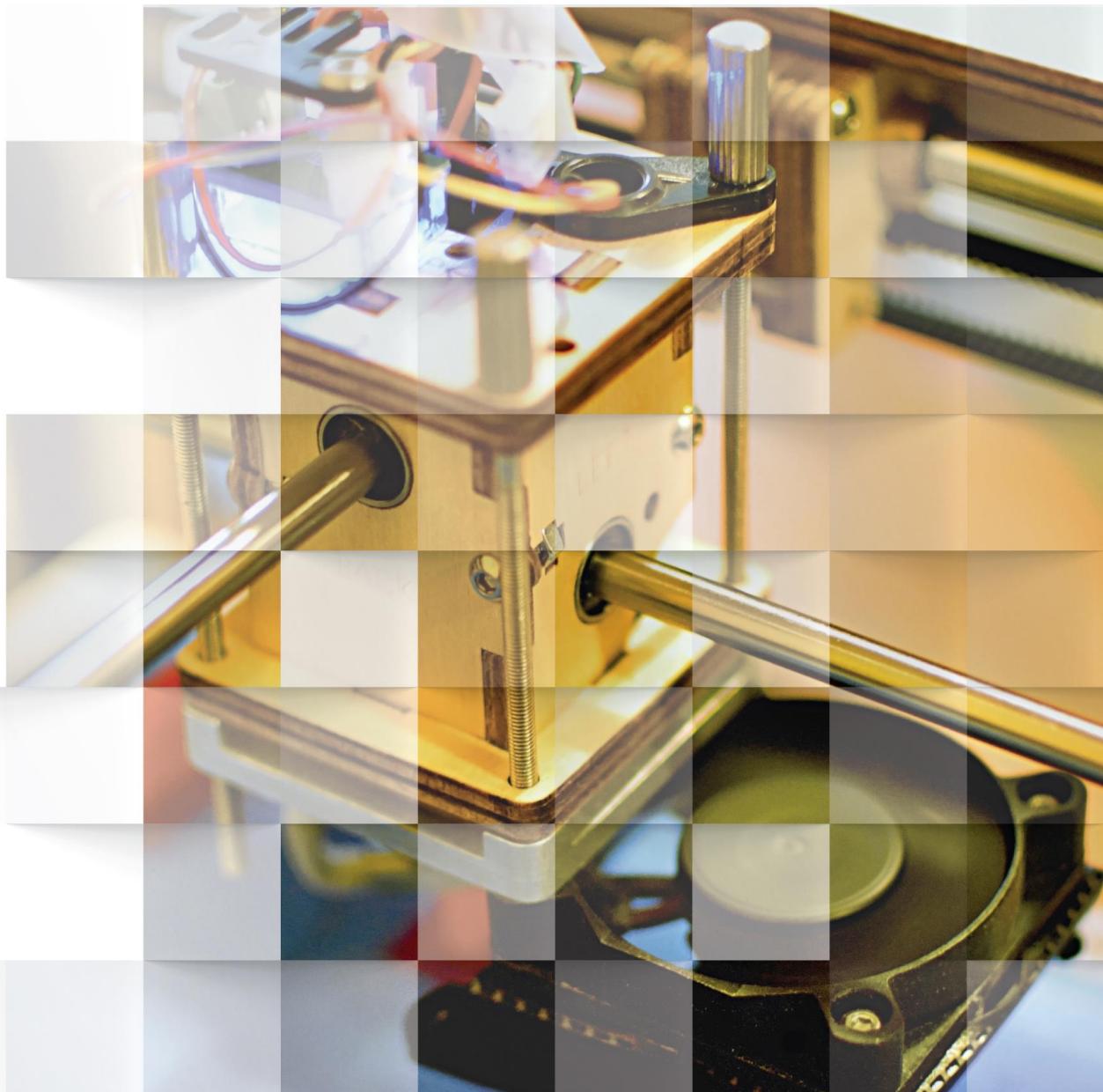


# 3D Printing of Manufactured Goods: An Updated Analysis

Second Edition  
December 2016



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# Letter from the Editors

Last year Reed Smith published a comprehensive white paper—*3D Printing of Medical Devices: When a Novel Technology Meets Traditional Legal Principles*—examining the legal issues associated with 3D printing of medical devices. Since that time, 3D printing has become even more widespread in the medical realm as well as the marketplace as a whole. Almost daily, a new 3D printed product is being designed, marketed, or sold.

This white paper, *3D Printing of Manufactured Goods: An Updated Analysis*, complements and expands on the issues raised by the first edition and examines the legal ramifications and risks associated with all aspects of 3D printing and the different products that this novel technology is capable of creating. While the technology is still in its infancy and the law is untested in many respects, understanding the legal issues is the first step to avoiding potential pitfalls for anyone associated with 3D printing, from designers, to manufacturers, to sellers, to consumers.

The chapters that follow include a wide range of developing legal, safety, and security issues:

- Constitutional Issues (regarding 3D printed guns)
- Commercial Litigation
- Product Liability
- 3D Printing/Component Parts/Raw Materials
- Insurance Issues
- Intellectual Property Issues
- Data Privacy
- Environmental Safety

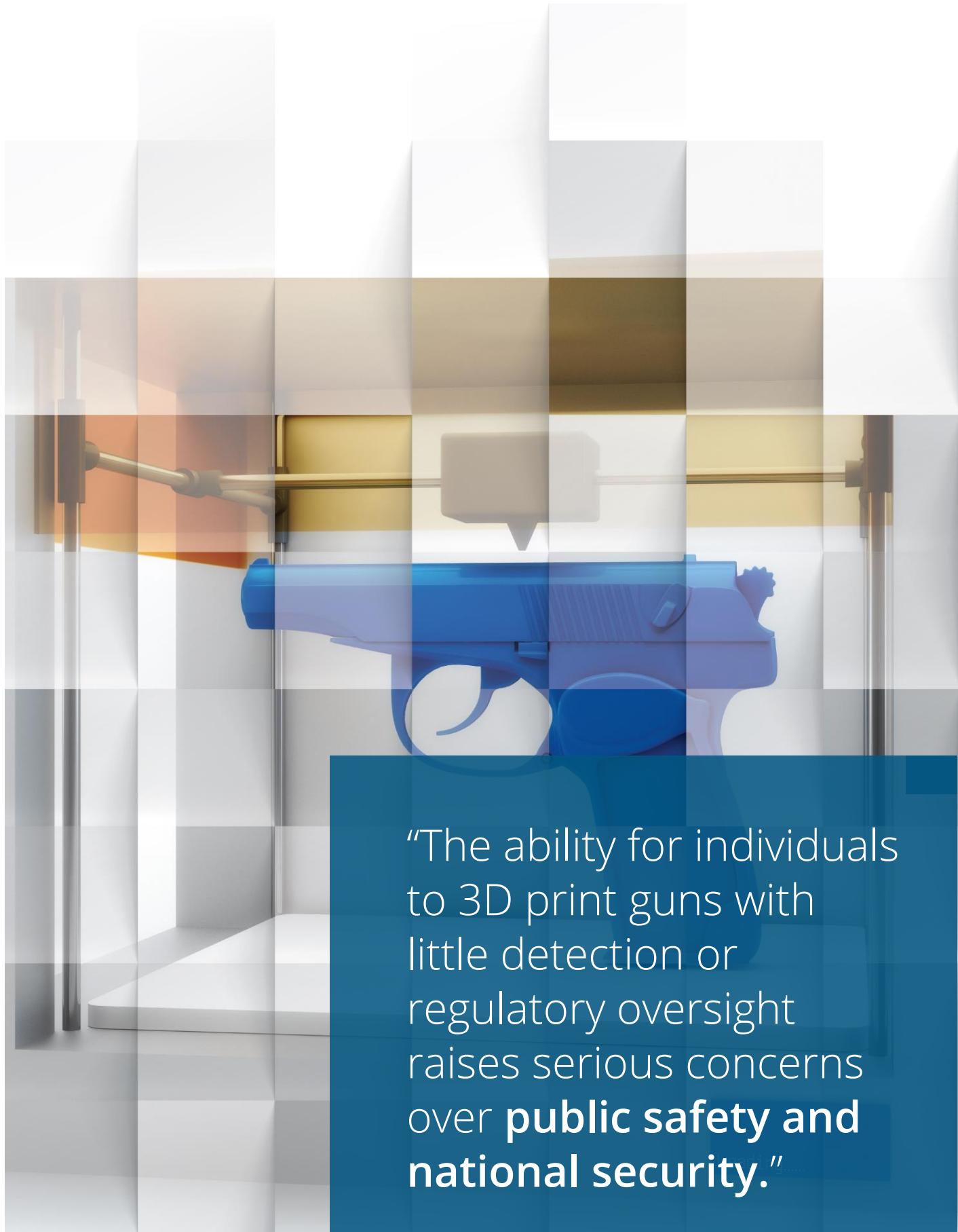
This is a truly collaborative work with contributions of many of our Reed Smith colleagues. It includes chapter authors Jim Beck, Chris Healy, Todd Maiden, Marilyn Moberg, Tracy Quinn, Bob Roth, John Schryber, Matthew Shiels, Mark Francis, David Krone, Michael Mandell, Jennifer Schramm, Johnathan Gershon, and contributions from Jonathan Kiel, Timothy Myers, Christian Page and Jason Van Sluytman from Exponent.

This white paper, along with the first edition, is meant to be a comprehensive, up-to-date resource, on the legal issues that are involved in 3D printing. As the law and technology develops, new and updated chapters will be released, with the prior editions serving as building blocks.

We hope that *3D Printing of Manufactured Goods: An Updated Analysis* provides readers with valuable guidance as 3D printing technology and the law surrounding it continues to develop and evolve. We welcome any comments or questions, which can be sent to [3Dprintingmedicaldevices@reedsmith.com](mailto:3Dprintingmedicaldevices@reedsmith.com)

Thank you.

**Lisa Baird, Colleen Davies,  
Matthew Jacobson and Farah Tabibkhoei**  
*Editors*



“The ability for individuals to 3D print guns with little detection or regulatory oversight raises serious concerns over **public safety and national security**.”

# 3D Printing: Public Safety, National Security and Constitutional Rights

Given that more than a million firearms are sold each month in the United States<sup>1</sup>, it should come as no surprise that individuals would use 3D printing technology to make guns, which can now be manufactured more rapidly, with greater customization, and less expensively than using traditional manufacturing methods. In September 2012, Defense Distributed became the first organization to publish a design for a functioning 3D printed plastic handgun for anyone with a 3D printer to replicate.<sup>2</sup> In November 2013, Solid Concepts manufactured the world's first 3D printed metal gun, which was sold for \$11,900.<sup>3</sup>

As 3D printing technologies advance, it will become more feasible for individuals to print firearms cheaply and quickly from the comfort of their own homes. 3D printing potentially allows anyone with a 3D printer to discretely manufacture a gun without going through a background check or registering the gun. A 3D printed gun may not even be detected by a metal detector if it is printed using non-metal materials, such as plastic.

In 1988, Congress passed the Federal Undetectable Firearms Act<sup>4</sup>, requiring that any non-metal gun contain a metal insert. The Federal Undetectable Firearms Act was passed over concerns that the Glock 17, a handgun with a plastic polymer grip and frame, could be smuggled past metal detectors by terrorists<sup>5</sup>; however, it also applies to 3D printed non-metal guns. Although the risks associated with non-metal weapons are not new, there is increased scrutiny of gun safety with the rise of 3D printing. In 2015, Congressman Steve Israel of New York introduced the Undetectable Firearms Modernization Act,

which would ban 3D printed guns altogether. To date, however, the bill has received little traction in Congress.<sup>6</sup>

The ability for individuals to 3D print guns with little detection or regulatory oversight raises serious concerns over public safety and national security. In August 2016, the TSA confiscated a 3D printed gun and five .22-caliber bullets from a passenger's carry-on bag at a Reno, Nevada, airport.<sup>7</sup> Given that the United States has one of the highest rates of gun violence in the world<sup>8</sup>, the proliferation of unregulated and untraceable weapons could potentially exacerbate the problem.

In response to this perceived threat, states have begun to pass legislation aimed at protecting against the risks of 3D printed guns. In December 2013, Philadelphia became the first city to outlaw 3D printed guns without a license.<sup>9</sup> On July 22, 2016, California Governor Jerry Brown signed California Assembly Bill No. 857, which will become effective in July 2018. This bill requires that prior to manufacturing or assembling a firearm, a person must: (1) apply to the Department of Justice for a unique serial number, (2) engrave or permanently affix the serial number within 10 days of manufacturing or assembling

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<sup>1</sup> Josh Sanburn, This Year's Gun Sales Could Set Record for U.S., *Time*, Dec. 7, 2015, <http://time.com/4138559/gun-sales-san-bernardino-mass-shooting/>

<sup>2</sup> Memorandum Of Points And Authorities In Support Of Plaintiffs' Motion For Preliminary Injunction at 5, *Defense Distributed, et al., v. United States Department of State, et al.*, No. 15-CV-372-RP (W.D. Tex. May 11, 2015).

<sup>3</sup> John Biggs, Solid Concepts Announces Another 3D-Printed Metal Gun, TechCrunch, Oct. 27, 2014, <https://techcrunch.com/2014/10/27/solid-concepts-announces-another-3d-printed-metal-gun/>

<sup>4</sup> 18 U.S.C. § 922(p).

<sup>5</sup> Constance Crooker, Gun Control and Gun Rights (Historical Guides to Controversial Issues in America) at 93 (2003).

<sup>6</sup> Andy Greenberg, Bill to Ban Undetectable 3D Printed Guns Is Coming Back, *Wired*, April 6, 2015, <https://www.wired.com/2015/04/bill-ban-undetectable-3-d-printed-guns-coming-back/>

<sup>7</sup> Julia Zorthian, Airport Security Finds 3D Printed Gun in Carry-On at Reno Airport, *Time*, Aug. 11, 2016, <http://time.com/4448069/tsa-3d-printed-gun-reno/>.

<sup>8</sup> Robert Preidt, How U.S. gun deaths compare to other countries, CBS News, February 3, 2016, <http://www.cbsnews.com/news/how-u-s-gun-deaths-compare-to-other-countries/>

<sup>9</sup> The Philadelphia Code § 10-2002.

the firearm, (3) notify the department that the serial number has been engraved or permanently affixed, and (4) provide sufficient information to identify the firearm, the owner of the firearm, and the unique serial number that was engraved or permanently affixed.<sup>10</sup>

Furthermore, it provides that a plastic firearm must contain 3.7 ounces of stainless steel embedded in it to allow detection of the gun by a metal detector.<sup>11</sup> As 3D printers become more accessible, it seems inevitable that these weapons will be subject to increased regulatory oversight and enhanced scrutiny at all levels of government.

## The Fine Line Between National Security and Constitutional Rights

The ability to upload and publicly disseminate a design file for a 3D printed gun over the internet to millions of people within seconds has raised national security concerns. Efforts by the government to limit the sharing of 3D printable digital designs to protect national security have been met with concerns of infringement on constitutional rights.

In June 2015, the State Department's Directorate of Defense Trade Controls ("DDTC") found that computer-aided design ("CAD") files, or digital designs, of 3D printed guns were "defense articles"<sup>12</sup> under the International Traffic in Arms Regulations ("ITAR")<sup>13</sup> of the Arms Export Control Act<sup>14</sup> (the "Act").<sup>15</sup> The Act prohibits unauthorized exports of defense articles, which is punishable by up to 20 years in prison, fines of up to \$1 million, and civil penalties of up to \$500,000.<sup>16</sup> Accordingly, the DDTC required Defense Distributed, a corporation organized to produce, publish, and distribute information and knowledge related to the digital manufacture of arms, to remove the digital gun designs from its webpage.

The DDTC required that the designs be removed to restrict access by foreign malevolent groups. The DDTC explained that the digital designs for 3D printed

weapons could be used abroad "in an assassination, for the manufacture of spare parts by embargoed nations, terrorist groups, or guerrilla groups, or to compromise aviation security overseas."<sup>17</sup> The DDTC did not, however, prohibit the transmission of the CAD files to U.S. citizens. In fact, by restricting access to the designs to persons with a U.S. IP address, one could potentially avoid liability for "exportation" of files under the Act.<sup>18</sup>

Defense Distributed filed a lawsuit May 6, 2015, in the United States District Court in the Western District of Texas<sup>19</sup>, challenging the DDTC's determination that it must remove the CAD files on the grounds that the DDTC was violating the company's First Amendment right to freedom of speech and Second Amendment right to manufacture firearms. Defense Distribute also sought a preliminary injunction allowing it to publish the digital designs, arguing that in addition to violating its constitutional rights, (1) the Act is not applicable to privately generated, unclassified speech and (2) posting CAD files on the internet is not an "export" under the Act.<sup>20</sup>

The district court denied Defense Distributed's request for a preliminary injunction, and found that Defense Distributed did not establish that (1) a threatened injury outweighed the harm to the State Department, (2) the preliminary injunction would not disserve the public interest, or (3) its case was likely to succeed on its claims.<sup>21</sup> Although there likely is a First Amendment interest in publishing CAD files, and a Second Amendment right to manufacture firearms, ITAR and the Act were constitutional, according to the court, because they survived intermediate scrutiny. Specifically, the court found that there is a substantial governmental interest in regulating the dissemination of military information abroad, and that since there was no prohibition against domestic communications, the regulations were no more restrictive than necessary.

Defense Distributed appealed this ruling to the Fifth Circuit.<sup>22</sup> On September 20, 2016, the Fifth Circuit

<sup>10</sup> Cal. Penal Code § 29180(b).

<sup>11</sup> Cal. Penal Code § 29180(b)(2)(B).

<sup>12</sup> The term "defense articles" includes technical data that relates to items designated under the United States Munitions List ("USML").

<sup>13</sup> 22 C.F.R. 120-130.

<sup>14</sup> 22 U.S.C. 2778.

<sup>15</sup> Defendants' Opposition To Plaintiffs' Motion For A Preliminary Injunction at 6, *Def. Distributed, et al., v. United States Department of State, et al.*, No. 15-CV-372-RP (W.D. Tex. June 10, 2015).

<sup>16</sup> 22 U.S.C. 2778(c) and (e).

<sup>17</sup> Defendants' Opposition To Plaintiffs' Motion For A Preliminary Injunction at 10, *supra*, n. 15.

<sup>18</sup> *Id.* at 6.

<sup>19</sup> Complaint, *Def. Distributed, et al., v. United States Department of State, et al.*, No. 15-CV-372-RP (W.D. Tex. May 11, 2015).

<sup>20</sup> Memorandum Of Points And Authorities In Support Of Plaintiffs' Motion For Preliminary Injunction.

<sup>21</sup> *Def. Distributed v. United States Dep't of State*, 121 F.Supp.3d 680 (W.D. Tex. Aug. 4, 2015).

<sup>22</sup> *Def. Distributed v. United States Dep't of State*, 838 F.3d 451 (5th Cir. 2016).

affirmed the district court's denial of the preliminary injunction.<sup>23</sup> The appellate court explained that providing U.S. citizens with access to 3D printing files is legal, and that this case concerns "Defense Distributed's desire to share all of its 3D printing... files online, available without cost to anyone located anywhere in the world, free of regulatory restrictions."<sup>24</sup> The Fifth Circuit declined to address whether Defense Distributed was likely to prevail on the merits, and instead affirmed the district court's ruling because the government's "exceptionally strong interest in national defense and national security outweighs [Defense Distributed]'s very strong constitutional rights."<sup>25</sup> The Fifth Circuit found that if the preliminary injunction were denied but Defense Distributed ultimately prevailed in obtaining a permanent injunction, Defense Distributed would only have its constitutional rights violated temporarily. However, the court noted that the 3D printing files previously published by Defense Distributed are now being hosted by foreign web-pages, such as Pirate Bay, and thus will likely remain online essentially forever. Therefore, if the preliminary injunction was granted but Defense Distributed ultimately failed to obtain a permanent injunction, the harm to national security and national defense by Defense Distributed's releasing of the files would last forever.<sup>26</sup>

Notably, the Fifth Circuit's ruling did not address whether there is a Second Amendment right to 3D print firearms or whether CAD files are expressive speech under the First Amendment. On November 4, 2016, Defense Distributed filed a Petition for Rehearing En Banc.<sup>27</sup> Defense Distributed argues that the Fifth Circuit panel was required to consider the likelihood of Defense Distributed succeeding on the merits, because without doing so, it could neither fully assess whether Defense Distributed suffered irreparable harm, nor balance the equities.<sup>28</sup> Defense Distributed further contends that the government cannot serve the public interest by violating the Constitution.<sup>29</sup> If a majority of the active Fifth Circuit judges vote for an en banc review, the case

will be reheard by all active Fifth Circuit judges.<sup>30</sup> If the Petition is denied, the merits of whether Defense Distributed is entitled to a permanent injunction will be litigated in the district court. For now, one can lawfully distribute 3D printed digital designs online with the exception of digital designs for 3D printed guns, which is prohibited because of national security concerns, and the risk that the designs will end up in foreign hands and result in a serious threat to national security.

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<sup>23</sup> *Id.* at 453.

<sup>24</sup> *Id.* at 455.

<sup>25</sup> *Id.* at 458.

<sup>26</sup> *Id.* at 460.

<sup>27</sup> Petition for Rehearing En Banc, *Distributed, et al., v. United States Department of State, et al.*, No. 15-15-50759 (5th Cir. 2015 Nov. 4, 2016).

<sup>28</sup> *Id.*

<sup>29</sup> Petition for Rehearing En Banc, *Distributed, et al., v. United States Department of State, et al.*, No. 15-15-50759 (5th Cir. 2015 Nov. 4, 2016).

<sup>30</sup> FED. R. APP. P. 35.



3D

“...domestic **choice-of-law issues are liable to arise** frequently where a CAD program is hosted in one state and downloadable in all 50 states.”

# Commercial Litigation Considerations Specific to 3D Printed Objects

Commercial litigation case law in the 3D printing world is virtually nonexistent because of the novelty of this industry. It will take some time before the issues discussed below are litigated and a body of law develops.

## State of the Law

3D scanning and printing provide a unique opportunity to offer customized goods to a variety of industries.<sup>31</sup> 3D printing allows for the quick, easy and cheap manufacture of custom goods.<sup>32</sup> The software of a 3D printer can be endlessly modified and it can produce "just about anything"; but at this time is typically most cost-effective in areas where unique circumstances need to be met, e.g., for hearing aids, dental implants, medical devices or defense equipment.<sup>33</sup>

3D printing does not drastically change the relationship between designers and manufacturers. There is still ultimately one individual or group of individuals who creates and engineers a product that is then produced, albeit through a different method, by a "manufacturer." The retailer is sometimes left out of that equation, and as a result of that and who the end manufacturer is (frequently a civilian), there is a redistribution of risk among the parties to the manufacturing process. Consequently, it is important that parties to commercial contracts reevaluate, among other issues, choice of law, intellectual property, tax, confidentiality, indemnification, covenants and quality standards, representations and warranties, and insurance provisions.<sup>34</sup> This chapter addresses choice of law, confidentiality, indemnification and insurance aspects of the 3D legal landscape.

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<sup>31</sup> Matthias Holweg, June 23, 2015, *The Limits of 3D Printing*, <https://hbr.org/2015/06/the-limits-of-3d-printing>

<sup>32</sup> *The Economist*, April 21, 2012, A Third Industrial Revolution, <http://www.economist.com/node/21552901>

<sup>33</sup> Id., see also Laura Griffiths, February 3, 2015, *3D Systems Awarded Over \$1M in 3D printing Research Contracts*, <http://www.tctmagazine.com/3D-printing-news/3d-systems-awarded-over-1-million-in-research-contracts/>

<sup>34</sup> Product liability, intellectual property, import/export and taxation issues will be addressed by other chapters in this white paper.

## Choice of Law

Every object produced by a 3D printer begins its design process with a CAD file that forms the "blueprint" for the object ultimately produced. The CAD file can be downloaded from anywhere by anyone who either pays for it or is granted open access. The downloading party then prints the final object using the 3D printer and either keeps it or sells it.

For U.S. clients, there isn't so much concern about international conflict of laws because most all online platforms dedicated to hosting CAD files are based in America and are governed by the laws of the United States.<sup>35</sup> However, domestic choice-of-law issues are liable to arise frequently where a CAD program is hosted in one state and downloadable in all 50 states. Current hosting sites, such as Thingiverse, Makerbot and 123D, all have some form of choice-of-law language in their terms of use, applicable to registered users of their websites (who may download CAD files). Examples include:

### Thingiverse:

"These Terms of Use shall be governed by the laws of the State of New York without giving effect to any conflict of laws principles that may require the application of the law of another jurisdiction ... Notwithstanding anything to the contrary, Company may seek injunctive relief in any court having jurisdiction to protect its intellectual property or confidential or proprietary information ... Any action or proceeding relating to a claim or controversy at law or equity that arises out of or relates to these Terms of Use or the Site or Services (a "Claim") must be

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<sup>35</sup> Dinusha Mendis & Devide Secchi: *A Legal and Empirical Study of 3D Printing Using Online Platforms and an Analysis of User Behaviour*, Bournemouth University, UK, March 2015 [https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/549045/Study-I.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/549045/Study-I.pdf)

brought in a federal or state court located in New York, New York, and each party irrevocably submits to the exclusive jurisdiction and venue of any such court in any such action or proceeding, unless such claim is submitted to arbitration as set forth below.

Notwithstanding anything to the contrary, Company may seek injunctive relief in any court having jurisdiction to protect its intellectual property or confidential or proprietary.”

<http://www.thingiverse.com/legal> (11.2).

#### **GrabCAD:**

“Any action or proceeding relating to a claim or controversy at law or equity that arises out of or relates to these Terms of Use or the Site or Services (a “Claim”) must be brought in a federal or state court located in New York, New York, and each party irrevocably submits to the exclusive jurisdiction and venue of any such court in any such action or proceeding, unless such claim is submitted to arbitration as set forth below. Notwithstanding anything to the contrary, Company may seek injunctive relief in any court having jurisdiction to protect its intellectual property or confidential or proprietary.” <http://grabcad.com/terms>

#### **Autodesk:**

“If you have an existing contractual relationship with Autodesk, the governing law and forum with respect to any disputes arising under or in connection with these Terms (including any of our policies referred to herein) and/or the Site will be the law and forum set forth in your existing contract with Autodesk. If you have more than one existing contract with Autodesk, the governing law and forum with respect to any disputes arising under or in connection with these Terms (including any of our policies referred to herein) and/or the Site will be the law and forum set forth in your most recent contract with Autodesk.

If you do not have an existing contractual relationship with Autodesk, then (a) you agree to the non-exclusive jurisdiction of an appropriate state court in Marin County, California, or an appropriate federal court located in San Francisco, California for any action or proceeding arising out of or related to these Terms; and (b) except to the extent expressly provided in the following paragraph, any disputes arising under or in connection with these Terms (including any of our policies referred to herein) and/or the Site shall be governed by and construed in accordance with the laws of the State of California in the United States without regard to applicable conflict of law provisions. Specifically excluded from application to these Terms is that law known as the United Nations Convention on the International Sale of Goods.”

<http://www.autodesk.com/company/legal-notices-trademarks/website-terms-of-use/terms-of-use-english>

As 3D printing becomes more common, and more CAD models become available, sellers and distributors of those models should protect themselves with choice-of-law language convenient to them and suitable for their specific needs. If and when CAD design/3D printing becomes a more global venture, contracts will need to take into consideration the interplay of international law and conventions.<sup>36</sup>

#### **Confidentiality**

3D printing facilitates rapid prototyping and requires the use of mutual confidentiality and nondisclosure agreements between the originating designer, CAD modeler and the printer.<sup>37</sup> 3D printers, especially those capable of high-volume output, are frequently quite expensive. Therefore, parties seek out CAD designers and 3D printing companies to generate models for them. Individuals making use of such services should be sure that any agreement contains language granting only a “non-exclusive, royalty free worldwide transferable license” that is strictly limited in use to modification for purposes of manufacturing the 3D model only. The agreement should also include provisions prohibiting the printer from discussing the project with third parties, sharing the print on any website, or permitting onsite visits during the printing process. Agreements should contain provisions assuring that all failed prints are mechanically shredded prior to fulfillment. It is also critical that anyone outsourcing any CAD design work verify that a non-disclosure agreement exists between the CAD designer and the 3D printer.<sup>38</sup>

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<sup>36</sup> See *supra*, note 5.

<sup>37</sup> Oliver Hertzfeld, *Protecting 4D Printing Designs and Objects: Part Three*, June 12, 2013, <http://www.forbes.com/sites/oliverherzfeld/2013/06/12/protecting-3d-printing-designs-and-objects-part-three/#2f24af311539>

<sup>38</sup> See e.g., 3D Print RVA, <http://3dprintrva.com/confidentiality-ndas/>

## Indemnification

Manufacturers must ensure that upstream and downstream agreements provide proper provisions regarding indemnification.<sup>39</sup> CAD designers or providers need to ensure that the risk is spread properly among themselves and the retailer, or even the individual who prints the 3D product.<sup>40</sup>

Numerous potential actors are involved in the chain of manufacturing: inventors, 3D model designers, CAD hosting sites, 3D printing companies and end users.<sup>41</sup> The potential for misuse of user-generated designs; misappropriation of other parties' designs, including the modification and printing of designs in violation of various intellectual property laws; and user licensing agreements is nearly endless.

## Insurance Implications

3D printing technology raises numerous risks, all of which will need to be insured.<sup>42</sup> Insureds that are marketing, selling or insuring 3D printed products will need to implement sound strategies for managing the risks unique to these products.<sup>43</sup> Because 3D printed products have the potential to spread quickly across new markets, companies will need to look at global coverage where products are sold internationally and across markets. Some suggested strategies for managing risk include: (1) ensuring traceability of designs, raw materials and components (in particular, placing physical identifiers on products in the CAD model itself that are replicated on printing); (2) working with risk managers to implement solutions early and predictively; and (3) the addition of recall insurance and expansion of worldwide coverage.<sup>44</sup> Insurance issues are covered more in depth in the insurance chapter below.

<sup>39</sup> Liquid Litigation Management Blog, June 14, 2016, *3-D Printing Redesigning Products Liability Law* <http://www.liquidlitigation.com/blog/3-d-printing-redesigning-products-liability-law/> (discussing indemnification in terms of intellectual property litigation)

<sup>40</sup> Lucas S. Osborn, June 29, 2016, *Doctrinal Quandaries with 3D Printing and IP*, <http://apps.americanbar.org/litigation/committees/intellectual/articles/summer2016-0716-doctrinal-quandaries-with-3d-printing-intellectual-property.html>

<sup>41</sup> See, e.g. [http://www.shapeways.com/terms\\_and\\_conditions](http://www.shapeways.com/terms_and_conditions) for sample indemnification provision by CAD hosting company.

<sup>42</sup> Karishma Paroha, June 2, 2014, *3-D Printed Products, Product Liability & Insurance Implications*, <http://www.kennedyslaw.com/article/3dprintedproducts/>

<sup>43</sup> Id.

<sup>44</sup> Id.

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“Although there is uncertainty related to how a court may approach such a lawsuit, what is certain is that 3D printing will present **challenges to traditional tort liability.**”

# Product Liability

As 3D printing becomes more commonplace, it is only a matter of time before courts are faced with the quandary of whether traditional tort liability principles will apply to 3D printed products and manufacturing techniques, or whether new laws will need to be created.<sup>45</sup> As of the date of this White Paper, the authors are unaware of any court faced with a product liability lawsuit where the product is manufactured using additive manufacturing techniques. Although there is uncertainty related to how a court may approach such a lawsuit, what is certain is that 3D printing will present challenges to traditional tort liability.

With access to a 3D printer and electronic CAD files, anyone can manufacture a product. Since traditional product liability is keyed to the manufacturing function, it is ill-suited to address products manufactured by non-traditional sources, such as 3D printing stores, public libraries, or hospitals. It is also ill-suited to address non-traditional products, such as computer files. Moreover, traditional strict liability would provide no relief at all to an end-user injured by a 3D printed product manufactured by the user's own 3D printer—a situation that, now rare, will become increasingly commonplace as 3D printers follow home computers into the mass market.

The complexity of these novel issues only grows when the 3D printed products are prescription medical devices and drugs, to which one must add the overlay and interplay of FDA regulation. FDA has already become more involved with 3D printed devices and drugs, holding workshops, webinars, and issuing a draft guidance for medical device manufacturers who are using additive manufacturing.<sup>46</sup> While FDA is becoming

more involved in this new technology, it has still not addressed truly novel 3D printed techniques, such as bioprinting, the printing of human cells and tissue, and point-of-care manufacturing—the printing of devices in hospitals and doctor's offices. Nor has FDA approved any medical devices using its Premarket Approval ("PMA") process; or in other words, new devices that are not substantially similar to anything else on the market. As these new techniques and devices make their way through FDA's regulatory framework, more guidances and regulations are expected.

As 3D printing technology develops and 3D printed products inexorably enter the marketplace, tort law will unquestionably need to develop as well. Understanding the relevant issues and anticipating the future of tort law should be of interest not only to traditional and untraditional 3D printing manufactures, but also to those who manufacture and sell 3D printers, the internet file sharer, the 3D printing service provider, the raw materials supplier, the 3D printing hobbyist, and even the end-user.<sup>47</sup>

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<sup>45</sup> This chapter contains substantially the same concepts as those published and expounded on in James M. Beck & Matthew D. Jacobson, *3D Printing: What Could Happen To Products Liability When Users (And Everyone In Between) Become Manufacturers*, 18 Minn. J.L. Sci. & Tech. \_\_ (forthcoming Jan. 2017).

<sup>46</sup> See Technical Considerations for Additive Manufactured Devices Draft Guidance for Industry and Food and Drug Administration Staff (May 10, 2016), <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM499809.pdf>. For a summary of this draft guidance, see Drug & Device Law, May 12, 2016,

<https://www.druganddevicelawblog.com/2016/05/guest-post-highlights-of-fda-draft.html> (last visited Sept. 18, 2016).

<sup>47</sup> This chapter of the White Paper supplements the Tort Liability chapter in *3D Printing of Medical Devices: When a Novel Technology Meets Traditional Legal Principles*, Reed Smith (1st ed. 2014), [https://www.reedsmith.com/files/Publication/130448b9-7565-4295-a697-5c5d7c6eb516/Presentation/PublicationAttachment/9ba9b53c-2009-488d-ba91-5cc5a19a38f7/3d-printing-white-paper\\_79444049.pdf](https://www.reedsmith.com/files/Publication/130448b9-7565-4295-a697-5c5d7c6eb516/Presentation/PublicationAttachment/9ba9b53c-2009-488d-ba91-5cc5a19a38f7/3d-printing-white-paper_79444049.pdf).

## Tort Liability and 3D Printing

Product liability itself is a relatively new legal area, arising largely from the perceived need to adapt the common law to account for the rise of mass-produced products and long, impersonal supply chains, and containing a mixture of tort and contract law. Since the early 1960s, product liability has slowly been developing, and is still developing as of today. While traditional negligence principles apply to products, claimants in a case alleging a defect in the product's design, manufacture, or warnings, can also bring claims under strict liability doctrines.

Traditional product liability principles may or may not apply to 3D printed products, depending on where and how the product is made and sold.<sup>48</sup>

### A. Strict Liability

Strict liability, whether under the Second or Third Restatement of Torts, is based on the defendant being a manufacturer or seller of a product.<sup>49</sup> To the extent that traditional manufacturers use additive manufacturing as simply a new production technique; manufacture the 3D printed products at a central hub; and continue to sell 3D printed products through traditional supply chains—liability for such products will not change significantly. The 3D printed products—although made differently—will not be considered any different in the eyes of the law. To the extent, however, that 3D printers are operated by other entities—specialty 3D printing stores, professionals using products in the performance of their services, parts suppliers, hobbyists, and most disruptively, end-use consumers—strict liability is unlikely to provide remedies to persons injured by 3D printed products. Moreover, if the sale is of a CAD file that can be printed anywhere, the product may not be the end result, but the computer file itself. This causes numerous legal issues, as well as the practical problem of the CAD file creator not being amenable to jurisdiction, not having assets available to satisfy judgments, or in some cases being unidentifiable. The advent of 3D printing has multiplied the number of possible “products” and “manufacturers,” and thereby is poised to scramble the

<sup>48</sup> For a more detailed background of tort liability law and its history, *see id.*

<sup>49</sup> Restatement (Second) of Torts, section 402A is titled “special liability of seller of product for physical harm,” and provides that “One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if the seller is engaged in the business of selling such a product.” Restatement (Second) of Torts § 402A(1)(a) (1965). On the other hand, the Restatement (Third) of Torts defines strict liability as “[o]ne 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.” Restatement (Third) of Torts, Products Liability § 1 (1998).

traditional “manufacturer”-based chain-of-sale concept on which strict liability has been based. Issues that arise with the intersection of 3D printing and tort liability include (1) what is the “product”; (2) what is a “sale”; (3) who is a “manufacturer”; (4) product identification; and (5) redefining manufacturing, design, and warnings defects.

#### 1. What is the “product”?

A physical object produced through 3D printing likely will fit within the traditional concept of “product”—as would any physical object produced by other manufacturing techniques. However, the CAD file used to produce that physical object is a different story. Can this software also be considered a “product”? Purely electronic data, such as code, does not constitute a “product” under the Restatement (Third) of Torts, which defines a product as “tangible personal property distributed commercially for use or consumption.”<sup>50</sup> The Restatement’s definition is based entirely on the law’s historic aversion to imposing strict liability on printed information, particularly in books and other publications,<sup>51</sup> but it has been extended to computer software.<sup>52</sup> Courts across the country have also held that publishers cannot be liable for “informational defects” in published material pursuant to the First Amendment.<sup>53</sup> On the other hand, whether or not something is tangible does not necessarily dictate whether it qualifies as a product for strict liability purposes. For example, courts have held that certain

<sup>50</sup> Restatement (Third) of Torts: Prods. Liab. § 19 (1999) (emphasis added). *Accord* Raymond T. Nimmer, *Law of Computer Technology* § 12:31 (“Software as a Product”) (2015) (“An issue largely left unaddressed in modern case law concerns whether computer software qualifies as a tangible “product”. . . . While the issue has yet to be addressed by courts, the proper answer holds that most software do not fall within the purview of product liability law under this definition.”).

<sup>51</sup> See Restatement (Third) of Torts: Prods. Liab. § 19, comment d. *See also*, e.g., *Winter v. G.P. Putnam’s Sons*, 938 F.2d 1033, 1039 (9th Cir. 1991); *Lewin v. McCreight*, 655 F. Supp. 282, 284 (E.D. Mich. 1987) (applying Michigan law and holding that publisher did not have duty to warn of “defective ideas” supplied by third-party authors); *Way v. Boy Scouts of Am.*, 856 S.W.2d 230, 239 (Tex. App. 1993) (holding that the information conveyed by magazine and supplement were not products within the meaning of the Restatement (Second) of Torts).

<sup>52</sup> *Sanders v. Acclaim Entm’t, Inc.*, 188 F. Supp.2d 1264, 1278-79 (D. Colo. 2002) (computer games not products for strict liability purposes); *Wilson v. Midway Games, Inc.*, 198 F. Supp.2d 167, 173 (D. Conn. 2002) (interactive “virtual reality technology” not a “product for purposes of strict liability”); *James v. Meow Media, Inc.*, 90 F. Supp.2d 798, 810 (W.D. Ky. 2000) (“While computer source codes and programs are construed as ‘tangible property’ for tax purposes and as ‘goods’ for UCC purposes, these classifications do not indicate that intangible thoughts, ideas, and messages contained in computer video games, movies, or internet materials should be treated as products for purposes of strict liability.”), *aff’d*, 300 F.3d 683 (6th Cir. 2002).

<sup>53</sup> *See* Drug & Device Law, Apr. 7, 2011, <https://www.druganddevicelawblog.com/2011/04/on-suing-publishers.html>(last visited Sept. 18, 2016).

non-tangible items, such as electricity, qualify as products for purposes of imposing strict liability.<sup>54</sup> Maps and navigational charts, particularly in aeronautical context, have likewise been held to be products.<sup>55</sup> To date, case law is nonexistent on the question of whether the code for 3D printing designs constitutes a “product” for purposes of product liability.

A non-product liability case, *ClearCorrect Operating, LLC v. Int'l Trade Commission*,<sup>56</sup> addressed 3D printing digital files specifically, and held they are not material things. A manufacturer of 3D printed products was sued for importing CAD files used in 3D printing, allegedly in violation of the plaintiff's patent.<sup>57</sup> The Federal Circuit held that digital files used in 3D printing were not “articles” under the Tariff Act of 1930<sup>58</sup> because digital files were not “articles.”<sup>59</sup> Articles must be “material things.”<sup>60</sup> Since CAD files were not “articles” under the statute, no administrative authority existed to stop their importation.<sup>61</sup> The patent implications of this ruling are

<sup>54</sup> See Restatement (Third) of Torts: Prods. Liab. § 19, comment d (discussing general rule that “electricity only becomes a product only when it passes through a customer's meter”). See, e.g., *Smith v. Home Light and Power Co.*, 695 P.2d 788, 789 (Colo. 1984) (holding “electricity itself is a product”); *Schriner v. Penn. Power & Light Co.*, 501 A.2d 1128, 1133 (1985) (holding that “electricity can be a ‘product,’ within the meaning of § 402A”); *Stein v. S. Cal. Edison Co.*, 7 Cal. App. 4th 565, 571 (1992).

<sup>55</sup> See *Brockelsby v. United States*, 767 F.2d 1288, 1295 (9th Cir. 1985) (holding that an aeronautical chart “was a defective product for purposes of analysis under section 402A”); *Saloomey v. Jeppesen & Co.*, 707 F.2d 671, 676-77 (2d Cir. 1983) (holding that navigational charts were products under section 402A, and that mass production and marketing of charts required that the defendant bear the costs of accidents proximately caused by the charts).

<sup>56</sup> 810 F.3d 1283 (Fed. Cir. 2015).

<sup>57</sup> *Id.* at 1287.

<sup>58</sup> *Id.* at 1291-93 (construing 19 U.S.C. §1337).

<sup>59</sup> *Id.* at 1301-02.

<sup>60</sup> *Id.* at 1296.

<sup>61</sup> *Id.* at 1293-94. A similar ruling that computer code does not constitute a “product” was reached in *U.S. v. Aleynikov*, 676 F.3d 71 (2d Cir. 2012), construing the National Stolen Property Act (“NSPA”). The court held that proprietary computer source code was not a stolen “good” within the meaning of this 1948-era statute. *Id.* at 73. The NSPA criminalizes only the illicit movement of “goods, wares, merchandise, securities or money.” 18 U.S.C. § 2314. The would-be “good” was source code allegedly illegally uploaded by the defendant and transported across state lines. *Aleynikov*, 676 F.3d at 74. Source code could not be “goods,” “wares,” or “merchandise” under the statute, “[b]ased on the substantial weight of the case law, as well as the ordinary meaning of the words.” *Id.* Intellectual property alone is beyond the scope of the NSPA, which requires “some tangible property must be taken from the owner for there to be deemed a ‘good’ that is ‘stolen.’” *Id.* at 77 (citing *United States v. Bottone*, 365 F.2d 389, 393 (2d Cir. 1966)).

addressed in the IP chapter<sup>62</sup>; as to product liability, the extensive discussion in *ClearCorrect* suggests, by analogy, that digital files used in 3D printing may not themselves be “products.”<sup>63</sup>

A product liability case, *Corley v. Stryker Corp.*,<sup>64</sup> addressing a non-3D printed product, may also be instructive in determining whether an electronic file may be considered a “product.” Although the product in *Corley* was not 3D printed, the Class II medical device was customizable and used electronic files and patient-matched imaging data. The device was a “single-use, disposable, cutting guide[] designed and manufactured from patient imaging data (MRI/CT).”<sup>65</sup> The cutting guide was created by a software program from a three-dimensional model of the patient's anatomy using images obtained through an MRI or CT scan.<sup>66</sup> The programmable device allowed the patient's surgeon to make incisions tailored to the patient's specific anatomy and guided the positioning of certain other components.<sup>67</sup> The suit followed a limited recall because of “potential issues associated with internal processes for planning cases.”<sup>68</sup> *Corley* allowed a design-defect product liability cause of action to survive a motion to dismiss.<sup>69</sup> The “software used in creating each cutting guide [was] a necessary part of the cutting guide.”<sup>70</sup> Therefore, the plaintiff's allegations that the software was defective, “sufficiently alleged that the cutting guide used

<sup>62</sup> See Intellectual Property Issues, *infra*.

<sup>63</sup> On March 31, 2016, the Federal Circuit Court of Appeals issued an order denying petitions by the International Trade Commission (“ITC”) and Align Technology, Inc. seeking a rehearing en banc of the Federal Circuit's opinion. *ClearCorrect Operating, LLC v. Int'l Trade Comm'n*, 819 F.3d 1334 (Fed. Cir. 2016). The order was nearly unanimous, albeit with Judge Pauline Newman filing a lengthy dissent. *Id.* With a rehearing and potential reversal by the full Federal Circuit bench now officially off the table, only a reversal by the Supreme Court or an Act of Congress can bring digital transmissions within the ITC's jurisdiction as “products.”

<sup>64</sup> No. 6:13-CV-02571, 2014 WL 3375596 (W.D. La. May 27, 2014), *adopted*, 2014 WL 3125990 (W.D. La. July 3, 2014).

<sup>65</sup> See 510(k) summary for ShapeMatch Cutting Guide, available at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K122053> (follow “Summary” hyperlink).

<sup>66</sup> See *id.* See also *Corley*, 2014 WL 3375596, at \*1.

<sup>67</sup> See 510(k) summary for ShapeMatch Cutting Guide, available at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K122053> (follow “Summary” hyperlink).

<sup>68</sup> Class 1 Device Recall ShapeMatch Cutting Guides, available at, <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=115791>.

<sup>69</sup> *Corley*, 2014 WL 3375596, at \*4.

<sup>70</sup> *Id.*

during [plaintiff's] surgery was unreasonably dangerous in design due to the alleged software defects," and could sustain a product liability claim.<sup>71</sup>

*Corley* has implications for the software used to create similarly customized 3D printed medical devices, since both use electronic files and patient-matched images. Courts may find the reasoning of *Corley* persuasive and hold that since the file is part and parcel of the completed product, it is therefore subject to product liability laws. Thus, if the software or electronic file is defective, the entire system is defective. Notably, *Corley* did not involve separate manufacturers for the device and the software, which could complicate the analysis.

Based on the reasoning in *ClearCorrect* and *Corley*, it is still uncertain if courts will find that electronic files are products under the Restatement of Torts. Given the lack of case law on the issue and the differing opinions in analogous cases, there may be different rulings in different jurisdictions, which may only compound the legal analysis. If electronic files are considered "products," then the designers and sellers of such files may be liable in strict liability. However, if electronic files are not "products" because of their intangibility, injured parties cannot pursue strict liability claims, which require proof of a manufacturing defect, design defect, or failure to warn with respect to a product, plus causation and injury.<sup>72</sup>

## 2.What is a "sale"?

Product users seeking to recover for injuries resulting from a 3D printed product, under a strict liability theory, must prove that the product was placed *on the market* by a commercial manufacturer or seller.<sup>73</sup> Again, if a traditional manufacturer produces a 3D printed product and sells that product directly, the viability of current tort theories is unaffected. However, a hobbyist who occasionally uses 3D printing to make, for example, a hard-to-obtain spare part, which then injures a consumer, will not be subjected to traditional strict liability laws. The difference being that current strict liability focuses on an entity that regularly makes, markets, distributes and sells products—3D printed or not—as part of its ongoing business activities.<sup>74</sup>

<sup>71</sup> *Id.* The plaintiffs' warning claim also survived to the extent they alleged that no warnings accompanied the product. *Id.* at \*4-5.

<sup>72</sup> See Restatement (Second) of Torts § 402A (1965); Restatement (Third) of Torts, Products Liability §§ 1-2.

<sup>73</sup> Restatement (Third) of Torts, Products Liability § 1, comment c.

<sup>74</sup> Heidi Nielson, *Manufacturing Consumer Protection for 3-D Printed Products*, 57 Ariz. L. Rev. 609, 617 (2015); Nora Freeman Engstrom, *3-D Printing & Product Liability: Identifying The Obstacles*, 162 Univ. of Penn. Law Review Online 35, 37 (2013). Generally, under existing product liability

Currently, many hobbyists are devoted to the restoration and maintenance of historic automobiles and airplanes that have not been in production for decades.<sup>75</sup> Spare parts for out-of-production vehicles are increasingly difficult to come by, so such hobbyists will undoubtedly turn to 3D printing, either by digitizing old blueprints, or reverse-engineering parts using 3D scanners. If such parts fail and injure someone, their sellers would be unlikely to face strict liability, unless they make a business out of selling them. The same would apply to any non-commercial seller who 3D prints any product for their own use or sold the 3D printed objects in very limited quantities and did not advertise.

## 3. Who is a "manufacturer"?

As long as 3D printers that are used to create tangible objects remain in the hands of traditional manufacturers, those manufacturers and their products will still be subject to traditional product liability litigation, as the manufacturer is easily identifiable. However, in a number of instances, the location of the printer, and thus what was traditionally considered "manufacturing," is elsewhere. For example, the hobbyist discussed above would probably print spare parts in his home. Or in the case of medical devices, 3D printers may be located on-site at hospitals and/or physicians' offices. For the reasons discussed above, a hobbyist who is not in the business of selling 3D printed products and does not advertise as such, will likely not be considered a manufacturer. If the hobbyist crosses the line and begins to sell the 3D printed objects that he makes, then he could be subject to strict liability as the manufacturer of the product being sold.

Since medical devices are regulated by the FDA, it is possible that the FDA could consider any entity or person who "prints" a medical device to be a "manufacturer" subject to inspection<sup>76</sup> and device-related record-keeping requirements,<sup>77</sup> but then use "enforcement discretion" to avoid creating excessively onerous requirements, as it has done with other Internet-based applications.<sup>78</sup> On-site use of 3D printers

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principles, so-called "occasional sellers" of products are not subject to strict liability. See Restatement (Third) of Torts, Products Liability § 1, reporter's notes to comment c, at 12 (1998).

<sup>75</sup> See, e.g., <http://www.aoai.org/> (for Studebaker Avanti); <http://www.edselclub.org/> (Ford Edsel); <http://www.mustangsmustangs.net/p-51/home> (for North American P-51 Mustang).

<sup>76</sup> 21 U.S.C. § 374.

<sup>77</sup> 21 U.S.C. § 360i(a).

<sup>78</sup> See Mobile Medical Applications: Guidance For Industry & Food And Drug Administrative Staff, at 9 (FDA Feb. 9, 2015) (interpreting "manufacturer" to

by health care providers, or what FDA refers to as "point of care" manufacturing, also implicates old product liability issues in a new context. First, many 3D printed medical devices are patient-matched, and will be customized for individual patients using electronically inputted data gathered by computed tomography or magnetic resonance imaging scans. If other forms of CAD files are considered "products,"<sup>79</sup> then the same is probably true of these sorts of anatomical scans.

Second, the majority of courts—supplemented in a number of states by statutory definition—have traditionally viewed doctors<sup>80</sup> and hospitals<sup>81</sup> as service providers, not sellers of products, as they are neither affiliated with drug or device manufacturers nor marketers in the commercial sphere. The rationale for rejecting strict product liability is that "[t]he thrust of the inquiry is thus not on whether a separate consideration is charged for the physical material used in the exercise of medical skill, but what service is being performed to restore or maintain the patient's health."<sup>82</sup> The majority rule's distinction between manufacturing and professional services will come under pressure as hospitals and doctors' offices incorporate on-site 3D

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include persons who "create a software system or application"), available at <http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm263366.pdf>.

<sup>79</sup> See "What is a 'product?'" section, *supra*.

<sup>80</sup> Beck & Vale, *Drug & Medical Device Product Liability Deskbook* § 8.06[1].

<sup>81</sup> *Id.* § 8.05[1].

<sup>82</sup> *Cafazzo v. Cent. Med. Health Servs., Inc.*, 668 A.2d 521, 532 (1995); see also *Hollander v. Sandoz Pharm. Corp.*, 289 F.3d 1193, 1217, n.22 (10th Cir. 2002) (applying Oklahoma law and following "majority of jurisdictions" in declining to hold hospital liable for strict product liability); *Vergott v. Deseret Pharm. Co.*, 463 F.2d 12, 16, n.5 (5th Cir. 1972) (applying Texas law and holding that a "hospital is not a seller engaged in the business of selling the product" under section 402A); *Wages v. Johnson Reg'l Med. Cent.*, 916 F. Supp. 2d 900, 904 (W.D. Ark. 2013) (holding that hospitals cannot be considered product suppliers under the Arkansas Products Liability Act merely because the hospital uses the product during a medical procedure); *Samuels v. Health & Hosp. Corp. of City of New York*, 432 F. Supp. 1283, 1284-85 (D.C.N.Y. 1977) (applying New York law and holding that "the doctrine of strict liability in tort is inapplicable to the service by the hospital of providing blood transfusions). But see *Cunningham v. MacNeal Mem'l Hosp.*, 266 N.E. 2d 897, 902 (1970) (finding hospital, which provided blood transfusions to patients, was liable for strict liability). With respect to the printers themselves, hospitals and other health care providers should have no greater liability than for any other item not sold to a patient. See *Racer v. Utterman*, 629 S.W.2d 387, 398 (Mo. App. 1981) (patient burned when disposable drapes caught fire; drapes not "sold" to patients so hospital "in no different position than any other business which purchases goods for its own use in conducting its business."). The majority rule is not universal, however. See *Netherland v. Ethicon, Inc.*, 813 So. 2d 1254, 1259-60 (La. App. 2002) (allowing negligence action against hospital for distributing allegedly contaminated sutures).

printing centers.<sup>83</sup> Hospitals have already begun using on-site 3D printing to create bespoke anatomical models for individual pre-surgical planning based on patient CT scans and MRIs.<sup>84</sup> To the extent, however, that doctors and hospitals operating on-site 3D printers are concerned with non-traditional liability going beyond professional negligence, they may seek indemnity through the contractual arrangements that accompany the installation of the printers and acquisition of the CAD files, and also may consider creating separately incorporated entities to own and operate 3D printers.<sup>85</sup>

#### 4. Product identification

Anything that can be digitized can, and almost certainly will, be pirated.<sup>86</sup> Inevitably, CAD files for 3D printed products will be available on Internet file-sharing sites from sources other than their original creators.<sup>87</sup> In most cases, a pirated electronic file, or even the 3D printed object that flows from such a product, will lack any sort of identification of the manufacturer. This makes it nearly impossible for a person injured by such a product to seek relief.

To the extent that the original creator of a pirated CAD file is identifiable,<sup>88</sup> it may find itself faced with claims that it is liable for products that it may have once "designed," but that it neither manufactured nor received any economic benefit from their sale. While there would be no liability under traditional strict liability principles,

<sup>83</sup> In June 2015, Materialise, a Belgian provider of high-end 3D printed products, announced that it partnered with Fuwai Hospital in Beijing, China, to open a medical 3D printing center at the hospital. See 3Ders.org, *Materialise & Fuwai Hospital Collaborate on China's First Cardiovascular 3D Printing Center*, June 25, 2015, <http://www.3ders.org/articles/20150625-materialise-fu-wai-hospital-collaborate-on-china-first-cardiovascular-3d-printing-center.html> (last visited Sept. 18, 2016).

<sup>84</sup> See Meribah Knight, *3-D Printing is Revolutionizing Surgery*, *Crain's Chicago Business*, Mar. 22, 2014, <http://www.chicagobusiness.com/article/20140322/ISSUE01/140229904/3-d-printing-is-revolutionizing-surgery> (last visited Sept. 18).

<sup>85</sup> See Commercial Litigation Considerations Specific to 3D Printed Objects, *supra*.

<sup>86</sup> John Hornick, *3D Printing Will Rock the World*, at 158-59, 175-77 (CreateSpace 2015).

<sup>87</sup> *Id.* at 59 ("Companies may find their products competing not only with their traditional competitors' products, but also with copies of their own products, with customized versions of their own products, with generic substitutes . . . , and with customized versions of generic substitutes . . . . Such products may be made by professional counterfeiters, 3D print shops, industrial customers, or consumers.")

<sup>88</sup> While there are various technological means for imbedding identifiers in CAD files, the possibility of liability for injuries caused by products made with pirated CAD files raises questions about the advisability of utilizing such identification techniques.

more expansive—and controversial—theories of liability, such as “innovator” liability,<sup>89</sup> “bare metal” liability,<sup>90</sup> or some duty to guard against the counterfeiting of one’s product,<sup>91</sup> exist that could be asserted in such situations. Moreover, these alternative sources—many Internet-based and often disreputable—are unlikely to be amenable to suit in most cases. Plaintiffs will be looking for deep-pocketed entities to sue.

## 5. Redefining manufacturing, design, and warnings defects

In order to recover under strict liability doctrines, a plaintiff must prove that the product was defective in either its design, manufacturer, or warnings. Given the nature of 3D printing, the interplay of electronic files, and the possibility for 3D printed products to be made off-site, several different situations may arise in determining the defect in a 3D printed product.

Possible scenarios in which “defects” in 3D printed products might arise include:

- The original product used to create the initial digital design was defective
- The original CAD file digital design was defectively created
- A defect was introduced into the CAD file as it was uploaded to a file-sharer
- The CAD file was corrupted during the process of downloading from a file-sharer
- The defect was caused by some problem or “defect” in the 3D scanner used to create the initial digital design

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<sup>89</sup> This theory would hold makers of branded drugs liable for labeling defects in largely identical generic drugs under negligence or fraud theories based on “foreseeability” of loss. *See Conte v. Wyeth, Inc.*, 85 Cal. Rptr.3d 299 (Cal. App. 2008). Most courts have rejected this liability theory. *See Drug and Device Law*, July 18, 2014, <https://www.druganddevicelawblog.com/2014/07/innovator-liability-at-100.html> (last visited Sept. 18, 2016).

<sup>90</sup> This negligence theory is asserted in asbestos cases against makers of non-asbestos-containing products, where it is “foreseeable” that these products will be used in conjunction with difficult-to-identify asbestos-containing products. *Compare O’Neil v. Crane Co.*, 266 P.3d 987 (Cal. 2012) & *Simonetta v. Viad Corp.*, 197 P.3d 127, 131-38 (Wash. 2008), with *May v. Air & Liquid Sys. Corp.*, 129 A.3d 984 (Md. 2015).

<sup>91</sup> *See Jones v. Ram Med., Inc.*, 807 F. Supp.2d 501, 510 (D.S.C. 2011); *Ashworth v. Albers Med., Inc.*, 410 F. Supp.2d 471, 476-477 (S.D. W. Va. 2005); *Fagan v. AmerisourceBergen Corp.*, 356 F. Supp.2d 198, 207, 210-11 (E.D.N.Y. 2004); *Arons v. Rite Aid Corp.*, 2005 WL 975462, at \*15-16 (N.J. Super. Law Div. March 23, 2005).

- The defect was caused by some problem or “defect” in the 3D printer
- The defect was caused by some problem or “defect” in the bulk material used in the 3D printer to create the product
- Human error in implementing the digital design caused the defect
- Human error in using the 3D printer and/or materials caused the defect<sup>92</sup>

Because of the numerous players involved in 3D printing a product, there will likely be issues in determining causation, especially if the product substantially changed from the time of design until the time it was “printed.” Determining where in the chain the defect occurred may be complicated, and a plaintiff may sue multiple parties in an attempt to determine where possible liability may exist.

Establishing a defect alone is not enough, though, as a plaintiff must also establish that the product was defective “at the time of sale or distribution.”<sup>93</sup> However, with the open source movement, where 3D designs are shared with a community of users who are encouraged to distribute and improve upon existing designs, plaintiffs may find it virtually impossible to trace the design to its original owner or show that it left the defendant’s control without substantial change by the time it reached the consumer.<sup>94</sup> Where 3D modeling and animation software is offered for free, another basic strict liability and implied warranty prerequisite—the “sale”—is eliminated.<sup>95</sup> Open source software also is generally distributed subject to terms of use that preclude recovery under product liability theories,

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<sup>92</sup> See Karishma Paroha, June 2, 2014, *3-D Printed Products, Product Liability & Insurance Implications*, <http://www.kennedyslaw.com/article/3dprintedproducts/>.

<sup>93</sup> Restatement (Third) of Torts, Products Liability § 2 (1998); accord Restatement (Second) of Torts § 402A(1)(b) (1965).

<sup>94</sup> There is also the question of which design defect test—risk/utility or consumer expectation—should be employed. *See* Restatement (Third) of Torts, Products Liability § 2, comment f (1998); Restatement (Second) of Torts § 402A, comment l (1965). To the extent that the 3D printed product is simple, such as a toy or household good, the consumer expectation theory could apply. However, to the extent that anything about the 3D printing process enters into the defect analysis, risk/utility would seem to be the only applicable test, since consumers cannot be expected to have any expectations about something as complex and esoteric as 3D printing.

<sup>95</sup> Restatement (Second) of Torts § 402A(1) (1965); UCC § 2-314. The Third Restatement is not as restrictive, recognizing liability for both “sale or distribution” of a product. Restatement (Third) of Torts, Products Liability § 2 (1998).

although the applicability of such exculpatory language to injuries suffered by third persons is dubious.

Issues also arise in who along the supply chain should provide the warnings and who may be liable if those warnings are allegedly inadequate. CAD file creators may be responsible for providing warnings with the electronic file.<sup>96</sup> Entities that create the raw materials used in the 3D printing process may have to supply their own warnings.<sup>97</sup> The manufacturer of the 3D printer may also have to supply warnings. The entity that ultimately prints the product may also be responsible for providing warnings to the end-user, and may even be responsible for passing through warnings from the other entities in the chain.

Regarding medical devices, there is an exception to the usual requirement that warnings be given to end-users, known as the learned intermediary doctrine. Patient-matched devices created from individualized patient scans to create CAD files for medical devices could blur distinctions between professional medical treatment and customized manufacturing that underlie the learned intermediary doctrine.<sup>98</sup> These were addressed in *Buckley v. Align Technology, Inc.*<sup>99</sup> *Buckley* involved 3D printed, custom-fitted dental aligners for treating misaligned teeth ("malocclusion"). The product required a dentist's prescription. The plaintiff in *Buckley* alleged that the defendant manufacturer of these 3D printed devices "falsely advertised, misled and deceived her and other consumers into believing that [its product] could treat their malocclusions."<sup>100</sup> The court dismissed the complaint, applying the learned intermediary doctrine to the prescription-only 3D printed medical device.<sup>101</sup> To avoid the doctrine, the plaintiff contended that the manufacturer necessarily conducted a medical evaluation of the dental impressions in order to custom

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<sup>96</sup> Holding that a CAD file is a "product" would also have significant practical consequences with respect to warnings. Product manufacturers have a well-established duty to warn about product risks. Restatement (Third) of Torts, Products Liability § 2(c) & comments i-m (1998). If a CAD file is itself a product, then presumably it would have to include product warnings in addition to the software necessary to 3D print whatever the file is intended to create.

<sup>97</sup> See 3D Printing/Component Parts/Raw Materials, *infra*.

<sup>98</sup> See generally Beck & Vale, *Drug & Medical Device Product Liability Deskbook* § 2.03.

<sup>99</sup> 2015 WL 5698751 (N.D. Cal. Sept 29, 2015).

<sup>100</sup> *Id.* at \*1.

<sup>101</sup> The learned intermediary doctrine "provides that in the case of prescription [products], the duty to warn runs to the physician, not to the patient." *Id.* at \*3.

fit the 3D printed device.<sup>102</sup> Plaintiff asserted a direct duty to warn because 3D printing a custom-made medical device was medical treatment, not mere manufacturing.<sup>103</sup> The court rejected the argument, holding:

The [products] are prescribed exclusively by the dentist, and are custom-manufactured... It appears, thus that [defendant] stands in the position of a manufacturer not a medical evaluator. As such, [defendant] has a duty to warn the dentist about any dangerous side effects pertaining to the [product's] treatment, but has no duty to directly warn Plaintiff.<sup>104</sup>

The learned intermediary doctrine barred the plaintiff's claims, because the complaint "did not allege that her dentist was misled by" the manufacturer of the 3D printed medical device.<sup>105</sup> This reasoning recognized that, although the 3D printing manufacturer played more of a role in customizing and fitting medical devices to specific patients, it nonetheless still functioned as a traditional manufacturer whose only contact with the patient was indirect, through the learned intermediary prescribers of the product. The dental aligner in *Buckley*, however, was a relatively simple application of 3D printing; whether the distinction between medical treatment and manufacturing can be maintained with more complex uses of additive manufacturing, such as those printed from living tissue, remains to be seen.

## B. Negligence

Given the challenges associated with asserting a strict liability claim in the context of 3D printing, plaintiffs seeking to recover for personal injuries caused by 3D printed products may be left having to pursue negligence claims. Negligence claims in product liability actions may look similar to strict liability claims for design, manufacture, or warnings defects, but are sometimes broader and more vague.<sup>106</sup> To prevail on a negligence theory, a plaintiff must prove the existence of a duty of care, breach of that duty, proximate causation, and resulting damages.<sup>107</sup> But who owes a duty of care to the plaintiff?

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<sup>102</sup> *Id.* at \*4.

<sup>103</sup> *Id.*

<sup>104</sup> *Id.*

<sup>105</sup> *Id.*

<sup>106</sup> *Lance v. Wyeth*, 85 A.3d 434, 440 n.8 (2014).

<sup>107</sup> e.g., Restatement (Third) of Torts, Physical & Emotional Harm § 6, cmt. b (2010).

The seller of a 3D printed product likely owes a duty of care. The individual or entity who printed the product likely does as well. The designer of the CAD file may have a duty to even an unknown third party, depending on whether the plaintiff suffered personal or economic injuries. Courts applying the economic loss rule have held that software developers do not have a duty of care to avoid intangible economic loss or emotional distress, and thus cannot be liable for negligence unless their software caused physical damages.<sup>108</sup> Other designers, such as architects and engineers, who provide design input but are not involved in manufacturing, may be liable in tort for their negligence.<sup>109</sup> Thus, a designer of a CAD file that creates a defective product may be liable in negligence, even if he did not ultimately manufacture the final product.

Assuming that the manufacturer or seller of the 3D printed product has such a duty of care, what does the duty entail for a 3D printed product? Generally, a manufacturer or seller has a legal duty to use reasonable care in response to a foreseeable risk of injury to others. When a manufacturer or seller knows or should know of unreasonable dangers associated with the use of the product and such dangers are not obvious to the user, there is a duty to warn of the dangers. Under these principles, CAD files, by themselves, may not present unreasonable and unknown dangers triggering a duty to warn, since computer code is not inherently dangerous. On the other hand, if a designer or seller distributes CAD files on how to 3D print a firearm, presumably a duty to warn of the dangers of the gun arises.<sup>110</sup> Whether a duty to warn exists is likely to be a fact-driven inquiry and will depend on the type of product being 3D printed.

Another possible target of liability is the manufacturer of the 3D printer. However, unless the 3D printer itself—as

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<sup>108</sup> e.g., *Hou-Tex*, 26 S.W.3d at 107; *Huron Tool & Engg Co. v. Precision Consulting Servs., Inc.*, 532 N.W.2d 541, 543-44 (Mich. App. 1995); *In re Sony Gaming Networks & Customer Data Sec. Breach Litig.*, 903 F. Supp. 2d 942, 961-62 (S.D. Cal. 2012); *Shema Kolainu-Hear Our Voices v. ProviderSoft, LLC*, 832 F. Supp. 2d 194, 206-07 (E.D.N.Y. 2010). Even so, however, product designers or inventors who were not also manufacturers of products have historically not been held strictly liable for product defects. James M. Beck & Anthony Vale, *Drug & Medical Device Product Liability Deskbook* § 8.09 (2016).

<sup>109</sup> e.g., Carl J. Circo, *When Specialty Designs Cause Building Disasters: Responsibility for Shared Architectural & Engineering Services*, 84 Neb. L. Rev. 162, 179-82 (2005); Constance Frisby Fain, *Architect & Engineer Liability*, 35 Washburn L.J. 32, 35 (1995).

<sup>110</sup> CAD files for firearms and other dangerous products already exist. Hornick, *3D Printing Will Rock the World*, at 169-72. 3D printed bombs will follow "soon." Id. at 177. See *Defense Distributed v. United States Dep't of State*, 838 F.3d 451 (5th Cir. 2016) (in the United States "virtually anyone with access to a 3D printer [can] produce" 3D printed firearms and gun parts).

opposed to 3D printed products—causes injury, such liability would be akin to holding makers of tools (such as industrial robots or plastic extruders) liable for defects in whatever products they make. There is no precedent for such broad liability, and in analogous situations—such as multi-use component parts—the law has refused to impose strict liability for all of the multiple possible uses of a product.<sup>111</sup>

The causation issues that arise in a strict liability analysis discussed above may also apply to negligence claims. If multiple entities are involved in producing the final 3D printed product, determining what defect caused the injury, and where along the chain of sale that defect occurred, may be hard, if not impossible.

Given that negligence is flexible in its "reasonableness" and "foreseeability" concepts, it could well make a comeback and be an alternative to strict liability claims.

### C. Non-Tort Liability Considerations

Other legal claims, mostly those that arise out of contract, such as breach of warranty, may also provide alternatives to strict liability claims, assuming that the other elements of such causes of action are present. Manufacturers or suppliers may face claims sounding in contract for breach of warranty, either express or implied. Express warranties are usually in a contract or other document from the sale of a product.<sup>112</sup> Implied warranties usually provide that the goods are merchantable if the seller is a merchant for goods of that kind, unless excluded or modified.<sup>113</sup> Subject to state-specific statutory limitations, liability may be imposed on any party in the manufacturing, selling or distributive chain.<sup>114</sup> This would alleviate the problems with what is defined as a product, and who is a manufacturer, as well as some of the other issues discussed above.

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<sup>111</sup> Restatement (Third) of Torts, Products Liability § 5, comment c (1998) (rejecting strict liability duties that "would require the seller to develop expertise regarding a multitude of different end products and to investigate [their] actual use."

<sup>112</sup> U.C.C. § 2-313.

<sup>113</sup> *Id.* § 2-314(1).

<sup>114</sup> See, e.g., *Passaretti v. Aurora Pump Co.*, 607 N.Y.S.2d 688 (N.Y. Sup. 1994); *Picker X-ray Corp. v. Frerker*, 405 F.2d 916 (8th Cir. 1969) (applying Missouri law); *Huebert v. Fed. Pac. Elec. Co.*, 494 P.2d 1210 (Kan. 1972); *Safeway Stores, Inc. v. L. D. Schreiber Cheese Co.*, 326 F. Supp. 504 (W.D. Mo. 1971), judgment rev'd on other grounds, 457 F.2d 962 (8th Cir. 1972); *Volkswagen of Am., Inc. v. Novak*, 418 So. 2d 801 (Miss. 1982); *Szrama v. Alumo Prods. Co., Inc.*, 462 N.Y.S.2d 156 (N.Y. Sup. 1983); *Vintage Homes, Inc. v. Coldiron*, 585 S.W.2d 886 (Tex. Civ. App. 1979); *Western Equip. Co., Inc. v. Sheridan Iron Works, Inc.*, 605 P.2d 806 (Wyo. 1980).

Regulatory laws may also apply, especially for 3D printed medical devices and drugs. Even if courts find that CAD files used in 3D printing are not “products,” the FDA could conceivably treat such files used for medical devices or drugs as “labeling,” since the definition is very broad.<sup>115</sup> In that case, FDA could require CAD files to include the same warnings and other information that must accompany the physical device, and CAD files without such information-labeling could be considered misbranded. If the CAD files are considered “labeling,” it may open digital designers to strict liability claims for inadequate warnings, even if the file itself is not considered a “product” and those claims are ultimately dismissed.

## Conclusion

3D printing brings many never before seen possibilities. It also brings a lot of unknowns. Understanding the tort liability unknowns and possible consequences is important to anyone who is interested or who is already involved in 3D printing. An understanding of the legal issues is the first step, and maybe most crucial, to being able to anticipate the changes in the law and protecting yourself from liability. 3D printing is not the first technology that has disrupted tort liability laws, and likely will not be the last. The law will find a way to address this novel technology, although it will likely take several decades.

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<sup>115</sup> *Kordel v. United States*, 335 U.S. 345, 350 (1948).



“Consumer products, including medical devices, frequently comprise component parts and raw materials **manufactured or supplied by unrelated entities...**”

# 3D Printing/Component Parts/Raw Materials

Consumer products, including medical devices, frequently comprise component parts and raw materials manufactured or supplied by unrelated entities, are assembled, and then sold as a finished product. If this product happens to be defective and injures its end user, a question arises regarding the apportionment of responsibility for the injury. The manufacturer of the final product could be liable, or, depending on the jurisdiction, the law may also apportion responsibility to the manufacturer of the defective component part or raw material that was incorporated into the final product and caused the injury.

Component parts and raw materials run the gamut from silver to microprocessors, but in the realm of 3D printing, the frequently used raw materials are most likely the powders utilized to build the product or device.

Selective laser sintering ("SLS") is among the more widely used additive manufacturing technologies for industrial applications, including the medical device industry. SLS systematically builds 3D parts layer-by-layer using a focused laser that rapidly scans across a fine layer of powder, generating a localized melt, followed by solidification, in a relatively short timeframe. This powder can be of metal or polymer form. The medical device industry is currently adopting this technology for the manufacture of patient-specific cranial implants, maxillofacial implants, spinal cages, hip-cup implants, surgical tools and guides, and prosthetics, to name a few.

The use of powder introduces a range of damage risks, not to mention health concerns that warrant attention for the additive manufacturing of parts, including the source supplier, additive manufacturer, trained personnel of the machine, and the end consumer. The following sub-sections outline the potential liability of suppliers of such powders and their available defenses; and the various risks, potential consequences, and plausible sequence of events that can result in injury to nearby workers or those implanted with the final product.

## Liability of Raw Material Suppliers

As with manufacturers of final products, component part and raw material suppliers generally are subject to traditional products liability principles. *Prod. Liab.: Design and Mfg. Defects* § 2:24 (2d ed.) (2015). Absent some overriding law, and depending on the jurisdiction, they may be liable for manufacturing, design, and warning failures, and for breach of warranty. *Id.*

That said, product liability legislation, doctrines, and defenses have developed to mitigate the liability of raw material suppliers, which may include suppliers of metal and polymer powders used by 3D printers. Such suppliers are in an especially unique situation because they have multiple uses, and suppliers usually exercise little control over the final use of them. For instance, the Third Restatement of Torts asserts that basic raw materials—like sand, gravel, or kerosene—ordinarily cannot be considered defective in design, nor can their suppliers normally be required to warn their usually sophisticated purchasers of the natural hazards such materials may contain. *See Restatement (Third) of Torts: Prod. Liab.* § 5 cmt. c (1998). To hold otherwise would expose raw material suppliers to almost unlimited risk for every product that uses their materials, and could deter supply of the materials altogether. *See id.* ("Courts uniformly refuse to impose such an onerous duty to warn.") Thus, product liability law puts limits on the supplier's liability in order to assure a proper supply of raw materials to manufacturers.

## Legislation, Doctrines, and Defenses

### A. The Biomaterials Access Assurance Act of 1998

The Biomaterials Access Assurance Act of 1998 (also known as the "BAAA") bars civil suits against raw material suppliers for harm caused by implantable medical devices, regardless of the legal theory for liability, provided the requirements of the Act are met.<sup>116</sup> See 21 U.S.C. §§ 1601–1606. Further, the Act supersedes any state law that would hold to the contrary. 21 U.S.C. § 1603(c)(1).

Among the various definitions in the Act, is the BAAA's unusual definition for "implant," which is defined as a medical device that is implanted in the body for at least 30 days or, if implanted for fewer than 30 days, a medical device implanted in a *surgically produced opening*.<sup>117</sup> See 21 U.S.C. § 1602(5). Accordingly, the BAAA excludes devices that are implanted in natural cavities, as opposed to surgically created ones, for fewer than 30 days.

This somewhat narrow definition of an implant is balanced by the BAAA's broad definitions for "component part" and "raw material." A "component part" is any manufactured piece of an implant, and a "raw material" is any substance or product that has a generic use and may be used in an application other than an implant.<sup>118</sup> See 21 U.S.C. § 1602(3),(8). The definitions likely encompass most raw materials used in the 3D printing of medical devices.

Suppliers, however, cannot use the BAAA if one of the following circumstances is true:

- The suppliers are also the manufacturer of the implant;
- The suppliers are also sellers of the implant; or
- The raw materials or component parts fail to meet applicable contractual requirements or specifications.

21 U.S.C. § 1604(a). Absent these circumstances, the BAAA remains a powerful—albeit limited—defense for raw material suppliers.

<sup>116</sup> The BAAA, however, does not bar suits for commercial loss or loss of damage to an implant. See 21 U.S.C. §§ 1602(4)(B). It also does not bar the manufacturer of the implant, other suppliers, or health care providers from bringing suit against the raw material supplier. See 21 U.S.C. §§ 1602(2) (defining "claimant").

<sup>117</sup> Suture materials used in the implant procedure are also included in the definition of "implant." See 21 U.S.C. § 1602(5).

<sup>118</sup> The BAAA expressly excludes silicone gel and the silicone envelope utilized in a breast implant containing silicone gel. See 21 U.S.C. § 1602(2)(D)(iii).

### B. The Component Parts Doctrine

Another defense for component part and raw material suppliers, regardless of the type of end product, is appropriately named the Component Parts Doctrine ("CPD"). The CPD apportions liability among the manufacturer of the end product and the manufacturer of the component part. In some jurisdictions, CPD is invoked by the plaintiffs as a basis for liability, and in others, CPD is raised by end product manufacturers as a defense.<sup>119</sup> Our focus, however, is the doctrine's use as a defense for component part manufacturers.

Under traditional characterizations of the CPD, a supplier of component parts generally has no liability for injuries caused by a finished product unless:

- The component itself was defective and caused injury; or
- The supplier was uniquely involved in causing the final product to be defective.

See Rest.3d Torts, Products Liability, § 5.

Accordingly, raw material suppliers for 3D printers may find themselves liable under the CPD only in extraordinary circumstances—for example, if the raw materials are contaminated, or if the supplier exercises substantial control of the manufacturing process, or if the supplier provides inherently dangerous raw materials without warning—and the *finished product*, not the material itself, causes injury. See Rest.3d Torts, Products Liability, § 5; see also Am. L. Prod. Liab. 3d § 8:12 (2016). Barring these circumstances, the raw material supplier may be able to use the CPD as a defense against liability.

### C. Warning Defenses – Sophisticated User, Sophisticated Intermediary, Bulk Supplier Defenses

Raw material suppliers usually cannot be held liable for risks created by a manufacturer's decisions regarding the use of the raw material that they took no part in. See Rest.3d Torts, Products Liability, § 5 cmt. c. To hold otherwise would require suppliers to develop expertise about all of their end products that they do not control. See *id.*

That said, plaintiffs often try to circumvent the CPD by alleging that the raw material had a *hidden inherent*

<sup>119</sup> See, e.g., M. Stuart Madden, *Component Parts and Raw Material Sellers: From the Titanic to the New Restatement*, 26 N. Ky. L.R. 535, 542; David A. Fischer, *Product Liability: A Commentary on the Liability of Suppliers of Component Parts and Raw Materials*, 53 S.C. L. Rev. 1137 (2002); *When Are the Pieces at Fault? Component Manufacturer Liability*, 45 No. DRI For Def. 45; Paul J. Riehle, et al., *Products Liability for Third Party Replacement or Connected Parts: Changing Tides from the West*, 44 U.S.F. L. Rev. 33, 38 (2009).

*danger*, of which the manufacturers or users were unaware, and the supplier had a duty to provide a warning about that danger. *See, e.g., Brady v. Calsol, Inc.*, 241 Cal. App. 4th 1212, 1223 (2015) (finding a triable issue as to whether mineral spirits were inherently dangerous); *Fisher v. Prof'l Compounding Centers of Am., Inc.*, 311 F. Supp. 2d 1008, 1020 (D. Nev. 2004) ("a genuine issue of material fact remains regarding whether fenfluramine is an inherently dangerous raw material about which the bulk supplier would be required to warn"). Requiring a supplier to warn of the dangers of an inherently dangerous product is appropriate because it does not require the supplier to "develop expertise regarding a multitude of different end-products and to investigate the actual use of raw materials by manufacturers over whom the supplier has no control." *See Artiglio v. General Electric Co.*, 61 Cal. App. 4th 830, 839 (1998). It merely requires the supplier to understand the dangers inherent in its own product. *Brady v. Calsol, Inc.*, 241 Cal. App. 4th 1212, 1223 (2015).

If a court is willing to entertain this allegation, the supplier has three closely related defenses that it may be able to assert: the sophisticated user defense; the sophisticated intermediary/learned intermediary defense; and the bulk supplier defense. These are considered "affirmative defenses" and as such must be asserted and proven by the defendant supplier.

### (1) Sophisticated User Defense

The sophisticated user defense arises if there is *no need* to warn because of the expertise of the users. *See, e.g., Johnson v. Am. Standard, Inc.*, 43 Cal. 4th 56, 65 (2008) ("Sophisticated users need not be warned about dangers of which they are already aware or should be aware"). Courts must consider if the user was knowledgeable about the material supplied and the user knew or should have known about the particular danger. *Id.* This is usually a factually intensive analysis, and the defense is limited to the *end users* of the product.

### (2) Sophisticated Intermediary/Learned Intermediary & Bulk Supplier Defenses

Somewhat different questions arise when the supplier sells to a purchaser, which then passes the product on to other users. In such instances, the sophisticated/learned intermediary defense or the bulk supplier defense may be applicable. These defenses often apply to situations in which it is impractical for the supplier to provide a warning directly to the end user.

The sophisticated intermediary defense allows a supplier to discharge its duty to warn about known or knowable risks in the use of its product if it (1) provides adequate warnings to the intermediary purchaser or sells to a "sophisticated intermediary," and (2) reasonably relies on this downstream purchaser to convey those warnings to

users who encounter the product. *See Swope v. Columbian Chemicals Co.*, 281 F.3d 185, 206 (5th Cir. 2002); *Webb v. Special Elec. Co.*, 63 Cal. 4th 167, 187 (2016). In the medical device and pharmaceutical context, this defense goes by the name "the learned intermediary doctrine," and it, too, allows a manufacturer to fulfill its duty to warn by supplying adequate warnings to the physician regarding the risks of the drug or device. *See, e.g., Niemiera v. Schneider*, 114 N.J. 550, 559 (1989); *Martin v. Hacker*, 83 N.Y.2d 1, 9, (1993).

The bulk supplier defense allows a supplier who provides its products in bulk to discharge its duty to warn the end user by warning the buyer of the material's risks. "For the bulk supplier doctrine to apply, a product must be delivered in bulk to an intermediary vendee. The relevant inquiry turns on the intermediary's knowledge of a product's hazards and its ability to pass on appropriate warnings to end users."<sup>120</sup> *See, e.g., Sara Lee Corp. v. Homasote Co.*, 719 F. Supp. 417, 424 (D. Md. 1989). Although this doctrine is similar to the sophisticated/learned intermediary defense, they are distinct:

While both doctrines involve situations where the duty to warn is left to a knowledgeable, but better positioned, warning party, the bulk supplier doctrine rests more on concerns of feasibility. A bulk supplier has no practical way of attaching a warning to its product in a manner which could possibly reach the ultimate user. The [sophisticated/]learned intermediary doctrine, on the other hand, is not concerned with the feasibility of a warning, but that someone else, a learned intermediary, is in a better position to communicate a warning to the product's ultimate user.

*Hoffman v. Houghton Chem. Corp.*, 751 N.E.2d 848, 854 (Mass. 2001).

That said, both defenses require the supplier to sell to a sophisticated intermediary. Whether an intermediary is "sophisticated," however, tends to involve a fact-intensive

<sup>120</sup> Other jurisdictions have a variation of this defense that is better described as a particularized application of the Component Parts Doctrine. These jurisdictions often have a four-part test for its application and may limit its application to injuries caused by *final* products. *See Webb v. Special Elec. Co.*, 63 Cal. 4th 167, 184 (2016) (requiring "(1) the material supplied is not inherently dangerous; (2) the material is sold in bulk to a sophisticated buyer; (3) the material is substantially changed during the manufacturing of a finished product; and (4) the supplier has a limited role in creating the finished product."); *In re Dow Corning Corp.*, No. CIV A 00-X-00001-DT, 2008 WL 4585249, at \*8 (E.D. Mich. Oct. 14, 2008) (same). Thus, this variation of the defense would not apply in the context of alleged lack of warnings given to an employer that causes injuries to employees using the raw material during the manufacturing process. *See Ramos v. Brenntag Specialties, Inc.*, - - P.3d ----, No. S218176, 2016 WL 3435777 (Cal. June 23, 2016).

analysis, similar to the sophisticated user defense discussed above. *See e.g., Webb*, 63 Cal. 4th at 188; *see also Cimino v. Raymark Industries, Inc.*, 151 F.3d 297, 334 (5th Cir. 1998).

Further, the underlying assumption of both defenses is that the seller may rely on an informed distributor to communicate warnings to the consumer. Thus, the supplier must show it “reasonably” relied on the intermediary to convey warnings to the end users. This often requires consideration of several factors, including “the gravity of the risks posed by the product, the likelihood that the intermediary will convey the information to the ultimate user and the feasibility and effectiveness of giving a warning directly to the user.” *See Restatement (Third) of Torts: Prod. Liab.* § 2 cmt. i (1998); *see also, e.g., Humble Sand & Gravel, Inc. v. Gomez*, 146 S.W.3d 170, 190 (Tex. 2004).

#### D. Lack of Privity of Contract Defense for Warranty Claims

##### (1) Implied Warranty

Since medical devices are ordinarily promoted and sold to the prescribing physician or hospitals, it is unusual for the manufacturer or seller to issue an express warranty to the patient/end user of the product. Accordingly, the most frequent medical device products liability issues in warranty relate to allegations of breach of implied warranties of merchantability and of fitness for a particular purpose.

The warranty of merchantability, implied by operation of law into every sale of goods by a seller, is breached by a sale of goods that are not fit for the ordinary purpose for which they are used. *See* 2 Owen & Davis on Prod. Liab. § 20:6 (4th ed.). Meanwhile, the breach of an implied warranty of fitness for a particular purpose requires that the seller had reason to know of the particular purpose for which the goods are required, that the buyer reasonably relied upon the seller's expertise in securing a suitable product, and that the product was defective for that particular use. *Id.*

In several jurisdictions, privity between buyer and seller (i.e., a direct sale) is a necessary element to any claim for breach of implied warranty. *See, e.g., Blanco v. Baxter Healthcare Corp.*, 158 Cal. App. 4th 1039, 1058-59 (2008) (“The general rule is that privity of contract is required in an action for breach of either express or implied warranty . . . .”) (quoting *All West Elecs., Inc. v. M-B-W, Inc.*, 64 Cal. App. 4th 717, 725 (1998)); *Frye v. L’Oreal USA, Inc.*, 583 F. Supp. 2d 954, 959 (N.D. Ill. 2008) (“in Illinois only a buyer in privity with a seller can maintain a claim for breach of implied warranty for recovery of economic damages”).

A raw material supplier sits at the top of the chain of distribution and therefore likely does not sell directly to the end user of the final product. In the medical context, the manufacturer of the device or implant most likely sold the product to hospitals or doctors and not to consumers. *See Currier*, 2011 WL 4898501, at \*4 (“Because this is a medical implant case, and the FAC alleges that the product was surgically inserted in a hospital, the Court cannot plausibly infer . . . that Plaintiff relied on anything other than his physician’s skill and judgment in selecting [the product], nor that any purchase of the product was based on a warranty from the manufacturer to Plaintiff.”); *Martin*, 83 N.Y.2d at 9 (“Warnings for prescription drugs are intended for the physician, whose duty it is to balance the risks against the benefits of various drugs and treatments and to prescribe them and supervise their effects.”). Thus, the consumers cannot allege that they dealt directly with the device manufacturer or its material suppliers or assert that they entered into a contract with any of them for purchase of the device. Absent such allegations, privity does not exist between the consumer and the manufacturer/supplier. As such, suppliers should look to the law of the relevant jurisdiction to see if the lack of privity is an available defense to implied warranty claims alleged against them.

##### (1) Express Warranty

An express warranty is breached when a product fails to exhibit the characteristics, properties, or qualities explicitly attributed to it by its warrantor and thus fails to conform to the warrantor’s representation. *See Am. L. Prod. Liab.* 3d § 19:28. They are less common in medical device and pharmaceutical product liability litigation. That said, in most jurisdictions that have considered the issue, economic damages can be recovered in a products liability action based on express warranty despite the lack of vertical privity. *See, e.g., Harris Moran Seed Co., Inc. v. Phillips*, 949 So. 2d 916 (Ala. Civ. App. 2006); *Prairie Prod., Inc. v. Agchem Div.-Pennwalt Corp.*, 514 N.E.2d 1299, 1302 (Ind. Ct. App. 1987) (“a plaintiff may recover against a manufacturer for economic loss for breach of express warranties, even though the plaintiff is not in privity with the manufacturer.”).

Although in some jurisdictions, certain types of economic damages may not be available to nonprivity buyers. *See Beyond the Garden Gate, Inc. v. Northstar Freeze-Dry Mfg., Inc.*, 526 N.W.2d 305 (Iowa 1995) (nonprivity buyer permitted to recover for direct economic loss in value of goods purchased but not permitted to recover for consequential economic loss such as lost profits, loss of goodwill, or business reputation). And in other jurisdictions, recovery of economic damages under express warranty may be prohibited in the absence of vertical privity. *See Flory v. Silvercrest Industries, Inc.*,

129 Ariz. 574 (1981); *Twin Disc, Inc. v. Big Bud Tractor, Inc.*, 582 F. Supp. 208 (E.D. Wis. 1984) (applying Wisconsin law). Accordingly, suppliers should ascertain whether privity is an available defense for express warranty in the jurisdiction where their case is pending and use the defense, if applicable.

## 3D Printing – Examples of Raw Materials Used, Health Risks, and Supplier Liability

### A. Combustible Powders

As described in the Environmental Effects and Health Risks in the Workplace Chapter in further detail, fine powders are typically used in the 3D printing sintering process, which raise health concerns because numerous elements, in powder form, are combustible. The SLS additive manufacturing process requires that the build chamber be filled with powder, even in the volumetric space not occupied by the printed parts. During build retrieval, the parts are extracted from within the chamber filled with unsintered powder, and powder on the parts is then brushed or washed off. The unsintered powder in the chamber is recycled for future builds. Therefore, a significant amount of raw powder is present throughout the SLS manufacturing process, and if poorly maintained, may result in explosions or flash fire exposure. Indeed, a few publications provide scenarios that may lead to combustion events. See T.J. Myers, A.F. Ibarreta, "Tutorial on Combustible Dust," *Process Safety Progress*, 2013, 32[3]: 298; see also T.J. Myers, A.F. Ibarreta, M.C. Stern, S.C. O'Hern, and C.D. Page, "Combustible dust hazards in additive manufacturing operations," *Proceedings POWDERMET 2016, International Conference on Powder Metallurgy & Particulate Materials*, Boston, MA 2016. The consequences can be personal injury, property damage, and damage to the equipment.

### B. Raw Metal Powder Exposure

The average powder grain-size of metallic powders used for additive manufacturing may introduce health concerns to operators, and nearby workers, of the additive manufacturing machine(s). The minimum dosages that lead to health risks differ between elements. A study reported by Kozlowski, et al., lists the health impacts as a result of the intake of various metallic elements into the human body – some of these elements are actively being used in additive manufacturing, such as nickel, iron, chromium, and copper, to name a few. See H. Kozlowski, P. Kolkowska, J. Watly, K. Krzywoszynska, S. Potocki, "General Aspects of Metal Toxicity," *Current Medicinal Chemistry*, 2014, 21: 3721. Aluminum, a widely used element in additive manufacturing, has been shown to impact the central nervous system. See C.A. Shaw, L. Tomljenovic, "Aluminum in the central nervous system (CNS): toxicity in humans and animals, vaccine adjuvants, and

autoimmunity," *Immunol Res*, 2013, DOI 10.1007/s12026-013-8403-1. Even though the works of both parties offer insight into the damaging effects of metallic elements within the human body, neither report mentioned the intake of metals through a scenario such as additive manufacturing. Thus, it's quite possible that detailed studies, which are available in literature, that investigate the impact metallic dust exposure has on humans that operate, or work near, additive manufacturing units, may still be in its infancy.

Nonetheless, the likely paths to failure include, but are not limited to:

- (1) The absence of a respiratory mask can lead to inhalation of these powders.
- (2) Skin contact or inhalation can occur because of improper handling/transfer of containers holding the powder to be used in the additive manufacturing process.
- (3) Improper removal of powder during post-processing or material change-over can lead to inhalation of these powders.

### C. Raw Polymer Powder Exposure

Process and component health and safety concerns associated with polymeric-based powders mirror many of the same concerns as with metallic powder exposure. Many general health and safety risks associated with polymeric materials are discussed by the United States Department of Labor Occupational Safety and Health Administration ("OSHA"), but additive manufacturing process-specific issues still exist. See OSHA Technical Manual ("OTM") Section III; Chapter 1 Polymeric Matrix Materials: Advanced Composites. Possible paths to safety incidents, health hazards or general failures include, but are not limited to:

- (1) Absence of the proper PPE, such as respiratory masks and skin coverings, can allow for inhalation or dermal contact of the material to the body.
- (2) Poor or improper cleaning of equipment and component parts may allow powder and dust to build up and spread, resulting in increased risk for personal exposure.
- (3) Improper or incorrect release testing from supplier, such as incomplete or inaccurate certificate of analysis ("COA"), or incorrect chemical or physical data, could result in a misuse of the product, leading to an increased risk of personal exposure or improperly formulated/manufactured product.

## D. Hazards to the End User

Components and devices manufactured through additive manufacturing processes are subjected to the same requirements as those made by other manufacturing techniques, and, as such, the majority of hazards present with traditionally manufactured components still apply. Manufacturers must perform adequate testing to show components created by additive manufacturing processes meet or exceed specifications. Additional testing and verification may need to be performed to ensure no process-specific changes occurred during manufacturing. Potential areas of failure that would be seen by an end user may be, but are not limited to:

- (1) Lack of appropriate release testing with respect to physical or chemical testing could result in improperly formulated/manufactured products.
- (2) Unintended chemical changes in materials, especially polymers, can occur because of the intense and direct heat used in sintering processes, increasing the likelihood of poorly manufactured products or exposure of end users to unintended materials.
- (3) Unintended modification of additive packages, because of the heat and energy applied in manufacturing, could result in product degradation and premature product failure.

## E. Medical Device Specific Hazards

Medical devices present specific challenges to be addressed with additive manufacturing produced products. As discussed above, the Biomaterials Access Assurance Act prevents suppliers of raw materials from being sued by allegedly faulty implanted materials or devices. However, this does not address all concerns, especially those of the device manufacturer. In general, the manufacturer of a medical device is solely responsible for demonstrating a device is safe and functional, and is appropriate for the specified use. This is accomplished through the regulatory pathway, such as obtaining 510(k) clearance, or other regulatory clearance, to legally market a medical device within the United States. In May 2016, the Food and Drug Administration (FDA) issued a draft guidance addressing technical considerations in additive manufacturing. *See Technical Considerations for Additive Manufactured Devices; Draft Guidance for Industry and Food and Drug Administration Staff. Issued May 16, 2016.* These technical considerations are not required by the FDA, but are manufacturing-specific considerations that any manufacturer should consider prior to regulatory submission.

Many published documents define overarching specifications, requirements and recommendations for medical device manufacturers on proper considerations

and testing needed prior to obtaining regulatory approval or clearance. *See, e.g., 21 CFR 820.70, 21 CFR 820.30, 21 CFR 820.75, ISO-10993; Biological Evaluation of Medical Devices.* While these documents contain the needed documentation and testing for most medical devices, such as specific biocompatibility testing, additive manufacturing-specific issues may not always be addressed directly. These issues may include, but are not limited to:

- (1) Improper or incomplete cleaning or sterilization may occur because of the availability of more complex geometries provided by AM, resulting in increased risk of patient exposure to poorly sterilized devices.
- (2) Higher intra-lot variation owing to the ability of additive manufacturing to provide multiple components on one machine, could lead to increased failure rates.
- (3) The increase in complex geometries could lead to inefficient or incomplete biocompatibility testing, such as cytotoxicity testing, extractables, etc., possibly resulting in increased exposure risk to improperly tested materials.

## Liability/Conclusion

Understandably, suppliers of the powders used in additive manufacturing may have some concern about the aforementioned risks and injuries to both trained personnel of the machine and the end consumer. When faced with a lawsuit, suppliers should consider the aforementioned defenses and whether they are applicable to the situation at hand. Raw suppliers may also want to consider other preventive measures, outside of legal defenses, such as working with manufacturers that are careful about the selection of raw materials, knowledgeable about the uses to which the materials will be subjected, and that have a history of adequately warning and instructing employees, intermediaries, and/or end users. These measures may help a supplier avoid liability or prevent injuries altogether.

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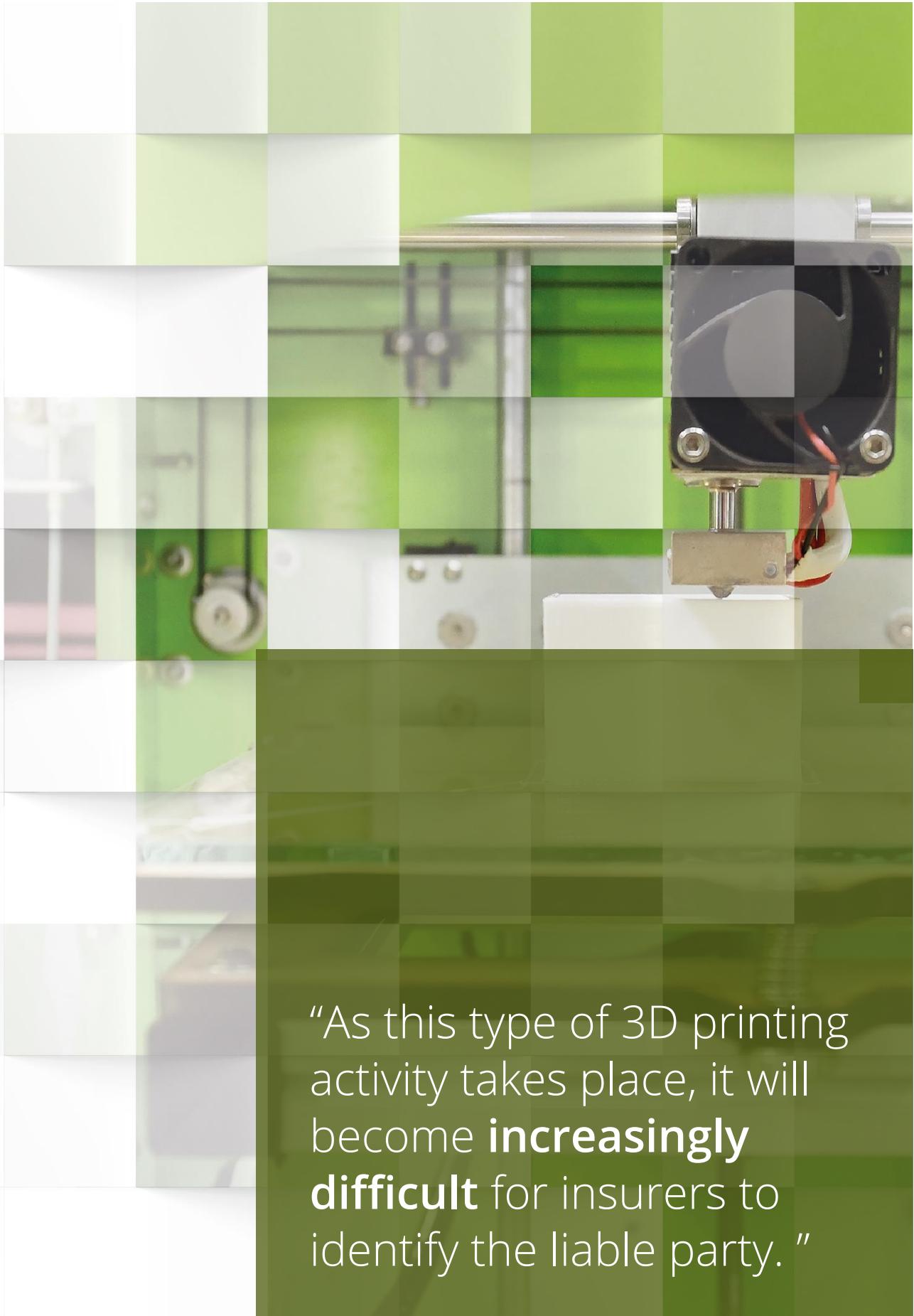
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"As this type of 3D printing activity takes place, it will become **increasingly difficult** for insurers to identify the liable party."

# Insurance Issues

As 3D printing becomes more prevalent, liability risks to individuals and businesses will likely climb in similar fashion—and with it, the need to explore whether existing insurance provides adequate coverage or whether additional coverage is needed. In addition to design and intellectual infringements, discussed *supra*, 3D printing presents many types of risks, including product liability risks and environmental liability risks, to name a few.

Because 3D printing will blur the line between manufacturers and end-users, it will create challenges in apportioning liabilities and pose accountability and traceability issues.<sup>121</sup> The number of persons potentially liable for injuries caused by a 3D printed defective product is an issue insurance companies will have to consider in measuring the risks and determining premiums. Because 3D printers are becoming more accessible—individuals can purchase the printers, use an online 3D printing service like Sculpteo<sup>122</sup>, or use the 3D printers in a brick-and-mortar communal workspace (or “hackerspace”) to print objects using designs and materials that may have been created or manufactured by a third party. As this type of 3D printing activity takes place, it will become increasingly difficult for insurers to identify the liable party.

Whether the injury will be covered by an insurer is a separate issue. Consider for example, a hobbyist who sells an object that was printed in his garage, which causes injuries to a customer. An issue will exist as to whether there will be coverage under the individual’s homeowners insurance policy, which typically contains a business exclusion, which bars coverage for activities carried out for financial gain.<sup>123</sup>

<sup>121</sup>Swiss Re, *3D Printing: Implications For The Re/Insurance Industry*, [http://www.swissre.com/reinsurance/insurers/casualty/3D\\_printing\\_implications\\_for\\_the\\_reinsurance\\_industry.html](http://www.swissre.com/reinsurance/insurers/casualty/3D_printing_implications_for_the_reinsurance_industry.html) (last visited May 8, 2015).

<sup>122</sup><http://www.sculpteo.com/en/>.

<sup>123</sup> Charlie Kingdollar, March 11, 2013, *3D Printers – A New Exposure for Personal Lines Carriers*, <http://www.genre.com/knowledge/blog/3D-Printers--A-New-Exposure-for-Personal-Lines-Carriers.html> (last visited June 12, 2015).

Not only does the finished 3D printed object present risks requiring insurance, but the 3D printing process itself also calls for environmental liability insurance because of the potential for raw materials being used to print 3D objects to release fine toxic particles into the atmosphere,<sup>124</sup> as discussed in the chapter on environmental issues below. Injuries arising from the release of toxic particles from a 3D printer, however, may implicate the pollution exclusion.<sup>125</sup> Courts that have addressed this issue are split on whether the pollution exclusion applies to indoor contaminants.<sup>126</sup> The circuit courts are split on the meaning of the terms “discharge, dispersal, seepage, migration, release or escape,” and whether the pollution exclusion bars coverage for all injuries caused by the release of pollutants where the pollutant is dispersed into a confined area.<sup>127</sup> Thus, whether a policyholder receives coverage for claims for bodily injuries caused by a 3D printer’s release of pollutants, may depend on the particular jurisdiction’s interpretation of these terms.

Against the backdrop of 3D printing, insurers will likely evaluate some or all of the following in evaluating coverage for policyholders:

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<sup>124</sup> See Phys.Org, 3D printers shown to emit potentially harmful nano-sized particles, July 24, 2013, <http://phys.org/news/2013-07-3d-printers-shown-emit-potentially.html> (last visited May 8, 2015).

<sup>125</sup> William F. Knowles and Kathleen M. Grohman, May 22, 2014, *Thorns of 3D Printing*, <http://claims-management.theclm.org/home/article/Thorns-of-3D-Printing> (last visited June 12, 2015).

<sup>126</sup> *Id.*

<sup>127</sup> *Firemen's Ins. Co. of Washington, D.C. v. Kline & Son Cement Repair, Inc.*, 474 F. Supp. 2d 779, 792-94 (E.D. Va. 2007).

- Whether there are any increases in the risk to the insured as a result of the manufacturing process (e.g., additive manufacturing is not heavily regulated and poses the risk of counterfeit goods being printed and sold, arguably more so than traditional manufacturing)
- Any supply chain issues
- Complexities associated with the ability to trace the parties responsible for the defects in manufacturing and its potential impact on subrogation/recovery rights
- The number of jurisdictions in which the insured operates and their regulators
- Discussions with product developers that the policyholder uses
- The risks at each stage, from manufacturing the product to testing and distributing to the end user, including the risks associated with the quality of the raw materials being used and potentially new combinations of materials, which may not have been properly tested<sup>128</sup>
- Whether applying for insurance or renewing one's insurance, businesses can reduce the risk to themselves by employing one or more strategies:
  - Develop strategies for managing the product risks through greater traceability of designs, raw materials and components (including physical identifiers on products)
  - Have an open dialogue with the insurer's risk manager to implement a risk-management solution
  - Consider the need for product recall insurance
  - Consider the need for worldwide coverage where products are sold globally
  - Take mitigating actions and have contingency plans in place
  - Implement negotiated (as vendor or buyer) disclaimers, non-liability clauses, or caps to limit one's liability

- Review risk-management processes and show underwriters that key issues, such as maintaining quality control, have been addressed<sup>129</sup>

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<sup>129</sup> Stuart Collins, Allianz, The universe in 3D, <http://www.agcs.allianz.com/insights/expert-risk-articles/the-universe-in-3d/>

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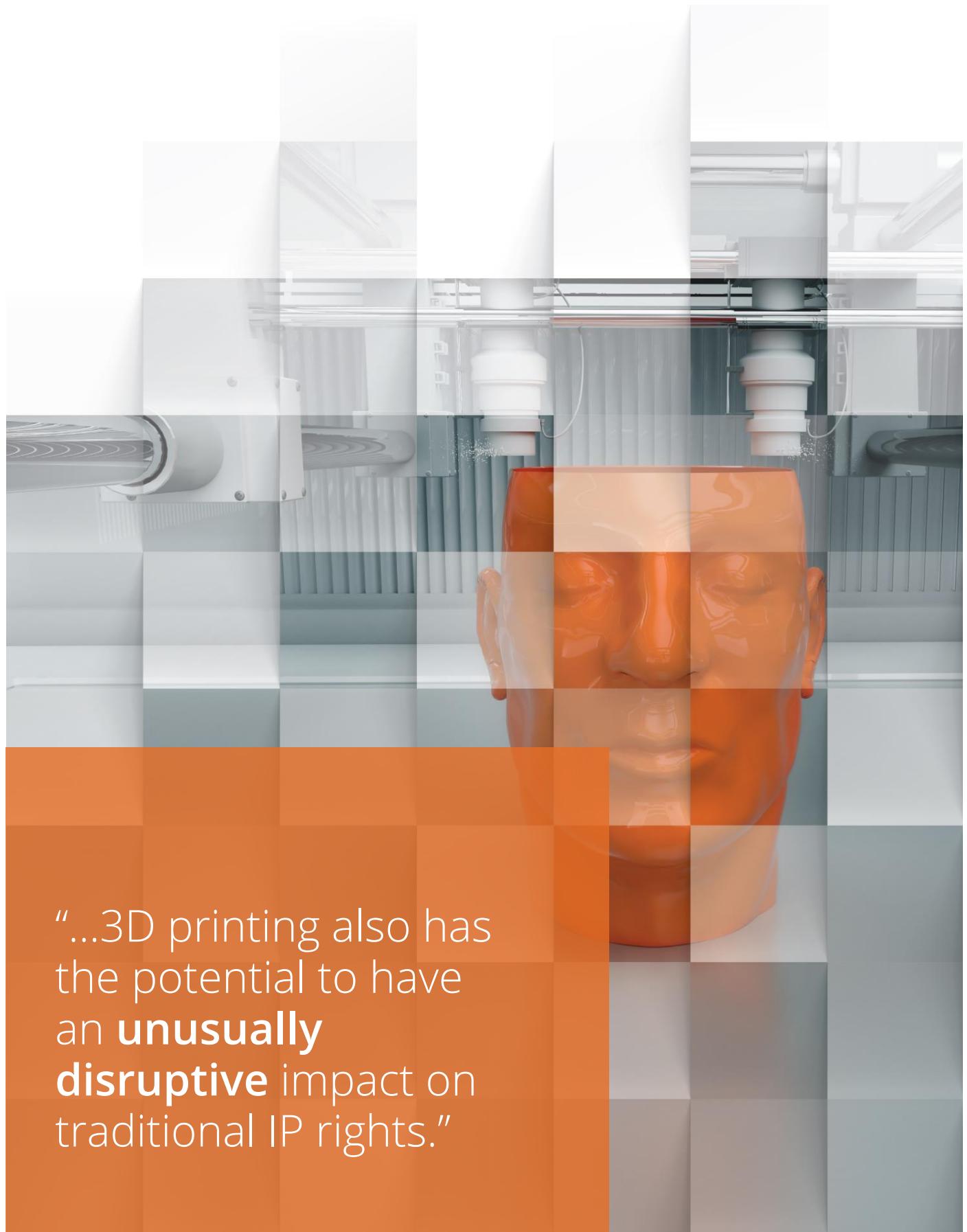
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<sup>128</sup> Karishma Paroha, June 2, 2014, *3-D Printed Products, Product Liability And Insurance Implications*, <http://www.kennedyslaw.com/article/3dprintedproducts/>.



“...3D printing also has the potential to have an **unusually disruptive** impact on traditional IP rights.”

# Intellectual Property Issues

Jewelry, automotive parts, medical devices, firearms and even replacement body parts: with each passing day, an increasing number of corporations, inventors and home-users (often referred to as “makers”) are harnessing the potential of 3D printing to change the way goods are designed, distributed and manufactured. Over the past several years, interest in 3D printing has increased dramatically.

As with any emerging technology, intellectual property (“IP”) rights protect new innovations in the 3D printing field and have already played a role in the technological development, and market availability, of 3D printers. This is to be expected, as IP rights, by their very nature, should impact the development of a new technology. But 3D printing also has the potential to have an unusually disruptive impact on traditional IP rights.

This chapter examines the interplay between IP rights and 3D printing. In it, we will discuss: (1) the current state of IP (particularly patent) coverage of 3D printing itself; (2) the applicability of existing IP laws to 3D printing; (3) the unique challenges associated with enforcing IP rights against users of 3D printers; and (4) some options that IP rights-holders may consider as the 3D printing industry evolves.

## 3D Printing IP Landscape

While “3D printing” and “additive manufacturing” have recently become popular technological buzzwords, 3D printing is not a new technology. Some of the earliest 3D printing-related patents were granted in the early 1980s<sup>130</sup> and, indeed, many of them have already expired, including, for example, several of the initial patents relating to fundamental 3D printing technologies, such as stereolithography<sup>131</sup>; selective laser sintering<sup>132</sup>,

<sup>130</sup> See, e.g., U.S. Patent No. 4,323,756 (filed Apr. 6, 1982) (“Method for Fabricating articles by sequential layer deposition”); U.S. Patent No. 4,575,330 (filed Mar. 11, 1986) (Apparatus for production of three-dimensional objects by stereolithography).

<sup>131</sup> See, e.g., U.S. Patent No. 4,575,330 (filed Mar. 11, 1986) (expired patent for “Apparatus for Production of Three-dimensional Objects by Stereolithography); U.S. Patent No. 5,569,349 (filed Oct. 29, 1996) (expired patent for “Thermal Stereolithography”); U.S. Patent No. 5,609,812 (filed Mar. 11, 1997) (expired patent for Method of Making a Three-Dimensional Object by Stereolithography”)

and fused deposition modelling.<sup>133</sup> Not surprisingly, the expiration of these core technology patents has coincided with a significant increase in interest in 3D printing. By way of example, data from Google.com shows a marked increase in searches for 3D printing starting around 2013:<sup>134</sup>

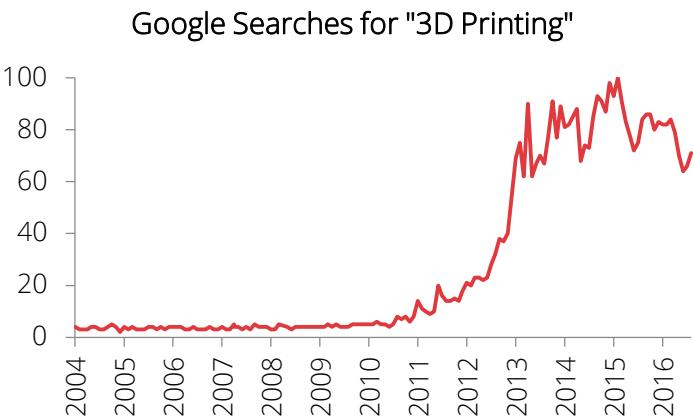


Figure 1: Google Trends Data for "3D Printing" Searches

<sup>132</sup> See, e.g., U.S. Patent No. 5,597,589 (filed Jan. 28, 1997) (expired patent for “Apparatus for Producing Parts by Selective Sintering); U.S. Patent No. 5,639,070 (June 17, 1997) (“Method for Producing Parts by Selective Sintering”)

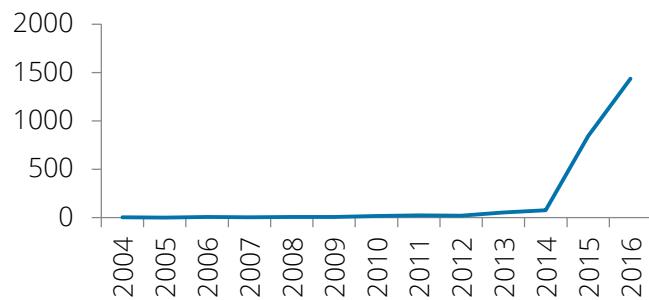
<sup>133</sup> See, e.g., U.S. Patent. No. 5,503,785 (filed Apr. 2, 1996) (expired patent for “Process of Support and Removal for Fused Deposition Modeling”)

<sup>134</sup> Data obtained from Google.com for unique searches for “3D Printing” where 100 on the x-axis represents peak interest and other values are measured relative to peak interest.

This increase in interest is likely because of a combination of factors. The expiration of key patents has placed core 3D printing technology in the public domain, allowing the public to access what was once a monopoly granted to a small group of patent holders. Further, technical advancements and reduced pricing – both likely related to the expiration of those fundamental patents -- have allowed hobbyists and smaller companies, previously priced out of the 3D printing market, to begin using the technology. Until recently, 3D printers were prohibitively expensive and their use was typically limited to rapid prototyping by businesses that could afford the devices' high price tags. At least one survey showed that steep start-up costs were a main factor that is dissuading companies from implementing a 3D printing program.<sup>135</sup> But the price of 3D printers has now dropped considerably and will continue to do so, with analysts predicting a significant continued reduction in price and an increase in printing speed over the next decade<sup>136</sup>, making 3D printing significantly more cost efficient for businesses and home users alike.

Mirroring this increase in availability and interest, the USPTO has seen a marked upswing in the number of patent applications filed for technologies relating to 3D printing over the past several years. A search of published applications in subclass B33Y (patent applications are typically published 18 months after their filing date), which contains patent applications relating to additive manufacturing, reveals that in 2013, there were 53 published applications relating to 3D printing. By 2014 the number had grown to 76 published applications. And in 2015, the number increased significantly to 845 published applications in the additive manufacturing subclass. This growth trend appears to be continuing in 2016. As of September 1, 957 applications had been filed in 2016. If this rate continues throughout the year, the USPTO will publish around 1,436 applications in the 3D printing space in 2016 (extrapolated figure shown in chart).

## Published Applications in Subclass B337



But while the growth in new patent applications is significant, it does not necessarily indicate the creation of a so-called “patent thicket” that would block newcomers from bringing novel 3D printing technologies to market. With many of the fundamental 3D printing technologies now in the public domain, more recent patents issued in the 3D printing space claim *specific* uses of, and improvements to, 3D printers, including, for example: (1) the use of 3D printing to manufacture custom eyewear<sup>137</sup>, patterns on turbine shrouds<sup>138</sup>, accurate models of a patient’s aorta,<sup>139</sup> and aerogels<sup>140</sup>; (2) improvements to 3D printers, including the detection of malfunctioning jets and nozzles<sup>141</sup>, as well as the use of sensors to assure proper alignment of the print platform<sup>142</sup>; and (3) new printing materials, including new radiation curable resins<sup>143</sup>, and even bio-ink (used for the 3D printing of living tissue)<sup>144</sup>. Thus, while the overall number of patents in the space is growing rapidly, start-ups, at-home users and other potentially budget-sensitive manufacturers will still have access to the basic, public-domain technologies involved in 3D printing – access that will likely increase as additional early patents expire over the next several years and the price of consumer 3D printers continues to drop.

Further, some members of the at-home 3D printing, or “maker” community, as well as multiple academic institutions, have focused their efforts on the development of so-called “open source” 3D printers,

<sup>135</sup> Gartner Survey Reveals That High Acquisition and Start-Up Costs Are Delaying Investment in 3D Printers (Dec. 9, 2014), <http://www.gartner.com/newsroom/id/2940117> (last visited Oct. 27, 2016).

<sup>136</sup> Siemens has predicted a 50% reduction in cost and 400% increase in speed for 3D printers between 2013 and 2018. *3D Printing: Facts & Forecasts* (Oct. 1, 2014), <http://www.siemens.com/innovation/en/home/pictures-of-the-future/industry-and-automation/Additive-manufacturing-facts-and-forecasts.html> (last visited Oct. 27, 2016).

<sup>137</sup> U.S. Patent No. 9,304,332 (filed Apr. 5, 2016).

<sup>138</sup> U.S. Patent No. 9,289,971 (filed Mar. 22, 2016).

<sup>139</sup> U.S. Patent No. 9,305,123 (filed Apr. 5, 2016).

<sup>140</sup> U.S. Patent No. 9,278,465 (filed Mar. 8, 2016).

<sup>141</sup> U.S. Patent No. 9,304,322 (filed Apr. 5, 2016); U.S. Patent No. 9,302,519 (filed Apr. 5, 2016).

<sup>142</sup> U.S. Patent No. 9,233,507 (filed Jan. 12, 2016).

<sup>143</sup> U.S. Patent No. 9,228,073 (filed Jan. 5, 2016).

<sup>144</sup> U.S. Patent No. 9,227,339 (filed Jan. 5, 2016).

rather than on patenting 3D printing technologies. This “open source” community develops and freely shares technology related to 3D printing, including “do it yourself” instructions on how to build 3D printers from available parts (such as the typically expensive SLS-type 3D printers<sup>145</sup>) and publicly available firmware to operate the assembled printers -- thereby providing easy, affordable entry into the 3D printing market for those previously priced out of it.

Overall, the patent landscape surrounding 3D printing appears as though it will continue to grow and diversify. The current increase in patent filings is likely to continue in the near future as a larger, broader group of innovators gains access to previously cost-prohibitive 3D printers. Similarly, the open-source community stands poised to make further contributions in the 3D printing space as additional core 3D printing patents expire over the next several years, assuring that the public has greater uninhibited access to the basic technologies of 3D printing.

## The Effect of 3D Printing on Existing IP Rights

The advances in 3D printing technology are exciting, but they also raise real concerns, not least of which is the fact that 3D printing can make it both easier to infringe IP rights and harder for an IP rights-holder to stop that infringement. Particularly for simple goods, like simple patented devices and products, a potential counterfeiter may have to do little more than scan an IP-protected object with a 3D scanner and then print an unlicensed, unauthorized copy on a 3D printer. More broadly, 3D printing has the potential to turn individual members of the public – traditionally end-users and consumers -- into manufacturers. With an at-home 3D printer, any “maker” can download an infringing 3D printable file from the internet and manufacture any number of infringing copies. Therefore, 3D printing is likely not just to make infringement easier for existing counterfeiters, but also to increase the number of potential IP infringers capable of creating, selling and using infringing goods -- thereby making effective enforcement of IP rights more difficult for rights-holders.

Current laws governing IP rights pre-date the advent of 3D printing and do not directly address the unique issues created by the use of 3D printers. The efficacy of traditional IP law to protect IP rights-holders may often depend on how 3D printers are ultimately used in the manufacture of infringing and counterfeit goods. In

<sup>145</sup> See Ian S. Kinstlinger, et al., *Open-Source Selective Laser Sintering (OpenSLS) of Nylon and Biocompatible Polycaprolactone*, PLoS ONE (Feb. 3, 2016).

some cases, 3D printers may be used in an otherwise fairly traditional manufacturing scheme, such that rights-holders can rely upon copyright, patent, trademark, trade dress and trade secret laws to protect their creative works, inventions, brands and valuable proprietary information. In other cases, however, IP rights-holders may encounter novel and unique enforcement issues because of the unconventional methods of manufacture and distribution that 3D printing has made possible. What follows is a discussion of the basic categories of IP rights likely to be affected by 3D printing, and an assessment of how 3D printing may affect enforcement of those rights under certain circumstances.

## Copyright

“Original works of authorship,” including literary, pictorial and sculptural works, are protected by federal copyright law automatically upon their creation in a fixed form.<sup>146</sup> To qualify for copyright protection, a work must be original and non-functional.<sup>147</sup> Purely functional works are not entitled to copyright protection.<sup>148</sup> Works that contain both artistic and functional elements are entitled to copyright protection only for those artistic elements that are separable from the work’s functional elements.<sup>149</sup> Thus, whether copyright protection extends to an item printed on a 3D printer will largely depend on whether the printed item is purely functional, purely decorative or some mixture of both. This is the same analysis traditionally used to assess the scope of copyright protection, regardless of whether the work in question has been 3D printed. For example, an original jewelry design, which is usually decorative and non-functional, is typically entitled to some degree of copyright protection. Therefore, replication of a piece of jewelry on a 3D printer may give rise to a claim of copyright infringement. In contrast, the act of printing a useful, non-decorative object on a 3D printer – such as a replacement bolt, a custom heart valve or an orthodontic retainer – is not likely to trigger a copyright claim.

Copyright protection may also attach to the electronic files used in 3D printing. 3D printing requires a “digital blueprint” of the object to be printed.<sup>150</sup> The blueprint may be designed using a CAD program on a computer or

<sup>146</sup> 17 U.S.C. §§ 101 et seq. (2016); see generally, e.g., Melville B. Nimmer & David Nimmer, *Nimmer on Copyright (“Nimmer”)* § 2.03 (Matthew Bender, Rev. Ed. 2015).

<sup>147</sup> See generally, Nimmer § 2.18.

<sup>148</sup> See generally, e.g., Nimmer § 2.18.

<sup>149</sup> See generally, e.g., Nimmer § 2.08.

<sup>150</sup> See, e.g., Sarah Swanson, *3D Printing: A Lesson in History: How to Mold the World of Copyright*, 43 Sw. L. Rev. 483, 484 (2014) (“Swanson”).

be created using a 3D scanner to scan an existing physical object.<sup>151</sup> While courts have yet to fully define the extent to which CAD files are covered by copyright laws, most commenters agree that CAD files may receive some copyright protection to the extent that the files contain creative elements.<sup>152</sup> As such, copying the creative aspects of a CAD file without the file author's (or assigned owner's) permission should constitute copyright infringement. However, even if a CAD file itself is entitled to some level of copyright protection, the *use* of a CAD file to print an object on a 3D printer likely will amount to a violation of copyright laws, only if some aspect of the printed object itself is also copyrightable.<sup>153</sup> And one who uses a 3D scanner to create an image of the object to be printed and then creates a blueprint from that image may escape liability for copyright infringement if (s)he copies only unprotected functional features of the object, and not aesthetic or artistic elements.<sup>154</sup>

## Patent

Patent law may give IP rights-holders greater protection against unauthorized 3D printing of their products. The owner of a utility patent claiming a new and novel product or process has the right to exclude others from making, using, selling, offering for sale and/or importing into the United States any products and/or processes covered by the patent.<sup>155</sup> A patent may be infringed directly (by one who makes, uses, sells, etc., the claimed invention); indirectly (by one who knowingly and actively induces others to infringe); or contributorily (by one who knowingly makes, uses, sells, offers to sell or imports components of a patented product, or materials for use in a patented process, that have no other substantial non-infringing use).<sup>156</sup> Thus, an inventor who has

patented a device and/or methods of using that device may invoke the patent laws to: (1) enjoin the manufacture, sale and importation of 3D printed copies of its product; (2) enjoin the use of 3D printed copies of its product; and (3) enjoin deliberate attempts by third parties to encourage others to use 3D printed copies of its product. Importantly, although one who creates a blueprint for 3D printing from a scanned image of a product may avoid copyright infringement liability, (s)he will not escape liability for patent infringement associated with the subsequent manufacture, use, sale, offer to sell or importation of that product, if the product and/or its methods of use are protected by patent.<sup>157</sup>

Separately, the question of what, exactly, has been 3D printed, and the purpose for which it has been used, may create close legal questions under the patent law. For example, repairing a patented device using a 3D printed replacement of a non-patented component may not constitute patent infringement. On the other hand, replicating a patented device by using a 3D printer to create all of its components may well constitute patent infringement.<sup>158</sup>

## Trademark, Trade Dress and Counterfeiting

Trademark law is intended both to protect brand owners against misappropriation of the goodwill they have built in their trademarks (e.g., brand names and logos) and trade dress (i.e., the distinctive packaging or design of a product), and to protect consumers from misperception caused by the use of confusingly similar marks and trade dress.<sup>159</sup> Generally, 3D printing likely will not implicate trademark and trade dress concerns so long as (1) what is printed lacks any company or brand names, or patterns or designs, and (2) the design of the printed article is functional rather than aesthetic.

Trademarks do, however, help manufacturers guard against counterfeiting. For products that bear a manufacturer's brand, a 3D printer who includes the manufacturer's mark on its 3D printed products will run afoul of federal trademark law and anti-counterfeiting law.<sup>160</sup> 3D printed products that do not include the manufacturer's trademarks, on the other hand, may be easier to spot as unauthorized copies.

<sup>151</sup> *Id.*

<sup>152</sup> See Nimmer § 2.18[D][2]; see also, e.g., Swanson, at 486-88; Perry J. Viscounty, et al., 3D Printing: A New Technology Challenges the Existing Intellectual Property Framework, 56-OCT Orange County Law. 16, 18 (Oct. 2014) ("Viscounty"); Micheal Weinberg, What's the Deal with Copyright and 3D Printing at 16 (Jan. 2013), [https://www.publicknowledge.org/files/What's%20the%20Deal%20with%20copyright\\_%20Final%20version2.pdf](https://www.publicknowledge.org/files/What's%20the%20Deal%20with%20copyright_%20Final%20version2.pdf) ("Weinberg")

<sup>153</sup> See Weinberg, at 16.

<sup>154</sup> *Id.*

<sup>155</sup> 35 U.S.C. §§ 101, 271. See generally 1-1 Donald S. Chisum, Chisum on Patents ("Chisum") §§ 1.01 (Matthew Bender Rev. Ed. 2015); 5-16 Chisum § 16.01. Design patents may also be used to protect ornamental, non-functional product design elements. 35 U.S.C. § 171 (2016). Given the limited applicability of design patents to the medical device industry, however, this chapter will focus on issues involving utility patents and 3D printing.

<sup>156</sup> See 5-16 Chisum § 16.01; 5-17 Chisum § 17.01.

<sup>157</sup> See generally, e.g., Davis Doherty, *Downloading Infringement: Patent Law as a Roadblock to the 3D Printing Revolution*, 26 Harv. J. Law & Tech. 353,359-61 (2012) ("Doherty").

<sup>158</sup> See, e.g., Doherty, at 361 & n 49.

<sup>159</sup> See, e.g., J. Thomas McCarthy, 1 McCarthy on Trademarks and Unfair Competition § 2.1 (4th Ed. 2016).

<sup>160</sup> See 15 U.S.C. § 1114(a) (2016).

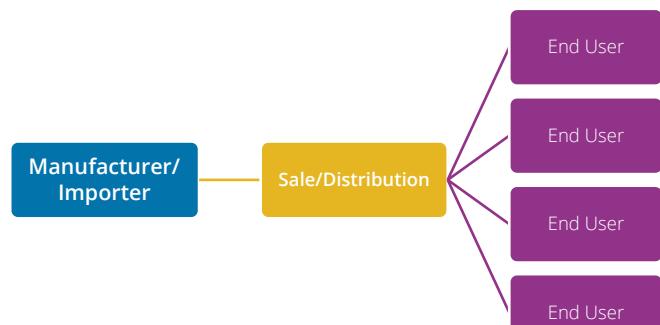
## Trade Secrets

If access to a particular object is all that is needed to derive a suitable digital blueprint of it, then 3D printing the object is not likely to be deemed a misuse of the manufacturer's trade secrets. On the other hand, someone who obtains and makes unauthorized use of a manufacturer's confidential and proprietary technical information (e.g., manufacturing tolerances) in creating a 3D printed copy of a device, or who otherwise obtains and uses confidential 3D blueprints without authorization, may be liable for misappropriation of the manufacturer's trade secrets.<sup>161</sup>

## Digital Distribution and Enforcement Issues

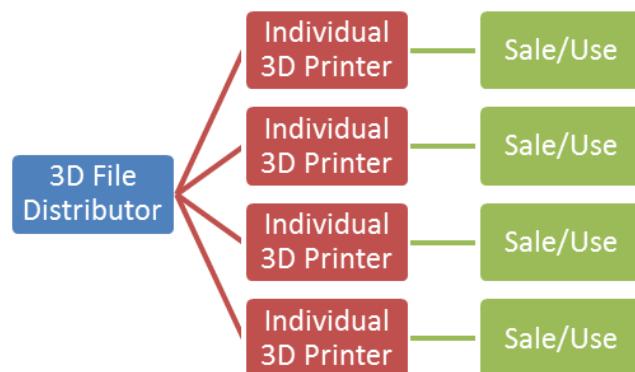
The impact that 3D printing will have on IP rights covering 3D printable products will likely often be tied to whether the product is distributed physically after printing, or digitally before printing.

When 3D printing is used by a single manufacturer in lieu of a more traditional method of manufacture to make and then distribute a large number of infringing or counterfeit products, enforcement of IP rights is likely to look no different than enforcement against other traditional manufacturers. In this context (physical distribution of 3D printed goods), a rights-holder will typically have one or more potential defendants to choose from who exercise control over the manufacture, importation or sale (or offer of sale) of all of the infringing products. Accordingly, as with any traditional case of IP infringement, a lawsuit can be filed against these pre-distribution infringers to stop the infringement in its totality, and collect damages based upon the number of infringing items that the single defendant controlled. Enjoining these upstream acts of infringement will prevent the infringing items from being distributed to the public at large, after which point enforcement becomes much more difficult.



<sup>161</sup> See, e.g., Roger M. Milgrim, et al., 1-1 Milgrim on Trade Secrets § 1.05 (Matthew Bender Rev. Ed. 2015).

In other cases, however, a product's design may be simple enough to be printed on-demand on inexpensive, consumer-owned 3D printers. In such cases, effective enforcement of IP rights – specifically patent rights – may become significantly more difficult because of the absence of a single controlling infringer. The real issue here is one of distribution. Products that can easily be 3D printed are unique in that their digital blueprints may be distributed to individual consumers *before* the products themselves have been made, used, sold, offered for sale, or imported (i.e., before they infringe any patent rights):



Because most patent claims cover *physical* objects (and/or methods of using them) and not the digital blueprints of physical objects, 3D printed objects will typically not be deemed to infringe a patent until the products are actually manufactured (i.e., 3D printed) by end-users, many of whom may print only a single copy for personal use. Thus, in situations where digital blueprints are distributed to end-users before any manufacture takes place, patentees may lack the single, controlling defendant typically needed to successfully stem the flow of infringing products or collect significant damages in an infringement lawsuit. Instead, rights-holders may be faced with (potentially) thousands of individual infringers, each having only printed a small number of infringing items.

Without an obvious target against which to assert their IP rights, IP rights-holders could be left with few viable enforcement options. One such option would be to file myriad infringement suits against the individual infringing users of 3D printers. But such mass litigation will often be undesirable for a number of reasons. First, there is the challenge of locating the individual consumers who have printed infringing products for their personal use. Second, suing individual users of 3D printers is not likely to result in the recovery of meaningful damages or workable injunctive relief. Third, the very same individual users may often be a rights-holder's actual or potential customers. For example, a medical device company that filed IP infringement suits against doctors, hospitals or

patients using 3D printers to print simple patented medical devices would do so at the risk of alienating its own customer base. Finally, lawsuits filed against consumers, as opposed to suits filed against competitors, may do damage to a rights-holder's public image – not unlike the copyright infringement cases filed by the music industry against individual file downloaders a decade ago.<sup>162</sup>

Another option may be to seek enforcement against the file distributors themselves. If the digital blueprints used to print the copyrighted or patented items are themselves copyright protected, then the copyright holder may have recourse against file distributors under the Digital Millennium Copyright Act ("DMCA"), which provides a mechanism by which a copyright holder may send a take-down notice to any website hosting and distributing copies of copyrighted files.<sup>163</sup>

For digital blueprints that lack clear copyright protection (such as files created by a 3D scan of a functional, non-decorative patented invention<sup>164</sup>), patent holders wishing to enforce their patent rights may be limited to asserting a claim of induced (not direct) infringement. Unlike direct infringement, induced patent infringement is not a strict liability tort. Instead, a plaintiff asserting induced infringement must show that the alleged induced infringer both (1) knew of the patent-in-suit and (2) knew that the actions that it actively induced (by selling the 3D blueprint) constituted patent infringement.<sup>165</sup> A plaintiff must also show that an actual act of direct infringement occurred.<sup>166</sup> This heightened evidentiary burden renders claims of induced infringement more difficult to prove, and less useful to rights-holders, than direct infringement claims.<sup>167</sup>

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<sup>162</sup> See Matthew Sag, *Piracy: Twelve Year-Olds, Grandmothers, And Other Good Targets For The Recording Industry's File Sharing Litigation*, 4 Nw. J. Tech. & Intell. Prop. 133, 133 (2006).

<sup>163</sup> 17 USC § 512(c)(1) (2016).

<sup>164</sup> See Weinberg, at 16.

<sup>165</sup> See *Commil USA, LLC v. Cisco Sys., Inc.*, 135 S.Ct. 1920 (2015).

<sup>166</sup> Id.

<sup>167</sup> Daniel Harris Brean, *Patenting Physibles: A Fresh Perspective for Claiming 3D-Printable Products*, 55 Santa Clara L. Rev. 4, 837, 839-41 (Oct. 7, 2015) ("Brean"). In theory, IP rights-holders could also consider asserting claims for contributory patent infringement under 35 U.S.C. § 271(c). To prove contributory infringement, the rights-holder would need to prove that: (a) the infringer knew of the rights-holder's patent; (b) the infringer made, sold, offered to sell and/or imported a component of the patented device that the infringer knew has no substantial non-infringing use; and (c) the infringer's acts led to an act of direct infringement. 35 U.S.C. § 271(c) (2016); see also, e.g., *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 377 U.S. 476, 488 (1964). In addition to the evidentiary challenges presented by proving

Finally, unlike physical objects, digital blueprints originating abroad cannot be excluded from the United States by the ITC. Indeed, a recent Federal Circuit ruling denied the ITC jurisdiction over electronic signals entering the United States from abroad, thereby further reducing the avenues of enforcement available to rights-holders seeking to stop the distribution of digital blueprints.<sup>168</sup>

## Planning Ahead: Strategic Considerations

3D printing is likely to add new challenges and barriers to traditional IP enforcement as access to this disruptive technology becomes more commonplace. But this does not necessarily mean that IP holders are unable to take affirmative measures to adapt to a future in which 3D printing plays an ever-bigger role in product manufacturing.

First, device manufacturers and other IP rights-holders can take steps to protect their IP position against the coming impact of cheap, widespread 3D printing. An anti-counterfeiting protocol, for example, including the use of proprietary product markings (some known only to the manufacturer) to distinguish genuine products and their component parts from counterfeit, can help manufacturers more readily spot unauthorized 3D printed goods in the marketplace. And while its jurisdiction is limited to physical objects, and excludes transmissions of data, seizure proceedings and actions before the ITC to enjoin the importation of counterfeit goods may help keep infringing goods out of the marketplace even when enforcement against individual users, printers and/or distributors of 3D printed goods might be difficult. A protocol for policing websites that allow sharing of CAD files, and for seeking the prompt take-down of copies of a manufacturer's design files pursuant to the DMCA, may also be a useful tool. And a preemptive IP protection strategy, which evaluates whether to seek patent protection not just for covered products as a whole, but also for their component parts and methods of use – as well as possible opportunities for trademark and/or trade dress protection – may help manufacturers develop a portfolio of IP rights more

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an accused infringer's knowledge of both the patent and the fact that the accused component has no substantial non-infringing use, however, at least under current law it seems unlikely in most instances that courts would find CAD files to be a "component" of a patented product for purposes of the statute. See generally, Timothy R. Holbrook, et al., *Digital Patent Infringement in an Era of 3D Printing*, 48 U. Cal. (Davis) L. Rev. 1319, 1344-53 (2015) (discussing challenges in asserting contributory infringement claims to address distribution of CAD files for printing patented products).

<sup>168</sup> See *ClearCorrect Operating, LLC v. Int'l Trade Comm'n*, 810 F.3d 1283 (Fed. Cir. 2015), rehearing en banc denied, 819 F.3d 1334, 1335 (Fed. Cir. 2016).

specifically suited to protecting against encroachment from 3D printing.

Additionally, careful claim drafting may help patent owners enforce their rights against the importation and/or distribution of 3D files under certain circumstances. 35 U.S.C. § 271(g) prohibits the importation of goods manufactured abroad using a process patented in the United States.<sup>169</sup> And while the Federal Circuit has stated that 271(g) only applies to the manufacture of physical articles<sup>170</sup>, at least two subsequent District Court opinions have suggested that, when a computer file is the “product” of the patented process, the file may qualify as a manufactured physical article under 271(g) when the computer file is created abroad and is then later sold or used in, or imported into, the United States.<sup>171</sup> While not yet tested in the courts, claims covering the method of creating computer-readable three dimensional models suitable for printing specific patentable items may give patentees the ability to use 271(g) to battle free-riders who scan patented products abroad, and then import the resulting digital blueprints for distribution to end-users in the United States.

Another potential claim drafting strategy involves the use of so-called *Beauregard*-type claiming. *Beauregard* claims originated in the mid-1990s as a way to claim computer programs stored on “physical media” (floppy disks). Because computer programs were typically claimed as process claims, a program had to be executed on a computer before infringing a software patent. The *Beauregard*-type claim was developed to claim a computer-readable physical medium containing a copy of the computer program, thereby enabling software patentees to sue for direct infringement when pirated copies of their programs were distributed on disks without having to wait for end-users to actually execute the programs on individual computers. Some commenters believe that *Beauregard*-style claims may be the best available option for directly claiming digital

<sup>169</sup> 35 U.S.C. § 271(g) provides, in relevant part, that: “Whoever without authority imports into the United States or offers to sell, sells, or uses within the United States a product which is made by a process patented in the United States shall be liable as an infringer, if the importation, offer to sell, sale, or use of the product occurs during the term of such process patent.”

<sup>170</sup> See *Bayer AG v. Housey Pharms., Inc.*, 340 F.3d 1367, 1377 (Fed. Cir. 2003).

<sup>171</sup> See *CNET Networks, Inc. v. Etilize, Inc.*, 528 F.Supp. 2d 985, 992-95 (N.D. Cal. 2007) (electronic catalogue made abroad was a “physical article” for the purposes of 271(g) when the claims of the asserted patent were directed toward the manufacture and creation of the catalogue itself); *Ormco Corp. v. Align Tech., Inc.*, 609 F. Supp. 2d 1057, 1075-77 (C.D. Cal. 2009) (3D printable file created using patented process abroad was a “product” for the purposes of 271(g)).

blueprints.<sup>172</sup> Specifically, a patentee may claim a computer readable medium (i.e., physical memory on a computer or printer) containing an executable file (a digital blueprint), which, when executed on a 3D printer, results in the manufacture of a patentable physical item. Like claims directed toward § 271(g), *Beauregard*-type claiming has not yet been successfully enforced in the 3D printing context.

In addition to taking proactive measures to protect their IP rights, rights-holders should consider the benefits of 3D printing. A licensing program that allows customers to 3D print replacement parts, for example, or to print products that are relatively simple to make and frequently used, could be a source of both revenue and customer goodwill.<sup>173</sup> Indeed, products and services are already on the market that allow for the protected streaming of digital blueprints to specific 3D printers, thereby allowing a customer to print a single authorized replacement part while still limiting the number of copies that the customer can print.<sup>174</sup>

Changes to the technology associated with 3D printing may also aid in the protection of IP rights as the field continues to develop. Stakeholders in the 3D printing industry already appear to be taking steps toward greater IP protection for 3D printable files. Specifically, the 3MF Consortium, a group of several major technology and 3D printing companies, including Microsoft, Autodesk, HP and Shapeways, has published a draft specification for a standardized file format for digital blueprints that explicitly includes the ability to add metadata relating to copyright and licensing terms, and also provides for digital signatures and content protection to prevent unauthorized file usage.<sup>175</sup>

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<sup>172</sup> Brean, *supra*.

<sup>173</sup> See McCue, TJ, Authentise Helps Lowe's Innovation Labs Build 3D Printing Experience For Consumers, (June 11, 2015), <http://www.forbes.com/sites/tjmccue/2015/06/11/authentise-helps-lowes-innovation-labs-build-3d-printing-experience-for-consumers/#569c978a40d4>

<sup>174</sup> See, i.e., AUTHENTISE SECURE: Security and intellectual property protection for Additive Manufacturing (2015) <http://authentise.com/tech/secure.pdf>

<sup>175</sup> Kurke, Tom, *Intellectual Property in the Coming World of Distributed Digital Manufacturing: Redux*, <http://3dprintingindustry.com/2015/12/16/intellectual-property-in-the-coming-world-of-distributed-digital-manufacturing-redux/>; 3MF Consortium. (2015). *3D Manufacturing Format* (Version 1.0), [http://www.3mf.io/wp-content/uploads/2016/03/3MFCoreSpec\\_1.1.pdf](http://www.3mf.io/wp-content/uploads/2016/03/3MFCoreSpec_1.1.pdf)

Further, commentators are already debating what changes, if any, should be made to existing IP laws to address the growing 3D printing industry.<sup>176</sup> Some suggest explicitly allowing patent coverage of digital blueprints.<sup>177</sup> Others suggest the adoption of a “Digital Millennium Patent Act” to provide take-down procedures akin to those available to copyright holders under the DMCA.<sup>178</sup>

Pending any such changes, manufacturers will have to both avail themselves of the options available under current law to protect against unauthorized 3D printing of their devices, and find ways to take advantage of the opportunities that 3D printing may offer.

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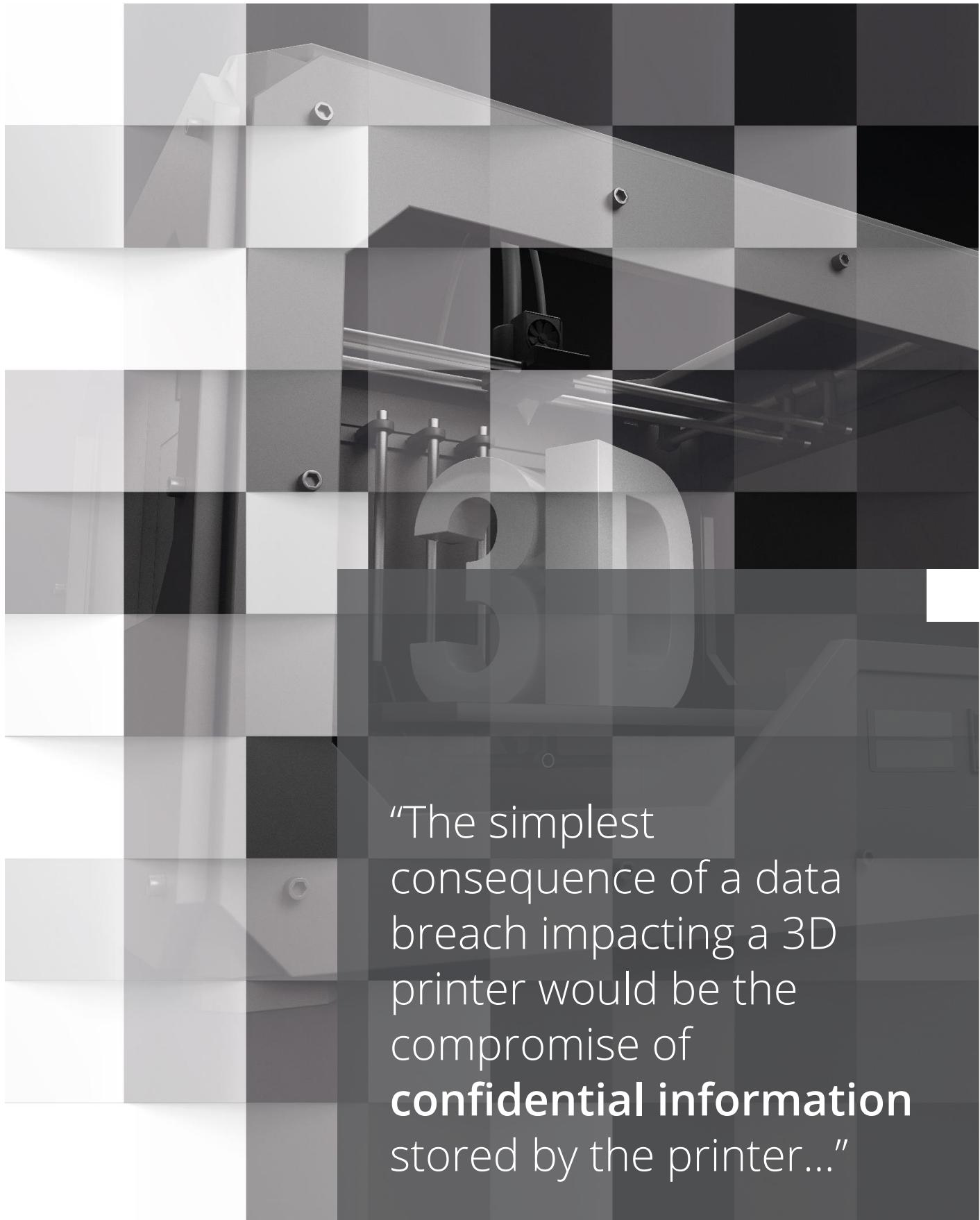
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<sup>176</sup> See generally, e.g., Doherty and Swanson, *supra*; Brean, *supra*.

<sup>177</sup> Brean, at 841.

<sup>178</sup> Deven R. Disai, et al., *Patents, Meet Napster: 3D printing and the Digitalization of Things*, 102 Geo L.J. 1691, 1719 (2013).



“The simplest consequence of a data breach impacting a 3D printer would be the compromise of **confidential information** stored by the printer...”

# 3D Printing Security Implications

3D printing devices are frequently connected to the Internet (directly or indirectly), often on a persistent basis.<sup>179</sup> As with other Internet-connected devices, this connectivity can result in a wide array of security and privacy issues, including significant risks to the confidentiality or integrity of processing techniques or design schematics.

As with other devices that fall under the Internet-of-Things ("IoT") umbrella, many 3D printers may not be sufficiently secured.<sup>180</sup> These devices are therefore vulnerable to a wide array of exploits and cyberattacks. In addition, cyberattacks against the computers and other IT infrastructure of 3D printer manufacturers, 3D product designers, and customers, can be used to indirectly compromise the confidentiality or integrity of processing techniques or design schematics used by 3D printers.

The rise in cyberattacks and data breaches (including those against IoT devices)—coupled with the increasing reliance on 3D printing to fulfill critical or sensitive business and consumer needs—is driving more attention to the significant legal and business risks for industry participants who fail to take adequate security measures to protect their products and designs.

## Confidentiality and Privacy Concerns

The simplest consequence of a data breach impacting a 3D printer would be the compromise of confidential information stored by the printer, such as schematics, customer configurations, and system logs.<sup>181</sup> The exfiltration of technical information could result in substantial harm to an organization where it involves trade secrets or intellectual property.<sup>182</sup> In addition, the

<sup>179</sup> MakerBot, Network Connectivity for Enterprise Private Networks: Fifth Generation MakerBot 3D Printers

[http://support.makerbot.com/learn/makerbot-desktop-software/using-makerbot-desktop/network-connectivity-for-enterprise-private-networks-fifth-generation-makerbot-3d-printers\\_11902](http://support.makerbot.com/learn/makerbot-desktop-software/using-makerbot-desktop/network-connectivity-for-enterprise-private-networks-fifth-generation-makerbot-3d-printers_11902) (last visited Oct. 27, 2016).

<sup>180</sup> Ben Dickson, TechCrunch, Why IoT Security Is So Critical (Oct. 24, 2015), <https://techcrunch.com/2015/10/24/why-iot-security-is-so-critical/>.

<sup>181</sup> Deloitte LLP, *The Wall Street Journal*, 3D Printing: Data, Data Everywhere (June 25, 2013) <http://deloitte.wsj.com/cio/2013/06/25/3d-printing-data-data-everywhere/>.

<sup>182</sup> For more information on the intellectual property implications of 3D printing, see the "Intellectual Property" section of Reed Smith's white paper,

exfiltration of personally identifiable information could trigger security and privacy laws, such as data breach notification obligations.

As an example, 3D printers are often used to manufacture customized medical devices tailored to an individual's needs. The information used in this process could therefore contain intimate and sensitive details about a patient's condition. Under the Health Insurance Portability and Accountability Act ("HIPAA"), 3D printers that are used by health care providers or other covered entities, and that contain protected health information ("PHI"), could trigger requirements to comply with a broad array of privacy and security laws and regulations.

This would include administrative, physical and technical safeguards for PHI,<sup>183</sup> and data breach notification requirements and privacy protections that include limits and conditions on the use and disclosure of PHI.<sup>184</sup>

More generally, the FTC has broad authority under section 5 of the FTC Act to address unfair or deceptive commercial practices, and has asserted its authority to bring enforcement actions against businesses that offer products or services that fail to protect consumers' personal information. The FTC has increasingly focused its attention on IoT products, and has recently pursued a number of IoT manufacturers that sold products with poor security safeguards. For example, in 2013, the FTC filed a complaint against a company marketing Internet-connected video cameras (i.e., webcams) for failing to provide adequate security after hackers were able to

"3D Printing of Medical Devices,"

[https://www.reedsmith.com/files/Publication/130448b9-7565-4295-a697-5c5d7c6eb516/Presentation/PublicationAttachment/9ba9b53c-2009-488d-ba91-5cc5a19a38f7/3d-printing-white-paper\\_79444049.pdf](https://www.reedsmith.com/files/Publication/130448b9-7565-4295-a697-5c5d7c6eb516/Presentation/PublicationAttachment/9ba9b53c-2009-488d-ba91-5cc5a19a38f7/3d-printing-white-paper_79444049.pdf).

<sup>183</sup> 45 C.F.R. § 164.306(a).

<sup>184</sup> 45 CFR §§ 164.400-414 (HIPAA Breach Notification Rule); 45 CFR Part 160 and Subparts A and E of Part 164 (HIPAA Privacy Rule).

view consumers' video streams in their homes.<sup>185</sup> 3D printers need to be designed and configured safely by default, especially where capable of sharing information, and consumers need to be given sufficient notice and warning regarding their device's security and privacy posture.<sup>186</sup>

The SEC expects public companies to report on all materials risks to the organization in regulatory filings, and this has been interpreted to include cybersecurity risks, so public companies in the 3D printer business need to consider the adequacy of their public disclosures.<sup>187</sup>

## Device and Product Integrity Concerns

3D printed objects can be used for a wide array of sensitive or critical purposes. Medical devices, autonomous or manned aircraft, heavy machinery, and weaponry are just some examples. It is therefore critical that 3D printers and associated computing devices are equipped with safeguards that protect the integrity of the design schematics and manufacturing process. Under product liability law, a court may find that a manufacturer or commercial seller is strictly liable, even if it did not suspect the presence of a manufacturing flaw.<sup>188</sup>

A bad actor who gains access to a 3D printer or a schematics repository could make modifications or introduce manufacturing flaws in the printing process that will result in products with potentially undetectable defects that may cause critical failures during use. For instance, researchers at New York University's Tandon School of Engineering recently discovered that by rotating the orientation of the 3D printer as it generates an object, they could alter the direction of the grain in underlying material and reduce the strength of a

<sup>185</sup> Press Release, Federal Trade Commission, Marketer of Internet-Connected Home Security Video Cameras Settles FTC Charges It Failed to Protect Consumers' Privacy (Sept. 4, 2013), <https://www.ftc.gov/news-events/press-releases/2013/09/marketer-internet-connected-home-security-video-cameras-settles>.

<sup>186</sup> Federal Trade Commission, internet of things: Privacy & Security in a Connected World, at v (January 2015), <https://www.ftc.gov/system/files/documents/reports/federal-trade-commission-staff-report-november-2013-workshop-entitled-internet-things-privacy/150127iotrpt.pdf>.

<sup>187</sup> Division of Corporation Finance, Securities and Exchange Commission, CF Disclosure Guidance: Topic No. 2 (Oct. 13, 2011), <https://www.sec.gov/divisions/corpfin/guidance/cfguidance-topic2.htm>.

<sup>188</sup> See RESTATEMENT (SECOND) OF TORTS § 402A(1)(a) (1964); see also RESTATEMENT (THIRD) OF TORTS § 402A (1998).

manufactured object by as much as 25 percent.<sup>189</sup> Other researchers were able to produce a set of propellers for use in drones that would shatter after only a few minutes in flight.<sup>190</sup> Researchers could only identify these manufacturing flaws if they were able to visibly see the direction of the plastic grain in the resulting product.<sup>191</sup> This detection method was unavailable if ridges from the manufacturing process were grinded down or if the object was polished.<sup>192</sup>

The danger posed by such security risks will continue to grow as 3D printed objects are increasingly used in a wider array of critical activities. For instance, scientists and doctors are experimenting with 3D printed organs and implants.<sup>193</sup> In another instance, the danger of publicly disseminated schematics for 3D printed weapons is still being litigated, after the Fifth Circuit prohibited an organization from disseminating online blueprints that could be used to manufacture 3D printed handguns and other weapons.<sup>194</sup> Like drone propellers, all of these products could be subjected to hacker-introduced flaws that only come to light when failing during use.

An attack that introduces covert flaws into the process for 3D printed products could be a source of significant product liability and other legal exposure for supply chain manufacturers and systems integrators. These risks are magnified by the inability in some instances to reliably test for maliciously introduced defects.<sup>195</sup>

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<sup>189</sup> New York University Tandon School of Engineering, NYU Researchers Report Cybersecurity Risks in 3D Printing (July 12, 2016), <http://engineering.nyu.edu/press-releases/2016/07/12/nyu-researchers-report-cybersecurity-risks-3d-printing>.

<sup>190</sup> Jai Vijayan, Dark Reading, How To Crash A Drone By Hacking Its 3D Propeller Design (Oct. 20, 2016), <http://www.darkreading.com/endpoint/how-to-crash-a-drone-by-hacking-its-3d-propeller-design/d/d-id/1327244>.

<sup>191</sup> Marin Abernathy, Manufacturing and Security Challenges in 3D Printing, <http://130.216.33.163/courses/compsci725s2c/lectures/presentations/MariABernathy.pdf> (last visited Oct. 28, 2016)

<sup>192</sup> *Id.*

<sup>193</sup> Michelle Z. Donahue, *Smithsonian Magazine*, Doctors Can Study 3D Printed Models of Your Organs Before Surgery (July 17, 2015), <http://www.smithsonianmag.com/innovation/doctors-can-study-3d-printed-models-your-organs-surgery-180955622/>.

<sup>194</sup> *Def. Distributed v. United States Dept't of State*, 838 F.3d 451 (5th Cir. 2016).

<sup>195</sup> For more information about the potential for tort or products liability in 3D printing, please see the "Tort Liability" section of Reed Smith's white paper, "3D Printing of Medical Devices," <https://www.reedsmith.com/files/Publication/130448b9-7565-4295-a697->

## Conclusion

As with mobile devices, connected cars and other IoT devices, 3D printers and the broader 3D printing ecosystem face cybersecurity and privacy challenges with significant legal and business risks that need to be addressed by responsible organizations. Although some of the underlying challenges are similar to the threats facing other types of connected devices, the nature of 3D printers and increasing reliance on 3D printed objects with a wide array of use cases presents unique issues that need careful attention.

High-profile failures of 3D printed objects as a result of maliciously introduced defects could result in a loss of public faith in the technology, and significant impact on the industry at large. Likewise, exfiltration of schematics that comprise sensitive trade secrets could result in counterfeits flooding the market, or the public dissemination of an organization's crown jewels. The damage to affected companies could be irreparable.

Organizations in the 3D printing industry should understand their legal and business risks, develop secure practices, and implement product safeguards that will reduce the threats of espionage, sabotage and other malicious activity. For example, cryptographic techniques can be adopted to ensure the confidentiality and integrity of schematic files, and more general cybersecurity guidance like the NIST Cybersecurity Framework<sup>196</sup> can be adapted to meet industry-specific needs. The consequences for not addressing data security and privacy requirements may be considerable: now is the perfect time for organizations to act.

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5c5d7c6eb516/Presentation/PublicationAttachment/9ba9b53c-2009-488d-ba91-5cc5a19a38f7/3d-printing-white-paper\_79444049.pdf.

<sup>196</sup> National Institute of Science and Technology, Cybersecurity Framework (Feb. 12, 2014), <https://www.nist.gov/cyberframework>.

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# Environmental Effects and Health Risks in the Workplace

Additive manufacturing (aka “3D printing”) has the potential to provide significant environmental benefits over traditional manufacturing techniques: 1) a process which only requires the raw materials to build what is needed and avoid waste is simply more efficient; 2) on-site manufacturing making only what is needed when it is needed avoids unnecessary transportation costs and associated fuel use and air emissions; and 3) building lightweight parts from new materials may also reduce operating costs associated with the products utilizing the parts.

That said, potential environmental hazards must be closely monitored as 3D printing technology evolves. “3D printing” describes a wide variety of materials and chemical constituents, as well as numerous technologies. 3D printing technologies vary dramatically but need to be assessed for what types of occupational exposures could result from the printing operations, as well as waste generated in the post-production phase. If the printing operation is occurring at a consumer level, workplace safety precautions and infrastructure will not be present, so additional safeguards need to be identified and communicated to the consumer. Printer parts (e.g., printer cartridges) may offer the benefits of re-use and recycling, but precautions will be necessary if the chemical constituents used in the cartridges are themselves hazardous.

In December 2014, the Environmental Health and Safety Department of Carnegie Mellon University published a 3D Printer Safety Fact Sheet<sup>197</sup> on the various hazards of 3D printer use as a result of the highly combustible powders, flammable thermoplastics and high temperatures involved in the process of 3D printing. Employers are responsible for ensuring safe work environments for the health and safety of their employees, under the Occupational Safety and Health Act of 1970, as well as other federal, state and local regulations. As such, it is important that employers understand the risks posed by 3D printing in the workplace and, where appropriate, offer employee training and implement preventive and mitigating measures. This chapter briefly highlights some of the

<sup>197</sup> Carnegie Mellon University, 3D Printer Safety Fact Sheet, <http://www.cmu.edu/ehs/fact-sheets/3D-Printing-Safety.pdf> (last visited Nov. 29, 2016).

more common environmental (and occupational health and safety) issues that could be triggered by the more prevalent types of 3D printing technologies.

## Hazardous Materials Used in the Manufacturing Process

3D printing uses a variety of potentially hazardous materials including thermoplastics, which are heated to high temperatures, and release ultrafine particles in the process. If inhaled at high concentrations, these ultrafine particles may cause respiratory and other health problems.<sup>198</sup> 3D printer “ink” may include chemicals such as isobornyl acrylate, which is classified as an eye irritant and skin irritant. Other potentially hazardous 3D printer inks and support materials are shown in Figures 1 and 2, below:

Figure 1

Representative 3-D Printer Ink		
Chemical Name	CAS No.	Concentration (%)
Isobornyl acrylate	5888-33-5	15 to 30
Acrylic monomer	*	15 to 30
Urethane acrylate	*	15 to 30
Epoxy acrylate	*	5 to 15
Acrylic oligomer	*	5 to 15
Photo initiator	*	0.1 to 2.0

*Note: Data for Objet VerowhitePlus RGD835.*

*\*Claimed as proprietary by manufacturer.*

<sup>198</sup> <https://3dprintingindustry.com/news/ultrafine-particles-and-the-potential-risks-of-printing-without-ventilation-14944/> (last visited Nov. 29, 2016).

Figure 2.

Representative 3-D Printer Support		
Ingredient	CAS No. EINECS/ELINCS no.	Concentration (%)
Propane-1,2-diol	57-55-6 200-338-0	20 to 40
Polyethylene glycol 400	25322-68-3 203-473-3	20 to 40
Glycerol	56-81-5 200-289-5	5 to 20

Note: Data for Polymerized Fullcure 705

### Safety Data Sheets

The federal Hazard Communication Standard<sup>199</sup> requires that hazards associated with chemical use in the workplace be classified and communicated to employers and employees through comprehensive hazard communication programs. These programs include container labeling, warnings in the form of safety data sheets for the chemicals, and employee training. As an example, a review of a typical safety data sheet for cobalt (which can be used in several 3D printed medical and dental devices) reveals hazards stemming from skin contact, eye contact, ingestion or inhalation. The material is toxic to lungs; repeated or prolonged

exposure may cause organ damage, and the American Conference of Governmental Industrial Hygienists classifies the substance as carcinogenic to animals. Use of such chemicals in 3D printing therefore requires associated due diligence and mitigation measures for vendors / suppliers, employers and consumer-manufacturers.

### What Constitutes "Ordinary Conditions?"

Plastic filaments such as polylactic acid ("PLA") and acrylonitrile butadiene styrene ("ABS") are commonly used in the 3D printing industry to print things such as toys and other consumer products. The screenshots below from a typical safety data sheet for ABS indicate that ABS is classified as non-hazardous:

Additionally, the SDS states that health injuries are not expected and inhalation is not a "probable route of exposure under ordinary conditions." (emphasis added) Given the new uses for ABS brought about by 3D printing technologies, an issue exists as to what constitutes "ordinary conditions" or when a particular 3D alternative printing technology might require a different exposure assessment.

<sup>199</sup> 29 C.F.R. 1910

### Safety Data Sheet (SDS) — SDS-102-Acrylonitrile-Butadiene-Styrene

Emergency Overview	
GHS Classification	Non-hazardous
Physical State	Solid
Color	Typically clear or off-white
Odor	Waxy, mild
	HMIS
	HEALTH
	FLAMMABILITY
	PHYSICAL HAZARD
	PERSONAL PROTECTION
	See Section 8

Primary Routes of Exposure	Eyes or skin contact
Potential Health Effects	
Acute Effects	
Inhalation	Health injuries not expected. Not a probably rout of exposure under ordinary conditions.
Skin Contact	Health injuries not expected. Possible mechanical irritation.
Eye Contact	Health injuries not expected. Possible mechanical irritation from dust or powder.
Ingestion	Health injuries not expected. Not a probably route of exposure.
Chronic Effects	Ongoing exposure may aggravate acute effects
Carcinogenicity	See Section 11
Medical conditions aggravated by long term exposure	Ongoing exposure may aggravate acute effects.

At least one study comparing ABS to PLA has shown that ABS poses heightened human health risks than PLA<sup>200</sup> due to emission rates of ultrafine particles.<sup>201</sup> In a study conducted at the Illinois Institute of Technology and The University of Texas at Austin, researchers tested a variety of 3D printers and filaments and detected high levels of possibly carcinogenic particles when operating the 3D printers in a confined area.<sup>202</sup> The study suggests that caution should be used when 3D printing in confined areas without adequate ventilation. While 3D printing enclosures and gas or particle filtration systems may help protect against some of the hazards of 3D printing, companies should also be mindful of providing adequate warnings.

## Toxic Substances Control Act

The Toxic Substances Control Act ("TSCA")<sup>203</sup> regulates production, importation, use, and disposal of specific chemicals. TSCA also contains reporting, record-keeping and testing requirements, and restrictions relating to chemical substances and/or mixtures.

TSCA's Significant New Use Rules ("SNURs") require notice to the Environmental Protection Agency before chemical substances and mixtures are used in new ways that may create concern. This is significant for 3D printing because the potential hazards associated with heating filaments to high temperatures, causing the release of ultrafine particle emissions, has not been heavily tested or investigated.

Once the EPA is notified, it will make a determination about whether the chemical substance or mixture constitutes a new use by considering several factors including: a) projected volume of manufacturing and processing of a chemical substance; b) the extent to which a use changes the type or form of exposure to humans or the environment to a chemical substance; c) the extent to which a use increases the magnitude and duration of exposure of humans or the environment to a chemical substance; and d) the reasonably anticipated manners and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance. Once the EPA determines that there is a significant new use, companies are required to submit a Significant New Use Notice ("SNUN") to the EPA at least

<sup>200</sup> <https://3dprintingindustry.com/news/toxic-abs-pla-fumes-3dsafety-org-inquires-vocs-60796/> (last visited Nov. 29, 2016).

<sup>201</sup> <http://www.3ders.org/articles/20160201-new-study-shows-health-hazards-of-3d-printing-suggests-pla-could-be-your-safest-bet.html> (last visited Nov. 29, 2016).

<sup>202</sup> *Id.*

<sup>203</sup> 15 U.S.C. §2601, et seq.

90 days before manufacturing or processing the chemical substance for that use. The SNUN allows the EPA to consider the risks of the new use and potentially limit the adverse effects associated with it.

Applied to the current subject matter, a potential issue exists as to whether a previously known and EPA-approved chemical may trigger a SNUN in light of how the 3D printing technology utilizes that chemical in the manufacturing operations.

## Occupational Safety and Health

Although the 3D printing industry is not highly regulated in terms of specific laws focused on the industry itself, it is indirectly subject to numerous regulations of OSHA which sets industry standards to promote safe and healthful workplaces.

The General Duty Clause, Section 5(a)(1) of the Occupational Safety and Health Act ("OSH Act") of 1970, requires employers to provide employees with a workplace that "is free from recognizable hazards that are causing or likely to cause death or serious harm to employees." In other words, employers must provide a workplace that is free of hazardous conditions that cause, or are likely to cause, death or serious physical harm to employees, when there is a feasible method to abate the hazard. Employees are under a duty to comply with occupational safety and health standards and all rules, regulations, and orders issued pursuant to the OSH Act of 1970, which are applicable to one's own actions and conduct. What does this mean for companies using 3D printing?

Other more specific OSH Act standards apply to 3D printing as well. For example, employers using 3D printing have a general obligation to use engineering controls (air filters, etc.) to allow employees to breathe freely and work with minimal constraints. However, in more extreme conditions, employers may be required to supply personal protective equipment ("PPE") that includes eye, face, and respiratory protection for employees operating 3D printing equipment. Employers should also protect employees against occupational noise exposure, if necessary, by providing adequate sound baffles on equipment or in working areas, and PPE ear protection for employees when the above broader controls are not feasible.

The OSH Act also requires workplace safety and equipment training as well as clear warnings of workplace hazards. Since some 3D printers may emit ultrafine particles, it is important to ensure well-ventilated work areas and/or use 3D printer enclosures to reduce the risks associated with inhalation of ultrafine particles. Finally, ultraviolet radiation caused by UV lamps used in 3D printers is also a potential safety

hazard, which may require protective equipment and/or adequate warnings to reduce exposure.

## Combustible Dust

Another potential hazard in the 3D printing industry is combustible dust explosions.<sup>204</sup> Dust from ultrafine particles heated to their melting point creates a higher risk of explosions where there is (1) material content that is combustible; (2) an ignition source; (3) oxygen in the air; (4) the dispersion of dust particles in sufficient quantity and concentration; and (5) confinement of the dust cloud.<sup>205</sup>

In May 2014, OSHA cited a 3D printing company for ten violations of workplace safety standards and fined the company \$64,400.<sup>206</sup> Following an investigation of an explosion and fire, which inflicted third-degree burns on a company employee, the company was cited for failing to prevent and protect its workforce from the fire and explosion hazards of reactive, combustible metal powders (titanium and aluminum alloys), which were used in the company's 3D printing process.<sup>207</sup> The company also allegedly failed to eliminate known sources of potential ignition and follow pertinent instructions from equipment manufacturers.<sup>208</sup> Also, OSHA alleged that the company placed an employee workstation and flammable powders next to an area with explosion potential, among other citations.<sup>209</sup>

OSHA has published advisory guidelines on combustible dust hazards and safeguards in the workplace for employers.<sup>210</sup> According to OSHA's Safety and Health Information Bulletin, *Combustible Dust in Industry: Preventing and Mitigating the Effects of Fire and Explosions*, the primary factors for assessing the potential for dust explosions are determining whether the dust is combustible, and identifying areas that

<sup>204</sup> OSHA, *Compatible Dust: An Explosion Hazard*, <https://www.osha.gov/dsg/combustibledust/guidance.html> (last visited July 23, 2015).

<sup>205</sup> *Id.*

<sup>206</sup> OSHA, May 20, 2014, *After Explosion, US Department Of Labor's OSHA Cites 3-D Printing Firm For Exposing Workers To Combustible Metal Powder, Electrical Hazards*, [https://www.osha.gov/pls/oshaweb/owadisp.show\\_document?p\\_table=NEW\\_S\\_RELEASES&p\\_id=26019](https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=NEW_S_RELEASES&p_id=26019) (last visited July 23, 2015).

<sup>207</sup> *Id.*

<sup>208</sup> *Id.*

<sup>209</sup> *Id.*

<sup>210</sup> *Id.*

require special electrical equipment classification as a result of the presence of combustible dust.<sup>211</sup> Once the hazards are identified, employers may implement preventive and mitigation methods to safeguard the workplace.

National Fire Protection Association standard NFPA 654, *Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids*, also provides guidance on the prevention of fire and dust explosions from the manufacturing, processing, and handling of combustible materials. 3D printing businesses can safeguard against the potential for dust explosions caused by 3D printing by:

- 1 minimizing the escape of dust from process equipment or ventilation systems;
- 2 using dust collection systems and filters;
- 3 utilizing surfaces that minimize dust accumulation and facilitate cleaning;
- 4 cleaning dust residues regularly;
- 5 using cleaning methods that do not generate dust clouds if ignition sources are in the vicinity; and
- 6 developing a hazardous dust inspection and control program.<sup>212</sup>

Employers can also protect against potential fire and explosion hazards by controlling ignition sources by using appropriate electrical equipment and wiring methods; controlling smoking, open flames, and sparks; and keeping heated surfaces away from dust.<sup>213</sup> In addition, 3D printing businesses should clean and maintain workplaces, including by removing dust accumulations.<sup>214</sup>

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<sup>211</sup> OSHA, November 12, 2014, *Combustible Dust in Industry: Preventing and Mitigating the Effects of Fire and Explosions*, <https://www.osha.gov/dts/shib/shib073105.html> (last visited July 23, 2015); see also 21 CFR Part 1910 Subpart S (general requirements for electrical installations in hazardous areas).

<sup>212</sup> *Id.*

<sup>213</sup> *Id.*

<sup>214</sup> See, 29 CFR 1910.22(a)(1).

## Product Warning and Labeling

### a) Consumer Product Safety Act

The U.S. Consumer Product Safety Commission ("CPSC") works to protect the public from unreasonable risks of injury or death associated with the use of consumer products and aims to ensure the safety of consumer products (*e.g.*, toys, tools, lighters and household chemicals). CPSC seeks to protect consumers and families from products that pose a fire, electrical, chemical or mechanical hazard. The Consumer Product Safety Act ("CPSA") authorizes the agency to develop standards and gives CPSC the authority to pursue recalls and ban products under certain circumstances.

In August 2015, the CPSC reached out to the public as part of its "Chairman's Challenge" to "promote innovation in injury prevention and find solutions to safety problems" for products including 3D printers.<sup>215</sup> The CPSC seeks to "determine the ventilation needs of 3D printers to lower exposure levels of fumes," "design an appropriate system for air quality control of household 3D printer fumes," "develop standards and systems to keep potentially harmful chemicals out of homemade or recycled 3D printer feed stock," and "develop a method for consumers to identify which plastics are not safe for recycling in a 3D printer."<sup>216</sup> Although we have not seen legislation by the CPSC specific to 3D printing, it is important for companies to become familiar with existing laws and regulations, which may implicate 3D printing.

### b) California "Proposition 65" Warnings

In addition to federal consumer product warning requirements, some states, most notably California, have their own enhanced warning requirements for certain chemicals in consumer products.

Proposition 65 is a California state public disclosure law that provides:

No person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual[.]<sup>217</sup>

<sup>215</sup> <https://www.cpsc.gov/Global/About-CPSC/Chairman%20Kaye/ChairmansChallenge.pdf> (last visited Nov. 29, 2016).

<sup>216</sup> *Id.*

<sup>217</sup> Cal. Health & Safety Code § 25249.6.

The State has published a list of over 800 Proposition 65 regulated chemicals<sup>218</sup> which is updated several times per year. Entities engaged in 3D printing should cross-check their Safety Data sheets with the Proposition 65 list of chemicals to determine whether a statutorily compliant "clear and reasonable" warning may be necessary.

A warning is "clear" if it clearly communicates that the individual will be exposed to a chemical known to the State to cause cancer, and/or birth defects or other reproductive harm.<sup>219</sup> It is "reasonable" if the method employed to transmit the message is reasonably calculated to make the warning message available to the individual prior to exposure.<sup>220</sup> The State offers some "safe harbor language" which can be utilized to claim compliance with the warning obligation. Alternative language can be used if it meets the standards cited above.

Although Proposition 65 offers exemptions from the general obligation to provide a warning, these exemptions are limited.<sup>221</sup> A typical client issue about whether to warn occurs where there is a belief that the product contains the regulated chemical in a concentration less than the Proposition 65 threshold for warning, or what is commonly referred to as "safe harbor levels." There are different safe harbor levels of carcinogens ("No Significant Risk Levels") and reproductive toxicants ("Maximum Allowable Dose Levels") that go beyond the scope of this article. Such analyses need to be made on a case-by-case basis.

## Hazardous Waste

Although 3D printing is "additive" manufacturing which minimizes waste, there is still some post-production product cleaning (for example, the use of caustics such as sodium hydroxide baths) which can generate waste. Additionally, some hardware (*e.g.*, printer cartridges) may contain residual amounts of chemicals in them, even when empty. Manufacturers need to address whether these waste streams contain hazardous materials or wastes that need to be marked, stored, transported and ultimately disposed of or recycled in special ways due to their hazardous characteristics.

<sup>218</sup> <http://oehha.ca.gov/proposition-65/proposition-65-list> (December 1, 2016)

<sup>219</sup> See 27 CCR § 25601.

<sup>220</sup> See *id.*

<sup>221</sup> See Cal. Health & Safety Code § 25249.10.

## International and Industry-led Standards

Even though government agencies may not be regulating 3D printing directly, private industry has begun to regulate itself by creating international standards to utilize common definitions and create common terms, standards and specifications to enhance commercial activities relating to 3D printing. ASTM International<sup>222</sup> created Committee F42 on Additive Manufacturing Technologies, which includes subcommittees including but not limited to F42.06 (Environmental, Health, and Safety). As of the date of publishing of this white paper, there were no future meetings, symposia or workshops posted for Committee F42, but representations from ASTM personnel indicate that this is a future area of interest.

## Environmental Risk Mitigation Techniques

### a) Environmental Management Program

Although we're still in the early stages of understanding the environmental hazards associated with 3D printing, it is important for companies to have measures in place to mitigate their exposure to liability. Companies can protect themselves by providing limited warranties and/or excluding warranties where their customers or vendors fail to comply with environmental standards and regulations, fail to follow warnings or instructions in the user manual, and/or use parts or material not approved by the 3D printer manufacturer. In addition, companies should consider shifting the risks to their vendors or service providers by requiring that they carry adequate insurance and/or add the company as an additional insured, and by maintaining adequate insurance for risks associated with their 3D printing business. In order to find appropriate insurance coverage, companies should work with a sophisticated broker and engage coverage counsel early and often. In a similar vein, companies should consider incorporating liability disclaimers and capping their liability up to a dollar amount in their contracts with third parties to manage risk.

## Conclusion

As this industry continues to evolve in terms of new chemicals, products and manufacturing techniques, environmental risks and issues will need to be reassessed and evaluated accordingly.

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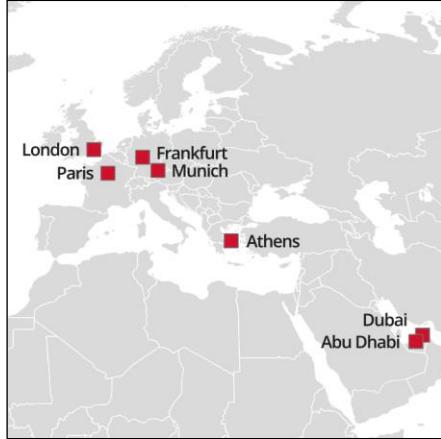
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