Casualty Insights
National Casualty Claim and Coverage Briefing
WELCOME to the inaugural edition of Willis Towers Watson’s National Casualty Claim and Coverage Briefing: Casualty Insights. Our casualty team will use Casualty Insights to provide clients with quarterly insights on key issues, emerging risks and other important developments in the dynamic casualty arena, supplementing our casualty expertise with insights and advice from leading coverage attorneys and technical consultants. Our intent is to educate, empower and prompt focused and open communication with our clients.

This edition discusses the history, process and risk management issues arising from “additive manufacturing,” which includes 3D printing, a new (but not as new as many people think) frontier filled with spectacular promise and risk. The Economist suggested in its February 2011 edition that the impact of 3D printing may be akin to that of the printing press, the steam engine and the transistor. Analysts estimate that the worldwide 3D printing industry will grow from an estimated $4 billion in revenue in 2014 to nearly $6 billion in 2015 and will exceed nearly $50 billion by 2025, a compound annual growth rate of over 23%.

Major technological advancements, proliferation of global use and potential applications that, until recently, would have challenged the imagination, all support the lofty aspirations for 3D printing. But, naturally, there are also new risk assessment, insurance coverage and risk management challenges for all insurance industry stakeholders to address. This issue of Casualty Insights will provide valuable insights to help meet these new challenges and ensure that we best identify and secure the necessary insurance protections (at the proper price) for our clients.

We welcome comments and questions and look forward to hearing from you!

/s/ Rob
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3D Printing

3D printing describes a manufacturing process used to create three-dimensional solid objects from digital files. It encompasses many additive processes, technologies, systems and applications that build finished products through successive layering of materials, most often today with inkjet-type printer heads.

Advancements in and the reduced costs of 3D printing have brought this technology into the public’s consciousness and excited the collective imagination of manufacturers. But 3D printing is not new. Historically called “additive manufacturing,” forms of 3D printing have been around for more than 30 years. As the technology has matured and expanded, the nomenclature coalesced around the phrase “3D printing.”

Generally, the 3D printing process begins with a digital design of the object to be manufactured. The design exists as a 3D model in a computer-aided design (CAD) file format. Designs can be created from scratch by compiling or modifying existing files, by importing a design derived from laser scanning a physical object or from a combination of these methods. CAD files provide the blueprint of an object to be 3D printed. “Printing” process time varies depending on, for example, the size and resolution of the product and the type of material used for “printing.”

Want to learn more about 3D Printing?
Search “3D printing” at www.TED.com.


For a general introduction, see www.3dprinting.com.

3D printing’s “additive” process contrasts with historical “subtractive manufacturing,” such as milling, cutting, routing and drilling, in which material is removed in successive layers. 3D printing can produce superior, faster results for parts with complex geometries or intricate designs as material is added perhaps a few thousands of an inch at a time. 3D printing is far more cost-effective for unique, low-volume objects. At present, subtractive manufacturing is generally still necessary for items intended for long-term or high-stress uses.
3D Printing Risks

3D printing may present the greatest risk in the product liability area, which is discussed below. It also presents emerging exposures such as:

- **Professional and Products Liability.** 3D printing may blur the line between product design and manufacturing, as CADs are increasingly implemented by end-user consumers. Entry-level consumer 3D printers are available at office supply stores for as little as $500. Widespread computer use may reveal unclosed seams between professional liability errors and omissions coverage and commercial general liability coverages. For example, the extent to which the law considers electronic files to be “products” for product liability purposes and how the law addresses the increasingly cloudy determination of who is the “manufacturer” of a product are important issues to monitor closely.

- **Workers’ Compensation and Employer Liability.** The increasing ubiquity of 3D printing may also implicate workers’ compensation and/or employer liability issues. New workplace health and safety exposures, including long-term health effects, may arise (e.g., release of emissions and/or particles from plastic filaments, powder-based or novel material-based 3D printing processes, dust combustibility).

- **Foreign Risk.** Imported products and/or components and foreign outsourcing highlight the need for intimate knowledge of business partners’ practices and policies, as well as thorough product liability prevention programs and strategies. While sound product liability risk management already focuses on the entire product life cycle (i.e., design specifications, manufacturing, distribution, logistics, post-sale monitoring, disposal), 3D printing may present heightened and new challenges.

- **Supply Chain.** The global economy, including insurers, presently works to manage “just in time” supply systems and the risks of significant interruptions and disruptions to manufacturing and retail businesses. As manufacturers move towards on-site and on-demand 3D printing, the potential benefits of, for example, decreased warehousing expense and increased speed of production come with potentially increased supply chain vulnerability. First-party policies typically contain some level of business interruption coverage, but 3D printing may heighten a need for enhanced Contingent Business Interruption coverage.

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**Insurers Studying 3D Printing Risks**

The risks associated with 3D printing will more clearly materialize as businesses and individuals increasingly utilize the technology, and the technology continues to progress. Insurers have begun to grapple with critical underwriting issues, such as whether 3D printing risks are novel or analogous, whether such risks are different in substance or in degree, whether such risks are adequately addressed by existing insurance products, whether current underwriting practices are sufficient to assess such risks, and many others. Willis Towers Watson continues to work with insurers to address these issues.
An Underwriter’s Insights:

Careful casualty underwriting of 3D printer manufacturers, designers, producers, or other related 3D printing accounts revolves around several areas of inquiry, including:

- What type of involvement does the account have with 3D printing? Is it a manufacturer of 3D printers, a manufacturer of 3D-printed consumer products, a designer of CADs, etc.? Accounts that are only tangentially involved in 3D printing have a wholly different profile and would be underwritten differently from those, for example, engaging in high-profile, large-scale consumer products manufacturing.

- What is the nature and scale of the account’s 3D printing? Is the account creating 3D products for consumer end use or components for other’s products? Underwriting challenges increase as accounts move from producing small-scale printers for home and/or hobby use to large-scale consumer products, life-science applications and medical implantable devices. These types of exposures (particularly implantables) exponentially increase an insurer’s risk.

- If 3D-printed products are contemplated for consumer use, what quality assurance steps are being taken in the following areas?
  - Computer-assisted design quality
  - Substrates/manufacturing materials quality (supply stream issues, including foreign supplier quality control)
  - Research/studies on any long-term health issues/exposures as well as OSHA safety

- If there are 3D processes involved in the account’s physical plant, how is workplace safety affected, if at all, and addressed?

- Intellectual Property. Digitization enables 3D printing, but it also facilitates dissemination and, potentially, unauthorized copying (e.g., the music and film industries’ continuing battle against piracy) and modification. Easy and near-instant electronic file disseminations bring global risk exposures and the need for equally broad insurance coverage. As scanning technologies improve, the ability to digitize virtually anything will strain intellectual property protections and increase liability risks from infringement and unauthorized design modifications.
Participants at each stage of the 3D printing process bring their own contributions and their own risks to the process. The integrity and quality of upstream and downstream business partners can multiply and exacerbate risk.

First, there are the designers of the proprietary technologies that enable 3D printing. Designer risks are multiple and permeate the entire process. The designed technology itself may be flawed or defective. Modeling and CAD files can be corrupted, counterfeited or pirated. In fact, the concept of “open design” encourages the acquisition and modification of an original design for broader public use and further modification. A 3D scan or CAD file could be flawed, and “cleanup” processes may be inadequate to identify and correct the flaws. Otherwise sound technologies may be incompatible with downstream users’ 3D printers. These and many other factors could increase the risk of defective products and, in turn, the risk of personal injury or property damage. Designers, in particular, face burgeoning professional liability risks as well, as their 3D models and other technology wares are distributed, modified and implemented in ways beyond their expectation or control.

The increasing variety of products that can be generated by 3D printing is a function of the increasingly diverse raw materials that can be inkjet “printed” in successive layers. Producers of these 3D printing materials comprise the next essential participants in the 3D printing industry. Their raw materials include: (a) various polymers, (b) metals and alloys, (d) ceramics and (e) other materials (e.g., wax, metal foil, paper); and the supply of which presents common supply chain risks. However, as the raw materials become more specialized, customized and even theorized (e.g., living cells to “build” human organs and body parts), issues of quality, consistency, performance, etc. are heightened, as are the associated risks.

3D printing technologies and raw materials converge at the 3D printer itself, where the models or CAD files instruct the printer how to dispense the raw materials. The 3D printer manufacturers comprise the next essential segment of the industry. Typical manufacturing risks remain but are compounded by the complexities and specificities of end users. Ironically, manufacturing and component-use risks are exacerbated by the very industry, giving rise to the 3D printer industry segment. End users need not acquire 3D printer replacement parts or software from the original manufacturer. Rather, end users can oftentimes simply download a particular CAD file and “print” their own replacement part on-site — or even “print” themselves another printer. Manufacturers, therefore, must contemplate and address the risk of product recalls and litigation for products or components that they did not even manufacture.

While the availability of 3D printers has increased and the price has generally decreased, the actual 3D printing may not be practicable or desirable for everyone. 3D printing service providers have filled that market and assumed an important role in the industry. These companies can effectively, efficiently and economically print and deliver an object from a digital file uploaded by the customer to the service’s website. Service providers also market third-party 3D designs for sale, which can then be conveniently printed and delivered to the customer.
Finally, there is the ever-increasing applications market, i.e., those employing 3D printing, including: (1) aerospace, (2) automotive, (3) individuals, (4) medical/health care/life-sciences (collectively, “life sciences”, including “bio”-printing), (5) government and defense, (6) industrial/business machines, (7) education and research, and many others. Each of these industries merit and will receive attention in subsequent editions of Casualty Insights, but arguably no industry excites the imagination (for concern, as well as hope) more than life sciences.

The 3D printing advances and applications in life sciences have been nothing short of astounding. The FDA has already granted clearance for numerous 3D-printed medical devices, including dental implants, facial implants, hearing aids, skull plates, hip cups and screws. Surgeons can print out models of a specific part of the patient’s body to better plan and practice complex procedures. Advancements in “bio-printing” support the vision of creating customized organs and other body parts, potentially eliminating the wait for transplants and many of the risks of rejection of such transplants. The company Organovo, for example, recently made a material advancement towards that future vision with its announcement of the first 3D-printed human kidney tissue. A researcher at the University of Glasgow, Lee Cronin, delivered a 2012 TED Talk in which he describes his vision for a 3D printer capable of assembling chemical compounds on the molecular level, thus enabling individuals to 3D print medicine and drugs with purchased chemical “ink” and the digital prescription’s “blueprint.”

Government and 3D Printing:

The technological advancements in life sciences may soon be straining its regulatory and legal frameworks. To their respective credit, the 3D printing industry and regulators, such as the FDA and the United States Patent and Trademark Office, have already begun cooperative discussions. The White House communicated its vision for the role of 3D printing in America in 2012, seeking to become a “global center of excellence for additive manufacturing.” Within this context, it remains to be seen how regulators will exercise their role, choosing among various means, including: interpretive guidance on existing regulations, administrative rulemaking or formal legislation.

Regulatory developments in all fields merit close attention.
3D printing may challenge the existing product liability legal framework, an issue that has received continuing scholarly attention.⁶

The Restatement (Third) of Torts: Products Liability⁷ identifies three major types of product liability claims: (1) manufacturing defect, (2) design defect and (3) a failure to warn. Such claims may be pled in court under causes of action based on negligence, strict liability, breach of warranty and consumer protection statutes.

Manufacturing defect claims, for example, generally expose the manufacturer of a product to strict liability under the theory that the manufacturer is in the best position to protect the public against potentially defective products. But a 3D printing world, in which virtually anyone can create and distribute a product, may challenge product liability fundamentals. For example, who is the “manufacturer” of a 3D-printed product? If the product is 3D printed and sold by an established manufacturing entity, the issue may be subject to traditional product liability analyses. Similarly, where a 3D-printed product is defective due to an error in a verifiable, commercially sold CAD file, then product liability would seem to be clearly cast on the commercial designer (as it would also be for a supplier of defective materials used in the 3D printing process). However, 3D printing gives rise to scenarios where a product may be designed by one party, scanned and digitized into a CAD file by another, sold for downloading by another and ultimately “printed” by the end user or printing service provider. Identifying all participants in a product’s “manufacturing,” tracing the respective role and contribution of each, and imposing accountability, among other things, all present challenges in determining and apportioning any product liability. The complexities of such a process present challenges to parties (e.g., insurers) seeking to enforce contribution, subrogation and other recovery rights as well.

### Another Dimension...

Even before industry and insurers have fathomed the nature and extent to which 3D printing may affect their relationship, technology has advanced into 4D printing—products printed with “smart” material that can transform on their own. The fourth “dimension” is this ability to morph over time and/or conditions. In 4D printing multi-material 3D printers (a significant advancement in and of themselves) are programmed with a precise geometric code that instructs a 3D-printed product how, when, etc. to transform itself, e.g., if exposed to water, movement or a change in temperature. Although a nascent technology, it holds fantastic potential in, among many others, construction (notable in extreme environments), aerospace and life sciences. (See, generally, MIT research scientist Skylar Tibbits’ February 2013 TED Talk, The Emergence of “4D Printing”)

### Starting the Conversation...

Willis Towers Watson prides itself on understanding its clients’ businesses. To assess any additional or new loss exposures from 3D printing, we’ll need to discuss:

- The nature and extent of your existing and potential use of 3D printing. For example, do you/will you print component parts of a product and/or end-use consumer products? Is your 3D printing in the life sciences sector?
- Are you involved in designing CAD files, designing 3D printers or component parts thereto?
- The nature and extent of upstream and downstream business partners’ use of 3D printing, now and in the future (e.g., scale of final 3D product usage, occasional professional use or whole consumer market).
- Do you have a risk assessment plan for Intellectual Property infringement?
- What are the materials (e.g., thermoplastics, polymers) you use in 3D printing and who are your sources for those materials?
- How have liability exposures been addressed contractually with suppliers, distributors, downstream manufacturers, etc.?
- Have you completed a workplace safety assessment for your 3D printing operations and any hazardous materials involved?
Oftentimes service providers print and sell products designed by third parties, of which the CAD file may have been designed by yet another third party. In many instances, the CAD file designer may not even be known or identifiable, especially if the files have been downloaded from public sources or edited and re-edited by multiple parties. In the intellectual property and product liability contexts, for example, parties may encounter difficult traceability, accountability and collection challenges.

Existing product liability principles and policies may need to adapt, be extended or even reformulated to apply in a 3D printing world. If, for example, an individual consumer printed (i.e., arguably “manufactured”) a product or component alleged to be defective, the analysis may well become complicated. Strict product liability generally applies only to commercial sellers. The “casual seller” doctrine protects parties not engaged in product sales as a regular part of their business from strict liability, even if the party derives substantial revenues from sale of the product. “Casual sellers” may still face claims based merely in negligence, but liability may be more difficult to establish; i.e., in a negligence context, plaintiffs generally must prove that the product was defective at the time that it left the manufacturer’s hands and not merely that the product manufactured was defective.

An early representative example of how 3D printing, medical devices, and the law may interact is the Invisalign® braces product. Invisalign braces are available only through prescription by a dentist and custom-manufactured by Align Technology, Inc. (Align). Align receives patient specifications through a scanned image sent by a dentist and prints the Invisalign braces to those specifications at a central facility. Invisalign braces differ from traditional medical device manufacturing in cost and means of production (i.e., they are 3D printed), but they share a notable common attribute: exposure to product liability litigation. A recent Invisalign lawsuit provided the first insights on how a court may handle a 3D-printed medical device, and those initial insights are favorable.

In Buckley v. Align Technology, Inc., No. 5:13-cv-02812, the federal court for the Northern District of California addressed Plaintiff Buckley’s various allegations regarding her unsatisfactory Invisalign experience. Of note here is that, although Align customized its product for Plaintiff based upon the specific characteristics of her teeth through 3D printing, the court ruled that: “... Align stands in the position of a manufacturer not a medical evaluator [and, as such] Align has a duty to warn the dentist about any dangerous side effects pertaining to the Invisalign treatment, but has no duty to directly warn Plaintiff.” The court’s ruling came in the context of its consideration of the “learned intermediary doctrine” (i.e., generally that a duty to warn runs to the physician, not the patient, in the context of prescription drugs), which the court applied to bar Plaintiff’s claim because Plaintiff’s complaint did not allege that Align had failed to warn Plaintiff’s dentist of any risk associated with Invisalign use. Thus, means of manufacturing notwithstanding, the court treated the 3D-printed Invisalign braces like any other medical device and Align like any other medical device manufacturer.

Product liability for 3D-printed products merits close and continuing attention. As with many new risk exposures, there are more questions than answers regarding the insurance and risk management ramifications of 3D printing. Subsequent editions of Casualty Insights will keep you apprised of relevant developments.
Coming Soon

Drones, Cyber-Risk, Emerging Issues in Life Sciences and Workers' Compensation

Resolutions

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2 Certain commentators believe that 3D printing will primarily be used in the future as it is today, i.e., for prototyping and unique products, not for large-scale manufacturing. See https://thoughtleadership.ubs.com/longer-term-investments-automation-and-robotics.


4 http://www.approto.com/Media-Center/Additive-vs-Subtractive-Manufacturing--Which-is-Ri.aspx.


7 The Restatements of Laws are summaries of case law on specific subjects intended to reflect the consensus of the American legal community as to the law on a specific subject. While not binding on an individual judge, the Restatements are highly influential.
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