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3DP, AM, 3DS and Product Liability

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INTRODUCTION

The capabilities demonstrated by 3D Printing/Additive Manufacturing (referred to collectively here as “Additive Manufacturing”) are giving flight to the imaginations of designers, engineers, manufacturers, and end customers foreseeing new potential of their manufacturing processes and
products. These new capabilities should do the same for lawyers, legislators, regulators, product safety teams, and risk managers. However, the potential for new theories of liability should not chill the excitement and preparation to capitalize on the technology. The basic tenets of product liability law will continue to apply, albeit to new players and new roles. The words of Hon. Benjamin Nathan Cardozo from over ninety years ago ring true again—“[t]here is nothing new here in principle. If there is novelty, it is in the instance only.”

Product liability law will adapt to Additive Manufacturing the way it always has for all trail-blazing innovations in America. The business side of the industry will meet market demand with cutting-edge products while defining, redefining, and creating the roles and responsibilities of the new landscape. The legal side will translate the traditional roles of manufacturer, supplier, retailer, and customer to the new Additive Manufacturing landscape and anticipate the issues as the market drives product development and the balance of responsibility.

This article will consider the realities of the new landscape of Additive Manufacturing and how it changes the accepted practical roles of the customer, supplier, designer, manufacturer, retailer, and distributor. The balance of legal responsibilities will shift and re-balance as Additive Manufacturing continues to grow and transform some business relationships. However, traditional product liability exposure and the courts’ response to injuries and losses from products generated from the new technology will still be based on traditional precedent. When injuries or losses occur because of Additively Manufactured products or component parts, the same familiar pressure points will present themselves in litigation, but with new players finding their place among the traditional product liability roles.

As the Cardozo court held in Glanzer, “[t]he controlling circumstance is not the character of the consequence, but its proximity or remoteness in the thought of the actor.” This foresight as to what would evolve over the next ninety years of tort law should give today’s additive actors the impetus to clearly define the responsibilities in line with their contractual wording, insurance coverage, and liabilities. To that point, the

2. Id. at 240.
more recent developments in the medical and digital industries may act as the best indicator for anticipating those changing relationships, future regulation, and case law in the Additive Manufacturing landscape. With each issue, we will examine the current analogous tensions in other industries to ascertain how to overcome the barriers in breaking-through the retail consumer world for this technology.

Last, we will explore the opportunities that likely will exist in both products and intellectual property law for the trailblazers in this technology who are out in front perfecting and defining their Additive Manufacturing processes, making it reliable, repetitive, and scalable. With all this change and loss of traditional controls, the new technology presents opportunities in risk management, quality control, and manufacturing safety control never before possible.

I. ROLES, RESPONSIBILITIES AND DEFINITIONS

Additive Manufacturing presents new legal challenges because the technology expands and re-writes the definitions of “manufacturer,” “supplier,” “retailer,” and “product.” The traditional brick and mortar confines of the physical world that previously defined the roles of the manufacturing process will have to be rethought in a virtual world based on digital files, scans, and screens. Before 3D printing, suppliers would provide material to a manufacturer, who would then take a tested and approved design and make a product or part at a specific location. Now, those same suppliers will be replaced when it comes to making certain products because those products will be made remotely with Additive Manufacturing (e.g., at home or by the customer at a service bureau). In the new virtual manufacturing world, the process of a final product or part being inspected, packaged, and shipped from that plant or facility to the seller or customer will not necessarily be the reality.

In this new virtual distribution world, the roles and responsibilities are not nearly as clear. The relative freedom of the digital world has replaced the physical world’s limitations and structures. If you can create an object on a screen through 3D CAD software, digital photography, or 3D scanning, you can create a physical manifestation of the object from the screen into the real world. The new landscape begs for definitions, risk management, and tangible process controls. While there are new problems and issues never faced
before, the analogs of the past provide a structure for adaptation in the law and the legal responsibilities of all entities, including new ones never introduced into the manufacturing process before.

II. WHY THE SAFETY NET IS THERE

The Introduction to the Restatement (Third) of Torts; Product Liability⁢ is instructive because it demonstrates the intent of lawmakers and regulators through the wildly innovative 1800s and 1900s in the United States as they attempted to keep pace with the industrial explosion of American manufacturing. In just one short paragraph, the authors of the Restatement reformulated the law to adapt to innovation, and give us a historical context to the attempt of the new Restatement to capture the new era.⁴ In so doing, the authors of the Restatement illustrate the ability to maintain balance of acceptable risk and reasonable responsibility for those risks in product liability law.

America went from a “buyer beware” nation in the 1800s, when injuries or damages from defective products went largely uncompensated, to an initial early acceptance of manufacturer responsibility for defects in their products by the mid-20th century, when a more expansive understanding of responsibility introduced liability based on design defect and inadequate warnings that still exists today. The Restatement sets forth the basis for recovery in product liability cases as follows:

A product is defective when, at the time of sale or distribution, it: (1) contains a manufacturing defect, (2) is defective in design, or (3) is defective because of inadequate instructions or warnings. A product:

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3. “To understand its place in the law, products liability must be examined in historical context. In 1964 The American Law Institute adopted § 402A as part of the Restatement Second of Torts, Section 402A was entitled ‘Special Liability of Seller of Product for Physical Harm to User or Consumer.’ “It marked the first recognition by the Institute of privity-free strict liability for sellers of defective products. The major thrust of § 402A was to eliminate privity so that a user or consumer, without having to establish negligence, could bring an action against a manufacturer, as well as against any other member of a distributive chain that had sold a product containing a manufacturing defect. Section 402A had little to say about liability for design defects or for products sold with inadequate warnings. In the early 1960s these areas of litigation were in their infancy.” Introduction to the Restatement (Third) of Torts, Product Liability (1998).

4. Id.
(a) contains a manufacturing defect when the product departs from its intended design even though all possible care was exercised in the preparation and marketing of the product;

(b) is defective in design when the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the alternative design renders the product not reasonably safe;

(c) is defective because of inadequate instructions or warnings when the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the instructions or warnings renders the product not reasonably safe.5

III. STRICT LIABILITY

Strict liability holds the manufacturer liable for defective products that cause injury or damage.6 The force of public policy in the United States in the 20th century, particularly in the 1960s and 1970s, resulted in manufacturers being held responsible. This was because they were in the best position to test and inspect retail products, insure against liability, and avoid the unfair results of uncompensated harm or damage to consumers. Strict liability sought to reach back through the distribution chain to the source and place responsibility on the creator of the product.

Traditionally, the first barrier to suit was proving that the defendant was the manufacturer, seller, or supplier of the alleged instrumentality of injury.7 Once the source of the product was determined, then the analysis continued to whether the product was defective in (1) design, (2) manufacture, or (3) by reason of a failure to warn of an inherent danger.8 Typically, the entities that were part of the distribution chain built tender and indemnification

5. *Id.* § 2.
6. *See* CNG Producing Co. v. Columbia Gulf Transmission Corp., 709 F.2d 959, 962 (5th Cir. 1983) (“A manufacturer is strictly liable in tort when an article he places on the market, knowing that it is to be used without inspection for defects, proves to have a defect that causes injury to a human being.”).
8. *Id.* § 2.
agreements into their relationships with each other so liability flowed back to the original manufacturer. As such, the first barrier eroded over time. In the Additive Manufacturing context, however, that analysis is not so straightforward, and ascertaining the manufacturer is once again an issue.

Under current strict liability regimes, as encapsulated by the Restatement, “[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.”9 According to the Restatement, such strict liability will “not apply to a noncommercial seller or distributor of such products . . . [but] [i]t is not necessary that a commercial seller or distributor be engaged exclusively or even primarily in selling or otherwise distributing the type of product that injured the plaintiff, so long as the sale of the product is other than occasional or causal.”10 As an example, the Restatement cautions that “a service station that does mechanical repair work on cars may also sell tires and automobile equipment as part of its regular business. Such sales are subject to the rule in this Section.”11

IV. IMPLIED WARRANTIES

The implied warranty of merchantability generally requires a manufacturer to guarantee that its products conform to industry standards, as ordinarily used.12 The product must be uniform as to quality and quantity as agreed by the contract for sale. It must be packaged and labeled and must meet the specifications listed on that labeling.13

Where courts are faced with significant loss or injury and are unable to determine what entity is liable for the project, it is likely the courts will not allow unattached liability, ultimately leaving the injured party without remedy. Instead, it is likely the courts will adapt a wide interpretation under the implied warranty theory. The argument posited would be that an Additively Manufactured product or part implies that the exact replica will function and perform as the original. There is a high probability, however, that—prior to sale—many

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9. Id. § 1.
10. Id. at Comment.
11. Id.
13. Id.
Additively Manufactured parts will not be tested or analyzed the same way as a traditionally manufactured version of the same product, from the same blueprint. Such a situation creates a break from the system of checks and balances that existed before.

How do manufacturers, distributors, and customers navigate this situation? In the case of a customer original piece, the path is clear. The manufacturer or retailer will have a final check once the scan is complete or the file loaded. The final digital product should be sent to the end user to confirm that it fits the use defined by the end customer who presented the design for manufacture before actual production. Included in that final review should be a caveat checklist limiting liability and explaining the services provided and roles accepted by the customer. The contract with the outside production service should indemnify the finished product for both its manufacturing process and the materials used.

Judicial approach to implied warranty in the Additively Manufacturing context is difficult to predict. If the demand is there, however, it is possible that the 3D scanning providers and Printing Centers will become more like a virtual authorized dealer distribution chain. At that stage, vendors would vet certain printing processes and material suppliers and provide CAD files for specific part and products. While the market is not there yet, this initial step into such a marketplace through scanning and remote print is feasible from a product liability standpoint due to careful selection of the product line offered below.

V. NEGLIGENCE

Under a negligence theory, the plaintiff needs to show: (1) a legal duty to exercise reasonable care, and (2) that the failure to exercise the care caused physical injury or property damage. Last, a proximate cause link must be shown between the lack of care and the ultimate injury or damage.14

Here is where the catchall sensibility of American law, courts, and juries will resolve any imbalance and inequity. Once again, Judge Cardozo’s words ring out from the 1920s to provide guidance on range of reasonableness of the extent of spreading liability. On the one hand, Palsgraf v. LIRR

14. Supra note 3 at Negligence.
supported the line of cases that ‘proof of negligence in the air, so to speak, will not do.’ Understanding that boundless consequences from any action would end “in a maze of contradictions,” New York’s highest court looked to temper the analysis to set liability at the feet of the actor closest to the risks that actor had taken. As the court held, “[t]he risk reasonably to be perceived defines the duty to be obeyed, and risk imports relation. . . .”

Instructive as an analogy is the role of 3D scanning in this new landscape. The scanning provider is neither supplying the material nor physically creating the object. The scanning service is only creating a digital file that is an exact copy of the object presented for scanning. There are still risks involved and analysis of recent FDA approaches and defective computer software litigation is instructive.

The FDA has very recently considered regulating smartphone medical device applications (hereinafter “apps”). The FDA’s initial suggested approach gives a glimpse at future regulation of the digital version of the manufacturing process. The FDA has included entities in the distribution chain that create and control the software as the manufacturers of the app, not just the entities included in the traditional definitions of manufacturer. Besides software designers and programmers, manufacturers include the companies that develop the specifications for the apps and contract with others to perform the programming. In fact, the providers who link to a website may now fall under the definition.

If this analysis is extended to Additive Manufacturing and 3D scanning’s role, we can expect to see the scanning provider included as a potential liability link in the distribution chain, but likely only for defects or errors in the scanning process itself, as Cardozo would predict. A court or regulator may identify the scanning service as contributing to the manufacturing process and subject to its associated product

16. MOBILE MEDICAL APPLICATIONS: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATIVE STAFF 9–11 (Feb. 9, 2015). In this guidance document, the FDA states that a “mobile medical app manufacturer may include anyone who initiates specifications, designs, labels, or creates a software system or application for a regulated medical device in whole or from multiple software components,” available at http://www.fda.gov/downloads/MedicalDevices/...UCM263366.pdf.
17. Id.
risk. With this background and knowledge, this risk and liability should be limited now by contract to insulate the rest of the chain from liability for the accuracy of the scan itself. This step would also define the scanning provider’s role and responsibility clearly. The strongest grounds for liability would be some defect or negligence in the manual replication during the scan. Any other theory or evidence would trigger indemnification clauses to deflect unnecessary liabilities away from the scanning provider to the responsible party in the chain.

Taking the analysis a step further, the liability surrounding software defects is instructive.\textsuperscript{18} For this proposed scanning application, the likely issues that will arise are software bugs, transmission errors, and inaccuracies in the replication of the original object itself. Again, the contract wording and indemnification and warranty wording should be negotiated in detail to ensure insulation on both sides of the scan. Such contractual terms can be used to limit liability to the actual damages of the end user not to exceed the cost of the scanning transaction.

So how do the new entities put aside the potential liability and get to work on the new manufacturing processes? Contract, regulation, innovation, and insurance.

VI. CONTRACT

With careful drafting of the business relationship agreements, all entities should attempt to own their responsibilities but insulate and define the other roles and their respective responsibilities. Again, this is not a new concept in the business world, but with the blurring of the lines between service and product in the Additive Manufacturing process, due to the reliance on digital files, a much deeper analysis is warranted. On the end user side, the disclaimer and warranty should attempt to provide the same insulation from liability for custom pieces and changes to the digital files.

Considering the probable other entities involved in the transaction, large manufacturers and retailers will likely be a target in any lawsuit that arises from a defect, be it physical injury or property damage. Notwithstanding, lawsuits will be expected if there are any defects, but the contractual

relationships, negotiated in detail, should afford tender and indemnification options.

Forging ahead into this space for manufacturing may seem difficult because the traditional business relationship models for the distribution chain are not an exact fit here. The responsibility for design, materials, testing, and manufacture are no longer set. With less control over the design and final digital file of the product, business partners along the chain need to clearly define what role they play in the production of the final product or design—or both—and what liability they agree to accept for their role and capabilities. The templates for business agreements need to be reworked to anticipate and capture the nuances of the new digital aspect of the process.

VII. REGULATIONS

Manufacturers in the Additive Manufacturing space should be hyper-focused on this phase of the evolving technology. The process as a whole, no matter the application, from the raw materials to the printers to the scanning technology or quality of the digital file to “printing” process to the finished product, needs standards and testing to provide the guideposts for everyone in the space. Once these standards are researched, tested, debated, and drafted, the industry takes a sharper focus. Once standards are set by product category and sub-testing is complete for more advanced performance products, e.g., sterilization for medical devices or print orientation for aerospace or industrial application for titanium, then the “what ifs” fade as the custom and practice of the particular trade using Additive Manufacturing molds.

Consequently, this is the moment for manufacturers in the industry to get involved with the standard committees and testing procedures. At no other time in the future will there be such an opportunity to make sure that the most knowledgeable individuals define and establish standards that strike a balance. Without a carefully constructed and informed background or history of developing standards and accepted practice, a triggering event poses the unfortunate risk for over-regulation or even possibly an over-reactive public response to the application and reliability of Additive Manufacturing. The legal side will look to these standards to resolve disputes and litigation down the line when the inevitable issues arise. The optimal result would be to have an anticipated industry response already prepared to apply to the triggering event.
rather than a scramble reaction to events.

VIII. INNOVATION

As with much of the industrial history of America, the advancing technology will continue to improve. In Additive Manufacturing, the cutting edge technical advances will have substantial effect on the law because it will either define or redefine the roles of the parties. With a technology based on digital images (either scans or photographs or digital files rather than the traditional blueprint or part design from the tool and die/injection molding method), the precision and accuracy of the digital file will be a crucial part of the process. Parties will need to know and rely on the capabilities of the digital file creator, the file-sharer, and the software components that handle that file along the way to be able to rely on the finished product and understand their liability in the chain. If an Additively Manufactured product fails in some way, the parties in the chain will need to be able to pinpoint what went wrong.

In considering the medical-app device world, the FDA has targeted the entities that create and control the software as the manufacturers of the app. Traditionally, manufacturers bear the primary and exclusive liability for defects and compliance for regulations. However, the question, “Who is a manufacturer?” is now much more complex.

The FDA, however, does not consider hardware manufacturers the same way. The FDA considers hardware makers as component manufacturers, which do not fall under the same strict regulations.19

If this analysis is extended to Additive Manufacturing, we can expect to see that the entire chain may be proposed as manufacturers; that is, the design owner, the CAD software company, the 3D printer company, and possibly even the filament source manufacturer, as well as the actual original maker may be identified as contributing to manufacturing and therefore liable for associated product risk.

To address some of these problems, the industry needs new analysis aimed at tightening risk management, the virtual distribution chain, and quality control. An update to the authorized distributor chain may be the “authorized

19. See Mobile Medical Applications, supra note 16.
distributor printer service bureau.” As Additive Manufacturing technology spreads and is applied, the distribution channel from manufacturer to end-user will become populated with entities the commerce chain has never seen before. Ultimately, the integrity of the manufacturing distribution chain will need to be airtight, which includes the software down to the click-wrap.20 Most significantly, the number of entities in the chain of liability will increase, which raises the exposure risks.

Above is just one example of how the digital file process in Additive Manufacturing will introduce new issues into product liability law. In general, the manufacturers and entities committed to perfecting the design process, materials, printing process, and software involved in all the steps along the way will create the structure that first answers the business problems of repeatability and reliability. At the same time they perfect the technology, they will be resolving the liability issues if the legal side is responsive and understands the best time to resolve these conflicts is now-as they develop-instead of allow the issue to dictate the response.

IX. INSURANCE

An important issue that remains for the industry is how insurers will treat Additive Manufactured materials, products, and processes. An instructive comparison is the treatment of nanotechnology by insurers. Many manufacturers are surprised to learn that while they may have a general commercial liability policy for traditional processes and products, that is not necessarily the case in nanotechnology. When nanotechnology is introduced to the same processes and products that are covered under the manufacturers policies, there are carve-outs triggered in the policies that could be grounds for non-coverage. Many manufacturers would be surprised to learn that such an exception existed in their coverage, exposing them to potential losses and liabilities. Even more difficult to decipher are those standing policies that either do not speak to innovated processes at all, or supply vague definitions or guidelines leaving the issues to grow and later to become larger issues.

Similarly, while Additive Manufacturing provides the

right answer for a particular product or project application, the insurance question needs to be explored and resolved. The main problem is that most manufacturers will believe or assume that the Additively Manufactured product is covered because while the process is new, the product is the same, and that is already covered. However, some insurers have not approached nanotechnology that way and the possibility is real that they will not treat Additively Manufactured parts as a different issue as well. Now is the time to resolve these issues and force the debate to make clear the demand for the product, the business need to have coverage in place to enter into vendor and distribution agreements and answer the loss and liability questions. We need to shine light onto these issues because ignoring them allows the problem to grow larger in darkness, ultimately paralyzing decision-making.

X. WHILE ADDITIVE MANUFACTURING ASKS NEW QUESTIONS, DOES IT ALSO GIVE NEW ANSWERS?

A. Risk Management

Introducing its product designs to this new virtual manufacturing process may seem like a loss of control for a manufacturer. There are, however, opportunities presented by Additive Manufacturing that would offer advantages to product developers and risk management teams that have never been available before. A major goal for any product liability team is loss avoidance. Promoting knowledge and environments that strive for openness, accuracy, and recognition helps to avoid any problems before they happen. From pre-sale design and testing to ongoing evaluations of products to insure the safety of customers, manufacturers are always trying to stretch that safety net. Imagine products that could continue a post-sale conversation: products that could report back to the customers or the manufacturer about its identification, its maintenance schedule, its lifecycle, even after a loss or injury? With the opportunity to embed devices inside of products as they are being built, micron-by-micron, imagine having the capability to avoid safety devices being disabled or circumvented and products that could record lifecycle events to anticipate and avoid product failure.

In addition to product liability, the perfection of the process also introduces new potential revenues for intellectual
property. As entities along the virtual distribution chain perfects software, materials, procedures for printing certain materials for certain products in certain temperatures, and orientations, there is a value in being the trailblazer who finds the new standard. Could this new process, new approach, new print, be protectable?

B. Intellectual Property Opportunities

As prefaced above, distributors of the software, scans, materials, and other components used in the Additive Manufacturing process should also consider patents and other means of protecting the intellectual property in their products and also in the various processes they use to control quality down the distribution chain.

The typical and strongest means of protecting inventions is by obtaining patents. Patents in the Additive Manufacturing space are nothing new. Already, companies and inventors have applied for and obtained patents for 3D printers, particular methods of 3D printing, software programs for controlling 3D printers, and materials used in the 3D printing process.

But the hardware, materials, and software used in the 3D printing process itself are only part of the story. One may also try to patent novel methods of virtual quality assurance in the 3D printing space, so long as the patent application is written carefully. Over the last five years, the courts—particularly the Supreme Court—have taken a dim view of so-called business method patents and have struck down patents that claim purely old school, brick-and-mortar business methods, as well as software that automated age-old business methods. Accordingly, one could not patent, say, a method of quality control simply by automating a brick-and-mortar quality control routine on a computer. But if one could claim that the quality control process is not simply a computer automation of

21. See, e.g., U.S. Pat. No. 8,827,684, entitled “3D Printer and Printhead Unit with Multiple Filaments.”
23. See, e.g., U.S. Pat. No. 8,668,858, entitled “Automated Build Process.”
an age-old quality control process but instead is inventive—that is, a new way of conducting quality control that has not been done before or, alternatively, that improves the 3D printing process itself, then the process could, theoretically, be patentable. In particular, if the new quality control process were tied to various physical components (e.g., an RFID chip, a GPS transceiver, etc.), then the process might be patentable.

Copyright law may also be used. Copyright protects not the idea or invention itself but rather the specific expression of an idea. Thus, one may copyright the lines of code used in a computer program used in a virtual or remote quality control process. A copyright registration is far less expensive and time consuming to obtain than a patent. But by the same token, it can be more difficult to prove copyright infringement because one must prove that the accused infringer actually copied the program. To do so, one typically needs to show access to the code and substantial similarity of the accused program to the copyrighted code.

Finally, one may guard the process as a trade secret. Trade secret protection is free. But you get what you pay for. Theft of trade secrets is often hard to prove in court. Further, in today's Internet age, nothing is secret. Thus, companies with trade secrets often turn to contract clauses (usually called “non-disclosure agreements” or “NDAs” for short) to require customers to keep the process or know-how secret. Such NDAs should be included with indemnification and warranty provisions in any end-use licenses or other agreements.

XI. PRODUCT LIABILITY LAW WILL RESPOND AND ADAPT

Additive Manufacturing presents issues in the product liability realm that are not new. They are the same issues analyzed, defused, and absorbed every time the market recognizes a new process or innovation that changes the way a product is made or distributed. The difference here is the unique opportunity for business, law, and regulation in American industry to prepare and anticipate the coming wave of innovation and application.

The innovators must educate the marketplace, business partners, regulators, and insurers of the capabilities, limitations, and risks of this new world. They must work together with their legal teams to craft the agreements, establish the standards, broker the policies and translate the new roles and responsibilities. This advocacy for the
technology and its potential will map an Additive Manufacturing landscape that will be navigable and recognizable by today’s traditional manufacturing community. The passive role carries much more risk. Let’s begin.