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# Products Liability in the Digital Age: Legal Issues Generated by Additive Manufacturing

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**T**RADITIONAL PRODUCTS LIABILITY LAW FOCUSES ON three major types of claims: design defect, manufacturing defect, and failure to warn.

Generally speaking, a design defect claim alleges that the original design of a product (i.e., the “blueprints” or instructions on how to make that device) is defective or unsafe.

A manufacturing defect, on the other hand, alleges that the manufacture of an individual product deviated from those design specifications. Finally, a failure to warn claim alleges that the manufacturer of a product did not adequately warn customers about the risks associated with the product.

Although products liability laws are slightly different from jurisdiction to jurisdiction, new legal questions are beginning to arise with the advent of additive manufacturing (“AM”).

The AM process allows “manufacturers” to create or “print” a three-dimensional product based on a digital design called a Computer Aided Design (“CAD”) file. The CAD file is essentially the instructions on how to make the device, much like the more traditional product specifications for a mass-produced product.

3D printing is already being used in the aerospace, architecture, consumer products and medical industries (to name a few) and, because of the unique manner in which these products are created, it could turn

the traditional products liability framework on its head. In the AM context, for the first time courts will need to address the seemingly obvious threshold questions of “What is the Product?” and “Who is the Manufacturer?”

## What Is the Product?

To prevail on a products liability claim, a plaintiff must show that the design or manufacture of a product caused an injury (i.e., damages). In the context of 3D-printing, however, what constitutes the “product” is not as obvious as it seems.



In considering this question, courts will need to determine whether it is the digital CAD file from which the product is created that constitutes the “product,” or whether it is the resulting object itself.

The few courts that have addressed this issue in contexts outside the realm of 3D printing have come to different conclusions. For example, the Second Circuit has found that a digital file was *not* considered a product under the National Stolen Property Act, but conversely the Ninth Circuit has held that a digital aeronautical chart *was* a “product” when incorrectly scaled, thus causing a plane crash under a product defect theory.

In one of the few 3D printing cases evaluated to date, the Federal Circuit held in the context of a patent infringement case that a 3D digital model of a patient’s teeth was likewise a product – a “creation” in and of itself, “produced by practicing each step of the patented process” and was more like an “ingredient,” a part of the actual product, than a “blueprint.” Thus, the federal courts appear to have taken different approaches to deciding this threshold question.

### **Who Is the Manufacturer?**

A second, but equally important question that courts will need to consider in the

3D-printing context is who constitutes the “manufacturer.” Products liability laws are designed to hold manufacturers liable when their products cause injury.

But in the AM context, the translation of a digital image into an object blurs the line between the designer and “manufacturer.” Furthermore, because 3D printing allows products to be printed outside the original designer’s facility, there are a variety of potential actors who might be considered the manufacturer.

In assessing fault, courts will need to parse the roles of these specific entities to determine whether the “manufacturer” is the creator of the CAD file, the creator of the 3D printer, or—potentially—the individual “printing” the ultimate product, particularly where that process involves a variety of steps that need to be carried out in a particular sequence.

The court’s analysis will be fact-intensive and may depend on the type of product at issue, as well as the harm alleged. For example, for manufacturing defect claims, courts may need to assess whether a printer malfunction or human error caused a deviation from specifications.

This distinction is not normally important because, under traditional manufacturing practices, the company

producing the product and its assembly-line operator are one and the same (i.e., to the extent the assembly line operator is acting within the scope of his employment, the company is liable for his acts or omissions).

In the AM context, however, assessing fault could become a thornier issue. For example, consider a physician or hospital employee “printing” a medical product designed by a device or pharmaceutical company, which is alleged to have caused an injury. The designer of the product will always be potentially liable, but under these circumstances the physician or employee may also be at fault not only under a medical malpractice standard, but potentially under a products liability theory.

### **Theories of Liability**

AM also raises interesting questions concerning what specific theories of liability may be available to plaintiffs alleging injury from 3D-printed products. While products liability laws differ from state to state, most jurisdictions draw a distinction between strict liability and ordinary negligence.

Traditional product manufacturers (e.g., assembly line toy companies) are generally held to strict liability standards (which do not take into consideration the reasonableness of the manufacturer’s actions), while

professional service providers are generally liable under a negligence standard, or one of a “reasonable” service provider in the provision of that service, only.

This distinction arises out of the recognition that service providers guarantee reasonable skill in the provision of a service, rather than the safety of a resulting product.

Accordingly, courts will need to determine whether the AM manufacturer is more like a traditional manufacturer guaranteeing safety, or a service provider guaranteeing a reasonable service. Where a product is designed with the participation and input of the customer (like a custom-made sculpture), courts may be more likely to find that the manufacturer is akin to a service provider.

On the other hand, when the consumer and producer are completely divorced from each other such that the consumer is a pure customer (such as the consumers of mass-produced automobile parts), the manufacturer may be held to the strict liability standard appropriate for traditional manufacturers. Of course, policy considerations often play a part in the court’s analysis and could potentially lead the court to entirely different results.

Even more complicated is the analysis of such questions in

the drug and medical device context, which is already a highly regulated field. In *Buckley v. Align Tech. Inc.*, the court held that Align, a custom dental manufacturer, was like a traditional manufacturer, even though it was involved in customizing a dental product for a particular patient based on impressions of that patient’s teeth.

As such, Align had a duty to warn the dentist only about the risks of the product, and the dentist, in turn, had the exclusive duty to warn the plaintiff. In other words, in this context the fact that the company made a custom, 3D-printed product did not change the traditional duty to warn, in which the manufacturer needs only warn the physician/dentist. Query whether the result would be the same had the dentist not only ordered the product, but also 3D printed it in his office and included it in the price of treatment. Under those circumstances, it is conceivable that the *dentist* might also be considered a “manufacturer,” thus cloaking himself with an independent duty to warn the patient.

### Other Considerations

In summary, there remains much uncertainty in the current law surrounding AM. Some other legal issues to explore

include the role of contributory negligence, potential spoliation of evidence for custom products, issues stemming from open source CAD files where the designer of the CAD file is unknown, as well as how AM may change indemnity and insurance agreements insofar as cost sharing is concerned.

Company counsel would be wise to stay abreast of the changing landscape.

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