The products of tomorrow

Rapidly changing technologies and exciting new products offer seemingly limitless opportunities for growth and progress across a broad range of industries

Inside Counsel
July 1, 2015

By Jana Jobes Wozniak, Elizabeth Curtin, Leslie Kuhn-Thayer

Rapidly changing technologies and exciting new products offer seemingly limitless opportunities for growth and progress across a broad range of industries. But the same innovative qualities that make new products likely to gain widespread publicity may also attract unwanted – and unwarranted – attention from the plaintiffs' bar and others wanting to exploit the success of the latest "it" products. As a result, emerging products may be susceptible to a variety of product liability and tort claims. The following are a few examples of the challenges and potential liabilities new products may face.

Health-Related Apps. The growth of health-related apps has exploded in recent years, with everyone from pharmaceutical and medical device companies, retail pharmacies, insurers, and nonprofit organizations claiming a spot in the digital marketplace. But if these health-related apps do not function as intended or advertised, app developers may face product liability litigation as well as other tort claims. The first question likely to arise in this context is whether health-related apps are products such that strict liability applies or whether they are considered medical and health-related services. According to the Restatement (Third) of Torts: Products Liability, § 19 cmt. d (1998), courts look to the Uniform Commercial Code (UCC) definition of a "good" when answering this question for computer software, the most analogous comparison to health-related apps. Under the UCC, the answer turns on whether the software is mass-produced, standardized, or generally available, as opposed to customized. Since health-related apps are standardized applications that are readily available and intended for mass consumption, courts will likely view health-related apps as covered by the UCC, and by extension, subject to strict products liability.

Biosimilars. With the recent FDA approval of the first biosimilar medicine in the United States under the abbreviated approval pathway created by the Biologics Price Competition and Innovation Act of 2009, and with patents soon expiring for several biological products, the first wave of biosimilars are expected to hit the U.S. market soon. But their complex properties and manufacturing processes may make biosimilars attractive targets for litigation. Unlike traditional generic drugs, biosimilars, which are derived from living cells, tissues, or blood components, are not identical copies of their brand-name reference product, thus exposing manufacturers to unique challenges in defending claims. For instance, there is no statutory or regulatory requirement that the biosimilar's labeling mirror that of its reference product, which suggests that preemption may not be an available shield for biosimilar manufacturers. Likewise, because biosimilars are only required to be "highly similar" to their brand counterparts, adjustments in product design may be permissible, therefore potentially foreclosing preemption as a defense against design defect claims as well. Companies may see manufacturing and design defect claims due to the complex, custom manufacturing processes, as well as the products' susceptibility to manufacturing variations potentially altering the end products. Companies could also face misrepresentation and false advertising claims due to the need to actively market biosimilars to prescribers in the absence of an interchangeability designation. Although the

Food and Drug Administration (FDA) has issued several guidance documents, many questions remain – as the industry continues to develop and adapt to new state and federal regulations, product liability law will continue to evolve in order to keep up.

Genetic Testing. Genetic testing has been around for some time, but recent technologies and expanded uses may present new and complex risks. For example, in "direct-to-consumer" genetic testing, a consumer can send genetic samples and receive a personalized risk profile, medical screening and other information for a relatively low cost. Manufacturers may face consumer fraud and product liability suits if consumers make health-related decisions (or forego treatment) based on testing results. Both the Federal Trade Commission and the FDA scrutinize the claims made by manufacturers with respect to these tests, and agency actions might lead to follow-on consumer fraud or product liability litigation. Direct-to-consumer genetic tests also pose interesting questions about insurance coverage: What obligation does a consumer have to disclose do-it-yourself genetic test results? Can a life insurance company deny coverage based on these results? Legal, ethical, and regulatory aspects of direct-to-consumer genetic testing are just shaping up, and we expect to see interesting developments and challenges in the years to come.

Smart Cars. Each year, cars become increasingly smarter, bringing us one step closer to widespread use and availability of autonomous cars. While new technologies and automated features improve the overall safety of our roads, taking control away from drivers (in certain conditions) effectively puts vehicle manufacturers in the "driver's seat" and increases their risk of liability. While the anticipated theories of liability in cases involving these futuristic cars will be familiar (*e.g.*, design defect, failure to warn, warranty, misrepresentation), smart cars will raise complex questions for the courts to decide. For example, how do you assess the fault of the driver versus the automated system in an accident? Is a smart car defective when an accident is caused by a glitch in the system but the owner failed to download the software update to repair the glitch? What warnings are adequate for a driverless car and does the responsibility for those warnings extend post-sale? The resolution of these and other emerging issues with smart cars are not likely to be limited to the courtroom – state and federal legislators, regulators, and insurers are paying close attention to this technology and will likely weigh in on these issues.

As these examples show, while companies continue to innovate and push the boundaries of existing technologies, they may also forge ahead toward new frontiers of liability and legal challenges. It is critical that companies think ahead and anticipate potential risks and liabilities in order to avoid potential claims where possible and prepare for defending themselves when necessary.

This article originally appeared in **Inside Counsel,** ***July 1, 2015.***
http://www.insidecounsel.com/2015/07/01/the-products-of-tomorrow?slreturn=1447966295