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# How To Prevent and Defend Claims Resulting from Counterfeit Products

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# How To Prevent and Defend Claims Resulting from Counterfeit Products

## I. Introduction

A family rents a minivan for their vacation. As the father rounds a curve in Yosemite National Park, the minivan's brakes fail, causing a wreck in which two children die. The brake pads turn out to be low-quality counterfeits.

A man is enticed by a spam email to buy his prescription drug online. Upon receipt, the man takes the recommended dose, becomes ill and dies shortly thereafter. His autopsy indicates poisoning, and further investigation reveals the drug in question was a counterfeit containing toxic industrial solvents.

A mother purchases an extension cord from the local flea market. She uses the extension cord to provide electricity to a guest bathroom being refurbished. After only a few days use, the extension cord frays and causes a fire killing all inside the home. An investigation reveals the extension cord was a counterfeit.

The above scenarios are indeed hypothetical, but such threats from counterfeiting are real. Counterfeiting is not a victimless crime associated only with currency and luxury goods. Counterfeiting is a concern for all product manufacturers and threatens not only the company's bottom line, but also consumers' health and safety.

Under traditional tort doctrines, a manufacturer was immune from liability for the injuries caused by counterfeit versions of its products. Given the tremendous increase in counterfeiting in today's markets, the plaintiffs' bar will be advancing theories to support a claim that a manufacturer should be held liable for counterfeit versions of its products under certain factual circumstances. This paper presents an overview of the counterfeiting problem, various methods a product manufacturer can use to prevent and deter counterfeiting and the current state of tort law in cases in which a manufacturer or other sellers, including distributors, face claims for harms suffered by victims of counterfeiters.

### A. Enormity Of The Problem

When a consumer sees a manufactured product in the market, he intuitively expects the product to be backed by the manufacturer's reputation for quality and safety. Counterfeiters pass off fake products, taking advantage of legitimate manufacturers' brand equity and resources. Consumers think they are getting genuine manufactured products but end up with substitutes bearing counterfeit logos and even unauthorized safety certification marks.

The extent of product counterfeiting is difficult to quantify, but experts agree the scope of counterfeiting is tremendous and spans almost every industry. The difficulty of measuring the prevalence of counterfeiting is due to various reasons: lack of attention to the problem; multiple distribution points, including the Internet and local flea markets; inadequate regulatory and inspection systems worldwide; and the sophistication of counterfeit products, which results in many counterfeits escaping notice. Thus, while the true extent of counterfeiting cannot be known, the International Anti-Counterfeiting Coalition, an

international organization comprised of a cross section of global business and industry, has estimated:

- 1) counterfeiting costs United States businesses \$200 billion to \$250 billion annually;
- 2) counterfeit merchandise is directly responsible for the loss of more than 750,000 American jobs;
- 3) since 1982, the global trade in illegitimate goods has increased from \$5.5 billion to approximately \$600 billion annually; and
- 4) approximately five to seven percent of world trade is in counterfeit goods.

See [www.iacc.org/counterfeiting/counterfeiting.php](http://www.iacc.org/counterfeiting/counterfeiting.php). These are alarming numbers. Moreover, the problem of counterfeiting is no longer a concern just for some industries. As stated in *Counterfeiting Exposed: Protecting Your Brand and Customers*: “[t]oday, no product is too cheap to counterfeit, and no brand immune from the gaze cast by counterfeiters looking to pirate a brand or in some cases hijack it altogether.” David M. Hopkins *et al*, *Counterfeiting Exposed: Protecting Your Brand and Customers*, 4 (2003).

## B. Manufactured Products Being Counterfeited

In today’s world of sophisticated software and information exchange, nearly any type of manufactured product can be, and most likely has been, counterfeited. This paper focuses on situations where counterfeiting could result in tort liability for a manufacturer because a consumer was injured by a counterfeit version of its products. Below are some examples of the industries where such risk is most evident:

### 1) The Pharmaceutical Industry

Because of several drug recalls in the past few years that resulted from discovery of counterfeits, the pharmaceutical industry has probably faced more public exposure in the counterfeiting realm than other industries. While most pharmaceutical manufacturers have identified counterfeits in time to prevent harm on a massive scale, there are exceptions to the rule. In 1990, eighty nine Haitian children died after taking counterfeit drugs containing antifreeze. In 1996, it is believed at least 2,500 people died in Niger due to a fake meningitis vaccine. See World Health Organization, *Prevention of Counterfeit Drugs: Working Together for Safer Drugs. Counterfeit Action Sheet* (2002).

Drugs with the largest sales, the highest profit margins and those that are easiest to counterfeit are the most commonly counterfeited drugs. The problem appears to be increasing. After averaging only five counterfeit investigations per year through the late 1990s, government investigations have exponentially increased over the last decade. The FDA has reported that there is an “increased sophistication in the methods used to introduce . . . counterfeits into the otherwise legitimate U.S. drug distribution system.” *Combating Counterfeit Drugs, A Report of the Food and Drug Administration*, (February 2004),

[www.fda.gov/oc/initiativescounterfeit/report02\\_04.html](http://www.fda.gov/oc/initiativescounterfeit/report02_04.html). With increased availability to distribute drugs via the Internet, there is good reason to believe counterfeiters will focus on the pharmaceutical industry for the foreseeable future.

There are numerous ways pharmaceuticals can be counterfeited. Examples include:

- a. re-labeling an expired prescription drug;
- b. diluting an active pharmaceutical ingredient contained in prescription drug to sell in greater quantity; and
- c. replicating a prescription drug.

All of these methods are dangerous for a consumer. An expired drug contains a less active or inactive ingredient. In diluting a drug, a counterfeiter not only decreases the active ingredient but also balances out the drug with some other, and possibly, toxic chemicals. In replicating a drug, a counterfeiter is only concerned with appearances and will likely fill the drug with the cheapest chemical available.

## 2) Automotive And Aircraft Industries

A representative for Ford Motor Company has stated that counterfeiting costs Ford about \$1 billion annually. See Coalition Against Counterfeiting and Piracy, *Supply Chain Best Practices Tool Kit*, 7 (2006). In October 2005, Thailand law enforcement seized approximately 50,000 counterfeit automotive parts bearing unauthorized trademarks of Mercedes Benz, Chevrolet, Honda, Saturn and BMW. Such counterfeiting is not limited to component parts—one raid resulted in the seizure of nearly 1,100 fully assembled motorcycles that were slavish copies of a patented Yamaha design. See E.J. Kelly, *Getting the Black Market to Knock it Off: Enforcing Trademark Rights in Thailand* (October 2007). Further, in 2006, police raided three aviation parts manufacturers in Rome and seized over \$2 million in repackaged used parts being sold as new. See E.J. Kelly, *New Elite Government IP Suppression Unit to Bolster Thailand's Drive to be Automotive Regional Hub* (August 2006).

There are numerous ways automotive and aircraft products can be counterfeited. Examples include:

- a. taking used or discarded parts, refurbishing them and selling them as new parts;
- b. making an unauthorized copy of a product by molding a fake from the actual product or its blueprint. Sophisticated computer programs now allow a mere digital photo to serve as a basis for modeling a counterfeit; and

- c. theft of intellectual technology (IT)—often IT is leaked when product specifications are emailed to subcontractors without any encryption devices and the information is stolen in transit.

Counterfeiters with relatively little sophistication can replicate basic automotive and aircraft component parts with ease, and even experts, at times, have difficulty identifying the genuine products from the counterfeits.

### 3) Electrical Products And Appliances

A manufacturer of electrical products should also be concerned about the potential tort implications of counterfeiting. From power strips and toasters to circuit breakers, counterfeiters have crafted fakes. For example, counterfeiters have crafted fake electrical cords having half the copper required under safety standards. Such counterfeit cords are not thick enough to handle the electrical current and may overheat, resulting in fires. Similar results occur where counterfeiters create fake circuit breakers that insufficiently prevent the wiring in one's home from overheating. Furthermore, consumers may be more vulnerable to counterfeiting here than with other manufactured products because some electrical products provide little in the way of distinguishable features, *e.g.*, an orange extension cord.

These examples should make clear that counterfeiting is prevalent and counterfeiters are capable of creating sophisticated fakes. Counterfeits have also become savvy in distributing their products around the world through outlets such as the Internet or flea markets.

## II. Prevention And Deterrence Of Counterfeiting

A manufacturer should have in place an effective anti-counterfeiting program to help protect itself from potential tort liability stemming from counterfeits. There is no single solution; a variety of techniques and actions should be taken to prevent counterfeiting. Furthermore, a manufacturer should take a zero tolerance approach against internal or external resources that take part in or facilitate counterfeiting.

The first step in creating an anti-counterfeiting program is to evaluate product susceptibility. Given the money to be made by successfully counterfeiting most any product on a large scale, odds are that most any given product is a candidate for counterfeiting. However, some products are more appealing to counterfeiting, so consider the following factors: premium pricing of a product that carries low production and distribution costs; availability of product specifications; reliance on outsourced manufacturing and distribution; and use of online sales networks.

Once the level of concern is recognized, a manufacturer should create a comprehensive plan to identify weaknesses in its distribution and supply chain. Most manufactured products change hands a number of times before ever reaching retailers. Products often pass between the hands of so many middle men that accountability and tracking are lost. Therefore, a manufacturer should evaluate its entire manufacturing and distribution channel, from raw materials to the consumer.

The following are a variety of methods a manufacturer can utilize to better police their manufacturing and distribution systems.

**A. Secure Legitimate Inputs**

- 1) Ensure the authenticity of raw materials and component parts.

This process is facilitated by purchasing raw materials from authorized suppliers only, and where possible, source from fully auditable suppliers who source exclusively from original manufacturers, franchised distributors or the first owners of the goods. Also, identify businesses having a higher probability of engaging in trade of counterfeit products. Businesses in certain regions of the world should be scrutinized more thoroughly than others: Eastern Europe and Southeast Asia, especially businesses in China. In the Department of Homeland Security's mid-year report for 2007, 81% of all counterfeit product seizures were transported from China. *U.S. Customs and Border Protection, Office of International Trade (2007)*,

[http://www.cbp.gov/linkhandler/cgov/import/commercial\\_enforcement/ipr/seizure/07\\_midyr\\_seizures.ctt/07midyr\\_seizures.pdf](http://www.cbp.gov/linkhandler/cgov/import/commercial_enforcement/ipr/seizure/07_midyr_seizures.ctt/07midyr_seizures.pdf). Further, periodically audit suppliers' facilities and documents. A manufacturer should demand such authority from its suppliers, and a manufacturer must act on this authority. To make this feasible, a manufacturer may be required to reduce its source base.

- 2) Employ the concept of zero tolerance.

Develop options for delisting suppliers as a trusted source of raw materials and component parts for repeated failures to comply with proper procedures. Terminate relationships with suppliers where audits reveal counterfeiting is occurring or possible. When appropriate, also provide evidence of counterfeiting to proper authorities and pursue legal action.

- 3) Institute shipping policies to protect the integrity of raw materials and component parts.

Develop guidelines to ensure the physical security of overseas factories in the supply chain. Fully inspect carrier documents. Use seals on containers and note seal numbers on shipping manifests to protect containers from being opened and resealed. Further, develop relationships with customs authorities to exchange information and target shipments suspected of containing counterfeit products. Customs and Border Protection and U.S. Immigration and Customs Enforcement may prove helpful in seizing incoming shipments of counterfeit products before they can enter the stream of commerce.

In some industries, such as pharmaceuticals, chemical markers may also prove useful to trace quantities being shipped. Such markers cannot be detected by human senses and are also difficult to detect through normal analytical techniques because the counterfeiter would need to know exactly which chemical marker has been used and be able to screen for it at the part-per-billion levels that can be achieved.

## B. Verify The Legitimacy Of Customers And Distributors

Counterfeiters prey on weaknesses in the legitimate supply chain. Often they pose as legitimate businesses and seek to purchase manufactured products in bulk in order to blend fake products. A manufacturer should be vigilant in ensuring it sells only to legitimate distributors and retailers. The following are some good practices:

- 1) Develop procedures for sales representatives to verify the legitimacy of purchasers.

Instruct sales representatives to investigate the purchaser's business background and scrutinize sales where the purchaser is willing to pay cash for very expensive orders or makes an unusually large order.

- 2) If feasible, employ investigators to track down purchaser history and provide leads on common spots for illicit trade.

Manufacturers can employ investigators worldwide to assist in their effort to prevent counterfeiting. Ford, for example, has a full-time staff dedicated to finding counterfeits, and they, in turn, rely on additional informants outside the U.S. to provide leads, particularly at common spots for illicit sales, such as trade shows. Such undercover work can be especially helpful because distributors and suppliers involved in counterfeiting tend to be a tightly knit community that can be extremely difficult to penetrate. *See Coalition Against Counterfeiting and Piracy, Supply Chain Best Practices Tool Kit, 8 (2006)*. A manufacturer does not have to make such an expensive commitment to utilize the advantages of market intelligence. "Mystery shopping," where random samples are collected and tested, can provide counterfeiting information for relatively low costs.

- 3) Monitor Internet sales of product and component parts.

The proliferation of the use of the Internet to purchase products, including electrical products, automotive components and pharmaceuticals, presents counterfeiters with direct access to the buying public. Manufacturers must actively and aggressively monitor Internet sales and secure products from the Internet to evaluate the authenticity and quality of the products marketed and sold using its brand. "Mystery shopping" from online sellers is a very useful tool in this setting.

- 4) Ensure subcontractors only produce authorized merchandise.

When performing audits, ensure subcontractors are not running "third shifts" to create undocumented products for distribution outside the proper supply chain. Unannounced audits may prove especially helpful, but this should be done only if this right has been negotiated into the contract with the particular subcontractor.



### C. Manage Product Waste And Damaged Inventory

Because counterfeiters often prey on scrap yards, waste repositories or reclamation centers, a manufacturer should take appropriate steps to ensure waste and damaged products are disposed of properly.

### D. Ensure The Legitimacy Of Purchased Products At Retailers

In addition to the top-to-bottom approach recommended above, a manufacturer should still ensure the legitimacy of the product upon delivery to retailers. Retailers can be provided a variety of information and techniques to ensure products are genuine. Retailers should audit shipments, verifying packaging, case markings, pallet configurations, etc. Where feasible, products should be opened to confirm the units have proper batch numbers, expiration dates, or other identification codes. Any repackaged products, or broken or altered seals should always be viewed with suspicion.

Covert track and trace technologies, such as the FDA's Radiofrequency Identification technologies (RFID), are an additional technique to be considered. This technology allows a manufacturer to trace its products through distribution channels with electronic tags that can be hidden on shipments. Using these technologies, a manufacturer can tell if a shipment has been diverted thereby allowing the retailer to more thoroughly scrutinized the shipment. In addition, this technology provides a manufacturer with a "head start" in tracking down the counterfeiter in question.

As opposed to covert tracing systems like RFID, which provides information to track diversions from normal shipping patterns, a manufacturer should also use overt security devices to deter counterfeiters from even attempting to replicate a product. Such technology includes using holographic labels where the use of expensive or difficult-to-obtain material makes it difficult for counterfeiters to mimic the product. Such technologies can be very creative. Anheuser-Busch recently faced a problem with counterfeiters in China refilling discarded bottles for resale. To deter such activity, the company started using expensive foil labels on the bottles that were temperature sensitive, turning red when cold. *See F. Balfour, Fakes!*, BusinessWeek, Feb. 7, 2005, at 60.

### E. Outreach To Law Enforcement, Regulatory Officials, The Public And Competitors

A manufacturer is not alone in the fight against counterfeiting. Law enforcement is in place domestically and abroad to assist in the attempt to stop counterfeiting. Indeed, the U.S. government is working to pressure other nations to crack down on the problem. In addition to governmental assistance, competitors and the public should be looked to for assistance.

#### 1) Assistance from law enforcement

As discussed above, developing relationships with customs authorities to exchange information and target shipments suspected of containing counterfeit products is an important factor in preventing counterfeits from entering the market. In addition to situations where a manufacturer tracks a known shipment of counterfeit products, it is important to assist custom authorities in identifying counterfeit products. Therefore, manufacturers should



develop and maintain goodwill with law enforcement. Where feasible, a manufacturer should provide customs authorities information regarding specific counterfeiters so they increase scrutiny of associated shipments, and also provide samples of legitimate and counterfeit products so authorities will better recognize potential counterfeit products.

## 2) Regulatory officials

Lobby government officials to pressure other nations to crack down on counterfeiting. To some degree, this is already being done, but the pressure must continue. Several commissions, such as the U.S.-China Economic and Security Review Commission and the U.S.-E.U. Action Strategy for the Enforcement of Intellectual Property Rights, have been formed to focus on this issue, but these meetings will only moved forward with the assistance of affected industries, which are in the best position to marshal the evidence of counterfeiting in today's markets.

## 3) Competitors

To some degree, an anti-counterfeiting program's goal is to make a manufacturer's own product less attractive to a counterfeiter than competitors' products, but industrial competitors' conflicts of interests with regard to counterfeiting ends there. Competing manufacturers face the same challenges, so working together may result in creative solutions and reduce overall costs of implementing a comprehensive anti-counterfeiting program.

## 4) The public

Consumers are often in the best position to discover counterfeits, so channels need to be available for consumers to contact a manufacturer regarding potential counterfeits. For example, in the 2003 Lipitor incident, complaints by twenty consumers regarding the strange taste of the pills triggered an investigation that traced the fake pills to a sophisticated counterfeiting enterprise in South America. *See* FDA, Enforcement Manual Newsletter, *Drug Anti-Counterfeiting Techniques Move Beyond Product Packaging to the Tablet—and Patient* (October 2005). Therefore, hotlines or other direct communication channels should be provided to consumers so they can directly contact a manufacturer when there is a concern.

## F. Product Identification

Given the tremendous increase in counterfeiting in today's markets, a manufacturer facing a claim that one of its products injured a consumer should be hesitant to assume the product was in fact a genuine product. Testing procedures should be implemented by manufacturers to analyze questioned products to ensure product authenticity. Such measures could provide significant defenses to a claim and reduce a manufacturer's annual litigation costs.

These examples should provide any product manufacturer with a framework for creating its own anti-counterfeiting program. No one program will work for every manufacturer, but all programs will require comprehensive and creative efforts. Furthermore, taking a zero tolerance approach when counterfeiters are found will ensure the program actually provides results.

### III. Potential Tort Liability

Personal injury victims seek to soften the consequences from their injuries by pursuing financial compensation from any and all parties that can be traced to their harm. In the context of counterfeiting, those who have suffered physical injury at the hands of a counterfeiter often have no way of bringing the counterfeiter into court and, even if they could, the counterfeiter is unlikely to have the comparably deep pockets of the genuine manufacturer. Therefore, personal injury victims often pursue their claims against findable, solvent entities like the manufacturer of the genuine product. When claims are brought against the manufacturers of genuine products, a court is asked to determine whether the victim, a person who intended to buy a genuine product but who instead purchased a counterfeit product and was injured by it, is entitled to damages against the manufacturer.

#### A. Manufacturers Have Been Protected By Traditional Tort Principles

Under traditional notions of tort liability, a manufacturer of genuine products has not been held liable for injuries caused by a counterfeit version of its product. A basic tenet of product liability law is that anyone in the chain of distribution may be held liable for a defective product. See *Restatement (Third) of Torts* § 6 (1998). When counterfeiting has been at issue, therefore, a manufacturer that was not in the supply chain has been insulated from tort liability.

The non-liability of a manufacturer in this context was recently discussed in *Ashworth v. Albers Medical, Inc.*, 410 F. Supp. 2d 471 (D. W.Va. 2005). In *Ashworth*, the plaintiff sued a manufacturer, along with a distributor, reseller, and repackager, alleging she was harmed as a result of taking counterfeit Lipitor, a cholesterol-lowering drug. *Id.* at 474. The plaintiff had purchased the drug at a Rite Aid pharmacy. *Id.* at 473. The plaintiff identified the product she took as a counterfeit version of Lipitor. *Id.* Nonetheless, she advanced several theories against the manufacturer, including claims for strict liability and negligence. *Id.* at 474-75. In granting the manufacturer's motion to dismiss, the court noted that essential to the claim of strict liability was a showing that the product was either defective when it left the manufacturer or the manufacturer was part of the distribution chain for the counterfeit product. *Id.* at 476. The court found that plaintiff's pleading, on its face, admitted that the manufacturer played neither role because the plaintiff admitted the drug in question was counterfeit. *Id.* Further, the court noted that arguing the manufacturer somehow participated in the counterfeit scheme "defies logic inasmuch as the scheme serves only to diminish [the manufacturer's] profits and dilute [its] trademark and patent rights." *Id.*

The court likewise disposed of the plaintiff's negligence claim, noting that selling a counterfeit drug violates the Federal Food, Drug & Cosmetic Act, and that the manufacturer had no duty to protect the plaintiff from the deliberate, criminal conduct of the counterfeiter. *Id.* at 479. The court also rejected the plaintiff's argument that the defendant should have taken steps to prevent the reasonably foreseeable risk of counterfeiting, relying upon law that a manufacturer does not have a duty to anticipate and prevent criminal tampering or counterfeiting. *Id.* at 480-482. Thus, under traditional tort principles, a manufacturer has been immune from strict liability for harms caused by counterfeit versions of its products. The protection has resulted from the court requiring the plaintiff to show the product was

defective when it left the manufacturer or show the manufacturer was part of the chain of distribution of the counterfeit product.

Causation is another basis for defending a claim asserted against a manufacturer for injuries caused by counterfeit products. For example, in *Ashworth*, the court reviewed the issue with causation already determined—the criminal act of the counterfeiter resulted in the harm at issue, therefore the manufacturer, another entity that was financially harmed by the counterfeiting, rationally appears remote from the injury. Further, a plaintiff’s claim that a manufacturer can be held strictly liable for failing to warn consumers of the dangers posed by counterfeiting has also been dealt with by focusing on the criminal, superseding act of the counterfeiter. See *Elsroth v. Johnson & Johnson*, 700 F. Supp. 151, 167-68 (S.D. N.Y. 1988) (holding a manufacturer not liable for criminal tampering that caused a consumer’s death subsequent to leaving the manufacturer’s control).

In cases in which dilution has occurred, the analysis is more complicated, but the result is the same. Such a claim could also be characterized as a design defect claim. In one of the few challenges where this claim has been tried, the manufacturer prevailed. See *Fagan v. AmerisourceBergen Corp.*, 356 F. Supp. 2d 198 (E.D. N.Y. 2004). In *Fagan*, the plaintiff was prescribed a drug while undergoing a liver transplant. *Id.* at 204. He ordered the drug via mail, and as part of his treatment, injected himself with the drug once a week to assist with anemia. *Id.* After repeated injections of the drug, his anemia worsened. *Id.* During this period, the manufacturer discovered a counterfeit diluted version of its drug in its distribution channel, and plaintiff had been a recipient of the diluted drug. *Id.* The court dismissed the design defect claim against the manufacturer, reasoning the plaintiff’s claim was that the defendant’s packaging was not “tamper-proof enough,” and that the plaintiff could not establish the feasibility of a safer design. *Id.* at 206-207. The court reasoned that, while the manufacturer’s failure to employ safer packaging technology might create a likelihood of harm to a consumer in the plaintiff’s position, the plaintiff was unable to prove the packaging created a “substantial likelihood of harm.” *Id.* Thus, the *Fagan* court required the plaintiff to show that it was foreseeable a substantial change in the product would occur, an alternative design would have prevented the adulteration, and there was a “substantial likelihood of harm.”

These requirements place a substantial burden on the plaintiff because, in addition to proving a high likelihood of dilution and that dilution would result in injury, the plaintiff is required to present an alternative design that would prevent the dilution. Assuming the plaintiff in *Fagan* could have established the first two of these requirements, the plaintiff’s alternative design would have then been scrutinized under a risk-utility test that would have been difficult for plaintiff to overcome. See *American Law of Products Liability* § 28.19 (3d ed. 2004) (providing the seven factors to be considered). Overcoming such requirements and standards is difficult for a plaintiff even in today’s world where there is abundant evidence of the risk of counterfeiting, and technology and methods exists to prevent and deter counterfeiting.

**B. Manufacturers May Be Found To Have A Duty To Take Steps To Prevent And Deter Counterfeiting In The Near Future.**

Courts analyzing a manufacturer's liability under a negligence theory have rejected that assertion that manufacturers have any duty when it comes to counterfeiting, relying on traditional defenses to claims of negligence. For instance, in *Ashford*, the court dealt with plaintiff's claim that the manufacturer had to ensure counterfeit Lipitor was not sold to the public by reviewing situations where a person could be considered to have a duty to protect others from criminal activity, and found that those special situations were not sufficiently analogous to the circumstances to apply. *Id.* at 479. The court then addressed the plaintiff's contention that the manufacturer should have instituted reasonable safeguards to prevent counterfeit products from reaching the marketplace due to there being "well known risks of counterfeiting." *Id.* at 480. The plaintiff specifically argued the manufacturer could have designed a more counterfeit resistant product and packaging, and could have exercised more control over distributors. *Id.* The court found the manufacturer had no duty to ensure its products were counterfeit-proof. The court supported this assertion citing cases finding that a manufacturer is not required to anticipate and prevent criminal conduct, and even if the manufacturer "had implemented the strictest of available counterfeit measures to its product and product line, there is no assurance that the harm complained of would not have resulted." *Id.* at 481.

Although *Ashworth* and *Fagan* make clear that a manufacturer is immune from tort liability for harms caused by counterfeit versions of its products, there are reasons a manufacturer should be concerned. As the plaintiff indicated in *Ashworth*, in today's markets there are "well known risks of counterfeiting." This ever-increasing risk, combined with tort law's role as "a toll by which society places controllable limits on actions and inactions," *Elsroth v. Johnson & Johnson*, 700 F. Supp. at 156 quoting W. Prosser, *Handbook of the Law of Torts* § 53 (4th ed. 1971), makes it very possible that a court will accept a plaintiff's claim that a manufacturer should be held liable for counterfeit versions of its products in at least some situations.

Legal standards occasionally originate when an industry recognizes a need to correct potential deficiencies in their products even when government has not imposed substantial regulation in the area. See *The T.J. Hooper*, 53 F.2d 107 (S.D. N.Y. 1931) (imposed negligence liability on tug boat owner for not placing radios on its ships). The potential for liability increases with availability of safer technology in the marketplace. See *Uniroyal Goodrich Tire Co. v. Martinez*, 977 S.W.2d 328, 337 (Tex. 1998) (holding widespread use of advanced safety technology within industry is a consideration in assessing liability). Thus, with the prevalence of counterfeiting in today's markets and the numerous steps available for a manufacturer to make its products less attractive to counterfeiters, a manufacturer who does not take adequate anti-counterfeiting measures could be at risk for tort liability.

The most likely candidate as a successful claim against a manufacturer for harm caused by counterfeit versions of its product is a negligence theory based on a breach of duty to the plaintiff. Unlike design defect claims where several hurdles would have to be overcome, with a negligence duty analysis, the question is straightforward—given the current threat of counterfeiting, does a manufacturer have a duty to take steps to prevent and deter counterfeiting of its products?

All duty analyses confront a basic premise of tort law that no one generally is required to act for the benefit of another person. In the language of the *Restatement (Second)*

*of Torts*: “the fact that the actor realizes or should realize that action on his part is necessary for another’s aid or protection does not of itself impose upon him a duty to take such action.” *Restatement (Second) of Torts* § 314 (1965); see also A. Best, *Manufacturer’s Responsibility for Harms Suffered by Victims of Counterfeiters: a Modern Elaboration of Causation Rules and Fundamental Tort Law*. 8-Sum Currents: Int’l Trade L.J. 43, 44-45 (1999). Despite the common law’s recognition of one’s right to choose not to act, courts have often found that once an individual does take some action, society can demand the actor either carry out that action reasonably or follow it with some other conduct. Confronting novel cases, courts typically enumerate various factors they will consider in evaluating whether to impose a duty. For example, the Tennessee Supreme Court has stated:

those factors include the foreseeable probability of the harm or injury occurring; the possible magnitude of the potential harm or injury; the importance or social value of the activity engaged in by defendant; the usefulness of the conduct to defendant; the feasibility of alternative, safer conduct and the relative costs and burdens associated with that conduct; the relative usefulness of the safer conduct; and the relative safety of alternative conduct.

*McCall v. Wilder*, 913 S.W.2d 150, 153 (Tenn. 1995). A California decision enumerated similar factors, as well as the moral blame associated with the actor’s conduct and the availability of insurance to cover the proposed liability. See *Rowland v. Christian*, 443 P.2d 561 (Cal. 1968).

Because the risks of counterfeiting are becoming well known, those risks involve significant injuries and death for consumers, and anti-counterfeiting measures exists, a court could find a manufacturer has a duty to consumers to take steps to prevent and deter counterfeiting. Further, if a court is willing to find a manufacturer has such a duty, it is possible the same judge would be willing to find causation could stretch beyond the criminal act of the counterfeiter. See generally *Wheeler v. Andrew Jergens Co.*, 696 S.W.2d 326, 328 (Ky. Ct. App. 1985) (third party tampering with shampoo bottle is foreseeable and may not constitute superseding cause of injury such that manufacturer is absolved from liability); see also *Zueger v. Carlson*, 542 N.W.2d 92, 96-97 (N.D. 1996) (premises liability case where court has found businesses have a duty to act reasonably to protect customers from foreseeable criminal acts). As a result, manufacturers who opt not to create a comprehensive anti-counterfeiting program may find their failure to act is not only a breach of a duty but the cause of any resulting injury. Such a duty, breach of duty, and causation could expose manufacturers to negligence liability.

#### **IV. Conclusion**

Counterfeiting is a real and growing problem for product manufacturers. Under traditional tort doctrines, a manufacturer has been immune from liability for the injuries caused by counterfeit versions of its products. Given the tremendous increase in counterfeiting in today’s markets, and tort liability is an ever evolving doctrine, courts may accept a plaintiff’s claim that a manufacturer can be held liable for harm caused by counterfeit versions of its products under certain factual circumstances and an expansion or

modification of various legal theories. Therefore, product manufacturers should put in place comprehensive anti-counterfeiting programs to prevent and deter counterfeiting and to assist when facing a claim from a consumer who has suffered harm from a counterfeit version of the manufacturer's product.