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PHARMACEUTICAL COUNTERFEITING AND THE PUZZLE OF
REMEDIES

Sandra L. Rierson*

Introduction

The term “counterfeiting” provokes wide-ranging and almost universally negative connotations – at least to those who are not profiting from it – and generates images of everything from fake currency to poor-quality DVD’s and designer purses. The term “counterfeit pharmaceuticals,” or “counterfeit drugs,” as commonly understood, similarly evokes a wide range of (mostly) negative images, from poisonous cough syrup laced with Diacetyl (a chemical used in antifreeze) to generic versions of drugs that are safe and effective but are being manufactured and sold in violation of U.S. patent law. Current U.S. law sweeps too broadly in defining “counterfeiting,” and, as a result, a gross disparity often exists between the level of moral culpability and actual harm caused by counterfeiting and the remedies and/or penalties that arise from it. To put it simply, current law both under- and over-penalizes counterfeiting.

In both the civil and criminal context, a “counterfeit” trademark is defined as a “spurious mark” that is “identical with, or substantially indistinguishable from, a registered mark,” and whose use is “likely to cause confusion.”¹ Merely infringing marks are not that different. In terms of available remedies, however, the counterfeit mark and the mark that merely infringes sharply diverge. While

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¹ See *infra* notes 7 and 9 and accompanying text.

injunctive relief – not damages – is the typical form of relief in a trademark infringement case,² when defendant infringes via a counterfeit, the statute directs that the court “shall,” in the absence of extenuating circumstances, award treble damages or, at the plaintiff’s election, statutory damages of up to \$100,000 per mark (\$1 million per mark if its use is considered “willful”).³ Moreover, anyone who “traffics in” counterfeit goods or labels (or attempts to do so) is subject to criminal penalties of up to \$2 million in fines and ten years in prison.⁴

The current statutory regime both over- and under-compensates plaintiffs who are the victims of what is loosely termed “counterfeiting.” Similarly, in the criminal context, defendants are both over- and under-penalized for trafficking in counterfeit goods. The type of goods involved, as well as the nature and degree of deception perpetrated, should be considered when labeling a particular activity “counterfeiting” and the range of available penalties and remedies should be adjusted accordingly. The defendant who sells a \$25 “Rolex” to a bargain-hunting consumer should not be in the same category with the defendant who sells a \$25 sugar pill labeled azidothymidine, or AZT, to a sick and unsuspecting AIDS patient. The respective levels of moral culpability and economic harm perpetrated by these two defendants are not remotely comparable.

In its *least* virulent form, counterfeiting does not harm the consumer and, arguably, imposes a relatively minor cost on the trademark holder (particularly when compared to the remedies made available for the harm). If a defendant sells a cheap copy of a luxury good to the consumer – under circumstances such that the consumer knows exactly what she is buying – the consumer has suffered no injury. For example, the person who buys a \$25 fake Rolex watch from a street vendor, or on the Internet, has not been misled. Although the Rolex Company is, to put it mildly, unhappy about the existence of the fake Rolex watches, it also has not lost a sale; the person who buys the \$25 copy almost certainly is not in the market for the real thing, which costs about \$3,000. Instead, the injury to the trademark holder is best characterized as a form of tarnishment: if a third party sees a person wearing a tacky-looking watch bearing a Rolex label, that third party may think less of Rolex watches as a result.

At its worst, counterfeiting may be deadly to the consumer,

² See *infra* notes 33-34 and accompanying text.

³ 15 U.S.C. § 1117 (2006).

⁴ 18 U.S.C. § 2320(a) (2006). If defendant is a repeat offender (*i.e.*, if his conviction occurs after he has been convicted of another offense under this section), he may be fined up to \$5 million and imprisoned up to twenty years. *Id.* The maximum fine also increases if defendant is an entity rather than an individual person. *Id.*

particularly in the pharmaceutical context. When a drug is dispensed to a patient that lacks the active ingredient – or, worse, contains an ingredient that is toxic to the patient – that patient may die as a result. Although this form of counterfeiting may impose the ultimate cost on the consumer, the actual damage to the trademark holder/drug manufacturer may either be extreme or theoretically nonexistent, depending on whether the counterfeit drug is labeled with a brand name or purports to be a generic version of the same drug. If the counterfeit drug bears no copy of a trademark, then it is not actionable under the federal statutes mentioned above. Moreover, even if the drug is characterized as a “counterfeit” according to these laws, lawsuits may be filed and damages/penalties sought by the trademark holder or, in the case of criminal violations, the State, not the consumer, who presumably must rely on state tort law to be made whole.

Under the current system, the consumer who suffers at the hands of counterfeiters has no special avenue for relief under federal law when, in many situations, the consumer is the primary victim of counterfeiting activity and suffers severe injury as a result. Trademark holders, on the other hand, may be overcompensated for some forms of activity that are labeled “counterfeiting” under the Lanham Act. These laws should be revised to better deter the worst forms of counterfeiting and to more adequately compensate those who suffer as a result of it, while at the same time imposing more proportional remedies on the forms of the activity that are, by comparison, relatively innocuous.

I. Ascertaining the Boundaries of Counterfeiting under Existing Law

Intuitively, one might presume that anti-counterfeiting laws would reserve the most severe criminal punishments and highest civil damages for those who perpetrate the most harmful forms of counterfeiting: defendants who copy and sell substandard products that imperil human life. Ironically, however, the law makes no such distinctions. The trademark laws define counterfeiting broadly and impose a wide range of potentially harsh civil and criminal penalties, regardless of the type of good being copied or the impact of the counterfeiting on consumers. By contrast, the laws that exist to combat pharmaceutical counterfeiting encompass much weaker remedies, primarily in the form of tepid criminal penalties that provide no relief to the consumers directly harmed – potentially fatally – by counterfeiting.

A. Defining and Penalizing “Counterfeits” in the Trademark Context

Both the Lanham Act⁵ and the 1984 Trademark Counterfeiting Act⁶ (TCA), the two federal statutes that create civil and criminal liability for trademark infringement, define the term “counterfeit” vaguely and broadly. However, designation of a mark as “counterfeit,” as opposed to merely infringing, significantly increases – almost exponentially – the civil remedies and criminal penalties available to punish the defendant for misusing a trademark in this manner. Some of these remedies are disproportionate to the conduct being targeted by these laws.

1. The slippery distinction between counterfeit marks and those that merely infringe

The Lanham Act, the civil statute that establishes the federal boundaries of trademark law, defines a “counterfeit” as a “spurious mark which is identical with, or substantially indistinguishable from, a registered mark.”⁷ A mark that is infringing is described as a “reproduction, . . . copy, or colorable imitation” of a registered mark.⁸ Both the counterfeit mark and the merely infringing one are actionable only if their use “is likely to cause confusion, or to cause mistake, or to deceive.”⁹ Courts have defined a “spurious” mark as one that is

⁵ 15 U.S.C. §§ 1051-1141.

⁶ 18 U.S.C. § 2320. Congress criminalized trademark counterfeiting, via the TCA, because it found that the “penalties under th[e] [Lanham] Act have been too small, and too infrequently imposed, to deter counterfeiting significantly.” S. REP. NO. 98-526, at 5 (1984).

⁷ 15 U.S.C. § 1127; *see also* 15 U.S.C. § 1116 (d)(1)(B) (similarly defining the term “counterfeit mark”); 19 C.F.R. § 133.21 (2003) (same); 19 U.S.C. § 1526(e) (prohibiting importation of goods bearing counterfeit marks and incorporating by reference the definition of “counterfeit” in 15 U.S.C. § 1127); 18 U.S.C. § 2320(e)(1)(A) (defining the term “counterfeit mark” in the criminal context). Congress noted that “the two definitions of counterfeit mark [in the TCA and the Lanham Act] differ slightly in their terms, but they are identical in substance.” 130 CONG. REC. 31675 (1984).

⁸ 15 U.S.C. § 1114(1)(a).

⁹ *Id.* However, if a mark is designated a counterfeit, some courts have held that they do not need to consider the multi-factor test that is employed in cases of trademark infringement to determine likelihood of confusion; rather, counterfeit marks are considered “inherently confusing.” *Colgate-Palmolive Co. v. J.M.D. All-Star Import and Export, Inc.*, 486 F. Supp. 2d 286, 289 (S.D.N.Y. 2007); *see also* *Lorillard Tobacco Co. v. Jamelis Grocery, Inc.*, 378 F. Supp. 2d 448, 455 (S.D.N.Y. 2005) (same).

“false or inauthentic.”¹⁰ At least on the face of the statute, the infringing mark and the counterfeit mark are closely related, if not near-identical twins.

When Congress criminalized trafficking in counterfeit goods by passing the TCA in 1984, it tacitly admitted that the statutory definition of a counterfeit mark was somewhat inchoate, noting that the “definition of ‘substantially indistinguishable’ will have to be elaborated on a case-by-case basis by the courts.”¹¹ The sponsors of the legislation did attempt to distinguish counterfeiting from run-of-the-mill trademark infringement, however. While the sponsors emphasized that “a mark need not be absolutely identical to a genuine mark in order to be considered a counterfeit,” they also “did not intend to treat as counterfeiting what would formerly have been arguable, but not clear-cut, cases of trademark infringement.”¹² As an example, they suggested that a drug labeled “Prastimol,” which was the functional equivalent of a drug sold under the trademark “Mostimol,” should not be considered a counterfeit, regardless of whether “this sort of imitation violates the Lanham Act or other provisions of law.”¹³

In practice, courts have been reluctant to label a mark a counterfeit, at least in the word mark context, when defendant’s mark is not a fairly clear copy of the registered trademark. One district court observed that, although the determination of whether a mark is “substantially indistinguishable” from a registered trademark is an inherently factual one, “marks that are similar to the registered mark, but differ by two or more letters, are not likely to be considered counterfeit.”¹⁴ In this case the court summarily adjudicated the claim that Chinese toothpaste in a red box labeled “Colddate” was a counterfeit copy of the Colgate registered trademark, holding that although the products were “quite similar,” they were not

¹⁰ See, e.g., *United States v. Petrosian*, 126 F.3d 1232, 1234 (9th Cir. 1997) (holding that a genuine trademark affixed to a counterfeit product is “spurious”); see also 130 CONG. REC. 31673, 31675 (1984) (Joint Statement on 1984 Trademark Counterfeiting Legislation) (characterizing a “spurious” mark as one that is “not genuine or authentic”).

¹¹ 130 CONG. REC. H12076, at H12078 (daily ed. Oct. 10, 1983) (Joint Statement on 1984 Trademark Counterfeiting Legislation).

¹² *Id.* The phrase “substantially indistinguishable” was “intended to prevent a counterfeiter from escaping liability by modifying a protected trademark in trivial ways, while excluding arguable cases of trademark infringement involving trademarks which are merely ‘reminiscent of’ trademarks.” *Id.*

¹³ *Id.*

¹⁴ *Colgate-Palmolive Co.*, 486 F. Supp. 2d at 291 (citing Customs rulings).

“substantially indistinguishable.”¹⁵

When the relevant mark is a logo rather than a name, drawing the line between “quite similar” and “substantially indistinguishable” can be even more difficult. In *Montres Rolex, S.A. v. Snyder*,¹⁶ the Second Circuit reviewed a decision made by a Customs agent who examined a shipment of one hundred 18-karat solid gold watch bracelets bearing a crown-like design on the clasp. The agent found that the design imprinted on the imports was “very similar” to that of the crown emblem that functions as a Rolex[®] trademark, and could cause “some confusion” on the part of the average retail purchaser. However, he ultimately determined that the imported bracelets should not be classified as counterfeits, due to differences he found between the two designs.¹⁷ The district court and the Second Circuit held that the Customs agent had erred, primarily by failing to judge the “substantially indistinguishable” standard from the perspective of the average purchaser, rather than an expert.¹⁸ At oral argument, the circuit court examined the actual bracelets and found the defendant’s goods to be the “spitting image” of Rolex merchandise, and accordingly had “little difficulty” determining that they were counterfeits.¹⁹

As these cases illustrate, the line between a mark that merely infringes a registered trademark and one that is deemed a counterfeit is a subjective one that basically boils down to the degree of similarity between the two marks.²⁰ If the two marks are the “spitting image” of each other (even if not necessarily identical), courts may determine that the copy is a counterfeit. If the marks are confusingly similar (but not *too* similar), the defendant’s mark is less likely to fall into the

¹⁵ *Id.* At the end of the opinion, the court attaches a photo allowing the reader to compare the Colgate[®] trademark and packaging/trade dress with the allegedly counterfeit Colddate. *Id.* at 292.

¹⁶ 718 F.2d 524 (2d Cir. 1983).

¹⁷ *Id.* at 527.

¹⁸ *Id.* at 530-32. The court also held that the Customs agent erred by comparing the counterfeit watch to the Rolex[®] logo/trademark as depicted on the Rolex registration certificate rather than as it appeared on the actual merchandise. *Id.* at 532.

¹⁹ *Id.* at 533.

²⁰ The degree of similarity between the defendant’s mark and that of the plaintiff/trademark holder is one of the factors that courts consider to determine whether a “likelihood of confusion” exists between the two marks. *See, e.g.,* Perfumebay.com, Inc. v. eBay, Inc., 506 F.3d 1165, 1174 (9th Cir. 2007) (discussing similarity of marks factor); *see also* Barton Beebe, *An Empirical Study of the Multifactor Tests for Trademark Infringement*, 94 CAL. L. REV. 1581, 1600 (2006) (concluding that the similarity of the marks is “by far the most influential” factor in the multi-factor test for trademark infringement, based on analysis of empirical data). If a likelihood of confusion exists, defendant has infringed plaintiff’s trademark. 15 U.S.C. § 1114(1) (2006).

counterfeit category.

2. Counterfeiting in the context of post-sale confusion

As noted above, no matter how similar defendant's mark is to a registered trademark, its use is not actionable, in either a civil or a criminal context, unless such use results in a "likelihood of confusion."²¹ Civil or criminal liability for counterfeiting, however, is not limited to instances in which the *consumer* is likely to be confused at the point of sale. Under the post-sale confusion doctrine, a defendant who does not disguise – and even advertises – his merchandise as "fake" is still a counterfeiter.²²

The pre-1962 version of the Lanham Act specified that trademark infringement existed only when the use of a mark was "likely to cause confusion or to cause mistake or to deceive purchasers as to the source of origin of [defendant's] goods or services."²³ However, when the Act was amended, the limiting language regarding "purchasers" (the italicized portion of the statute above) was deleted.²⁴ Courts have almost uniformly held that, when Congress made this change to the Lanham Act, it intended to expand liability for trademark infringement to *any* instance in which a likelihood of confusion exists, not just confusion by the consumer at the point of sale.²⁵ When the TCA was drafted in 1984, it adopted the Lanham Act definition of a counterfeit mark, including the broader language regarding likelihood of confusion (not limited to purchasers).

²¹ 15 U.S.C. § 1114(1) (establishing standard for civil liability under the Lanham Act); 18 U.S.C. § 2320(a) (2006) (establishing criminal liability standard for trafficking in counterfeit goods under the TCA). *But see supra* note 9 (noting that some district courts have held that likelihood of confusion is presumed once a mark is designated a counterfeit).

²² *See generally* David M. Tichane, *The Maturing Trademark Doctrine of Post-Sales Confusion*, 85 TRADEMARK REP. 399 (1995); Anne M. McCarthy, Note, *The Post-Sale Confusion Doctrine: Why the General Public Should be Included in the Likelihood of Confusion Inquiry*, 67 FORDHAM L. REV. 3337 (1999).

²³ 15 U.S.C. § 1114 (1958) (amended 1962).

²⁴ Act of Oct. 9, 1962, Pub. L. No. 87-772, § 17, 76 Stat. 769, 773 (1962), reprinted in 1962 U.S.C.C.A.N. 2850.

²⁵ *See, e.g.*, *United States v. Hon*, 904 F.2d 803, 807 & n.2 (2d Cir. 1990) (citing legislative history); *Marathon Mfg. Co. v. Enerlite Products Corp.*, 767 F.2d 214, 221 (5th Cir. 1985) (1962 amendments to Lanham Act were implemented "specifically to allow any kind of confusion in support of a trademark infringement action"); *cf. Nike, Inc. v. "Just Did It" Enterprises*, 6 F.3d 1225, 1229 (7th Cir. 1993) (in parody context, confusion analysis should focus on the customer at the time of purchase, not the public viewing the relevant merchandise "from afar").

As a result, the TCA has likewise been interpreted to criminalize counterfeiting based on the theory of post-sale confusion.²⁶

Under a theory of post-sale confusion, the consumer of the relevant good or service need not be confused at all. Rather, the infringement or counterfeiting occurs when other people view the product after the consumer buys it and are led to believe that it was produced by the trademark holder. For example, a person who buys a relatively inexpensive imitation of an expensive clock, which is clearly labeled as such, is not confused at the point of purchase. The consumer wants to buy a cheap clock that looks like the more expensive version, and that is what she gets. However, when her neighbors see the clock in her home, they may be unable to tell whether it is the real thing or instead a cheap copy. Under the theory of post-sale confusion, this type of confusion is actionable, in part because the trademark holder's goodwill may be injured if the neighbors mistake the cheap clock for the real thing.²⁷

Although some courts have determined that post-sale confusion harms the public,²⁸ the primary policy justification for this

²⁶ See, e.g., *United States v. Foote*, 413 F.3d 1240, 1246 n.2 (10th Cir. 2005) (reasoning that, because Congress could have, but did not, include language limiting likelihood of confusion to actual purchasers when it drafted the TCA (as it did in the pre-1962 Lanham Act), "likelihood of confusion" under the Act should be interpreted to include post-sale confusion); see also *United States v. Torkington*, 812 F.2d 1347, 1351-52 (11th Cir. 1987) (same).

²⁷ See *Mastercrafters Clock & Radio Co. v. Vacheron & Constatin-Le Coultre Watches, Inc.*, 221 F.2d 464, 466 (2d Cir. 1955); see also *Gen. Motors Corp. v. Keystone Auto. Indus., Inc.*, 453 F.3d 351, 358 (6th Cir. 2006) (listing ways in which "downstream likelihood of confusion" can harm the public and trademark holders); *United States v. Yamin*, 868 F.2d 130, 133 (5th Cir. 1989) ("A trademark holder's ability to use its mark to symbolize its reputation is harmed when potential purchasers of its goods see unauthentic goods and identify these goods with the trademark holder."); *Ferrari S.P.A. Esercizio v. Roberts Motor Co.*, 944 F.2d 1235, 1245 (6th Cir. 1991) (even if "a person seeing [a Ferrari replica] driving down the road is not confused, Ferrari's exclusive association with this design has been diluted and eroded," and its "reputation for rarity and quality could be damaged"); *Lois Sportswear, U.S.A., Inc. v. Levi Strauss & Co.*, 799 F.2d 867, 872-73 (2d Cir. 1986) (post-sale confusion exists when consumers see passers-by wearing jeans (made by the defendant) and associate them with the "familiar stitching pattern" that is Levi's trademark).

²⁸ The Second Circuit reasoned that post-sale confusion may harm the public, even if the original consumer knows that she is buying a "knock off" due to the product's packaging or advertising, because a subsequent consumer in the resale market might actually be deceived. See *Hermès Int'l v. Lederer de Paris Fifth Ave., Inc.*, 219 F.3d 104, 108 (2d Cir. 2000). Courts have also suggested that consumers are harmed by counterfeiting, even "where there is no possibility that consumers will be defrauded," because the existence of counterfeits may reduce trademark holders' profits and therefore the trademark holders will have less incentive to invest in quality goods or services. *Id.* (citing *Torkington*, 812 F.2d at 1353 n.6).

doctrine focuses on the needs and interests of trademark holders, not consumers. In addressing this issue, courts have noted that “[the TCA] is not just designed for the protection of consumers. It is likewise fashioned for the protection of trademarks themselves and for the prevention of the cheapening and dilution of the genuine product.”²⁹

Under the post-sale confusion theory, criminal liability for trafficking in counterfeit goods exists even when the defendant openly advertises the relevant goods as fakes, or describes them, as did one particularly forthright defendant when speaking with a private investigator, as the “best damn copies in the world that money could buy.”³⁰ The defendant, Jerome Foote, sold counterfeit merchandise from a shop aptly-named “Replicas,” located first in his home and later in a strip mall in Lenexa, Kansas.³¹ Although the government’s indictment alleged that Foote sold numerous counterfeit luxury goods, he was ultimately convicted of one count of trafficking in counterfeit goods and one count of conspiring to traffic in counterfeit goods, based on the sale of one counterfeit Mont Blanc pen, for which he was sentenced to thirty-seven months in prison and fined more than \$104,000.³²

3. Liability and punishment in the trademark arena

Although counterfeiting is vaguely defined and sweeps broadly, the impact of designating a certain act “counterfeiting” – as

²⁹ United States v. Yamin, 868 F.2d 130, 132-33 (5th Cir. 1989) (quoting United States v. Gantos, 817 F.2d 41, 43 (8th Cir. 1987); *see also* Foote, 413 F.3d at 1245 (noting that the TCA is “not simply an anti-consumer fraud statute,” but rather serves the dual purpose of protecting “trademark holders’ ability to use their marks to identify themselves to their customers and to link that identity to their reputations for quality goods and services.”) (citing *Torkington*, 812 F.2d at 1352-53); *see also* David W. Barnes, *Trademark Externalities*, 10 YALE J. L. & TECH. 1, 41 (2007) (describing ways in which post-sale confusion harms trademark holders).

³⁰ Foote, 413 F.3d at 1243 (quoting statement made by Foote to Smith, a private investigator hired by trademark owners).

³¹ *Id.*

³² *Id.* at 1244. Foote’s case was remanded for re-sentencing because the district court applied the wrong version of the Sentencing Guidelines. *Id.* at 1248-51. The district court also erred in failing to consider Foote’s ability to pay in calculating his criminal fine. *Id.* at 1252-53. However, the circuit court did not suggest that Foote’s sentence should be reduced due to the nature of the counterfeiting or the low number of counterfeit goods comprising the conviction. Rather, the court upheld post-sale confusion as a basis for liability under the TCA and held that trafficking in a single piece of counterfeit merchandise constituted trafficking in counterfeit “goods” under the TCA. *Id.* at 1244-47.

opposed to mere infringement – is profound. The scope of monetary damages available to prevailing plaintiffs in counterfeiting cases significantly exceeds that which is available to the plaintiff who merely proves trademark infringement. Moreover, as illustrated by Mr. Foote’s case above, those convicted of trafficking in counterfeit goods face years of imprisonment and many thousands of dollars in criminal fines.

Injunctive relief is the preferred form of relief in the typical trademark infringement case.³³ Damages are available as a form of relief, as the statute empowers courts to award “(1) defendant’s profits, (2) any damages sustained by the plaintiff, and (3) the costs of the action” to prevailing plaintiffs, “subject to the principles of equity.”³⁴ However, most courts award such damages only when there is some suggestion of intentional or willful conduct on the part of the defendant – *i.e.*, that defendant was attempting to “palm off” his goods as those of the plaintiff.

Some circuits impose a six-factor test to determine whether damages and/or costs, as allowed by the statute, are appropriate in a given case of infringement, focusing on defendant’s intent and the economic impact of the infringement on plaintiff.³⁵ Other courts have held, however, that the costs and damages allowed under the statute are appropriate *only* when plaintiff can show that defendant’s

³³ See 15 U.S.C. § 1116(a) (granting courts the power to issue injunctive relief for violations of the Lanham Act); see also *Synergistic Int’l, LLC v. Korman*, 470 F.3d 162, 176 (4th Cir. 2006) (“If an injunction is an adequate remedy, this factor should weigh against a damages award.”); *Minn. Pet Breeders, Inc. v. Schell & Kampeter, Inc.*, 41 F.3d 1242, 1247 (8th Cir. 1994) (holding that “an accounting will be denied in a trademark infringement action where an injunction will satisfy the equities of the case”) (citations omitted); *Malletier v. Dooney & Bourke Inc.*, 500 F. Supp. 2d 276, 282 (S.D.N.Y. 2007) (holding that profits may be awarded in trademark infringement actions only when defendant has been unjustly enriched as a result of “willful deception”).

³⁴ 15 U.S.C. § 1117(a). Plaintiffs holding registered trademarks are not eligible to recover damages as a form of relief unless they have given notice that their mark(s) are registered by displaying the ® symbol, or unless they can show that the defendant had actual notice that the mark was registered in the U.S. Patent and Trademark Office. 15 U.S.C. § 1111. The Act also contains further exemptions from liability for damages for “innocent” printers or publishers, 15 U.S.C. §§ 1114(2)(A)-(C), and domain name registration authorities, 15 U.S.C. § 1114(2)(D).

³⁵ These courts consider (1) whether defendant intended to confuse or deceive; (2) whether defendant’s infringement has diverted sales from plaintiff; (3) whether other remedies (e.g., an injunction) are adequate; (4) whether plaintiff has unreasonably delayed in asserting her rights; (5) whether the public benefits by making the misconduct unprofitable; and (6) whether defendant’s infringement constitutes “palming off.” *Synergistic Int’l*, 470 F.3d at 175; see also *Banjo Buddies, Inc. v. Renosky*, 399 F.3d 168, 175 (3d Cir. 2005) (same); *Quick Techs., Inc. v. Sage Group PLC*, 313 F.3d 338, 349 (5th Cir. 2002) (same).

infringement was “willful” or intentional.³⁶ While the courts are somewhat divided on the degree of discretion accorded to district courts in determining whether costs and/or profits should be awarded to prevailing plaintiffs in trademark infringement actions, there is widespread agreement that a finding of willfulness is a key factor in making this determination.³⁷

Although there is some disagreement as to the extent of the district court’s discretion to award damages in a case of trademark infringement, when defendant causes a “likelihood of confusion” via a counterfeit, damages are no longer discretionary. The statute directs that the court “shall,” in the absence of extenuating circumstances, award treble damages or, at the plaintiff’s election, statutory damages of up to \$100,000 per mark.³⁸ The treble damages calculation is based on either defendant’s profits or plaintiff’s damages, whichever is greater.³⁹

If the defendant intentionally uses a mark, knowing that it is counterfeit, plaintiff is also entitled to an award of attorney’s fees.⁴⁰ Statutory damages range from \$500 to \$100,000 per mark, per type of goods or services sold.⁴¹ The maximum statutory damages increase ten fold, to a million dollars per mark, per type of goods or services sold, “if the court finds that the use of the counterfeit mark was willful.”⁴²

To prove her entitlement to the remedies described above, a plaintiff who alleges that a defendant has engaged in counterfeiting can make an *ex parte* application to the court – in other words, without

³⁶ See, e.g., *George Basch Co. v. Blue Coral, Inc.*, 968 F.2d 1532, 1537 (2d Cir. 1992) (“a finding of defendant’s willful deceptiveness is a prerequisite for awarding profits” in trademark infringement actions); *Malletier*, 500 F. Supp. 2d at 281 (same); *but see* *Burger King Corp. v. Mason*, 855 F.2d 779, 781 (11th Cir. 1988) (awarding of profits does not depend on a “higher showing of culpability” on defendant’s part) (citing *Wolfe v. National Lead Co.*, 272 F.2d 867, 871 (9th Cir. 1959), *overruled in part on other grounds*, *Maier Brewing Co. v. Fleischman Distilling Corp.*, 359 F.2d 156, 165 (9th Cir. 1966)).

³⁷ See *supra* notes 35-36.

³⁸ 15 U.S.C. §§ 1117(b) & (c) (1984). The statute was amended in 1984 to make these types of damages mandatory; under the previous version of the statute, courts were authorized but not required to award such damages in counterfeiting cases. Congress made this change because it found that “in appropriate instances, some courts apparently have not exercised this discretion [to award damages].” H.R. REP. NO. 6071, The Committee on the Judiciary, Report on Trademark Counterfeiting Act of 1984, at 6, available at http://ipmall.info/hosted_resources/lipa/trademarks/PreLanhamAct_071_A_Report_04.pdf.

³⁹ 15 U.S.C. § 1117(b).

⁴⁰ *Id.*

⁴¹ 15 U.S.C. § 1117(c)(1).

⁴² 15 U.S.C. § 1117(c)(2).

notice to the defendant – to have the allegedly counterfeit goods seized, pending resolution of the lawsuit.⁴³ Congress added these provisions to the Lanham Act because it found that “[m]any of those who deal in counterfeits make it a practice to destroy or transfer counterfeit merchandise when a day in court is on the horizon.”⁴⁴ The *ex parte* seizure procedure is “intended to thwart this bad faith tactic.”⁴⁵

In addition to the civil remedies described above, a defendant who counterfeits a registered trademark may also be subject to significant criminal penalties. The 1984 Trademark Counterfeiting Act (TCA), as amended by the 2005 Stop Counterfeiting in Manufactured Goods Act, applies to anyone who intentionally traffics, or attempts to traffic, in goods, services or labels, knowing that they bear a counterfeit mark, where the use of such mark is “likely to cause confusion, to cause mistake, or to deceive.”⁴⁶ At trial, the government must prove that the defendant (1) *intended* to traffic in the relevant goods, services or labels, and (2) *knew* they were counterfeit.⁴⁷ If

⁴³ 15 U.S.C. § 1116(d)(1)(A) (2006). Only trademark holders whose marks are registered with the Patent and Trademark Office may use the seizure provisions of the Act, but the Act does not require them to prove that the defendant accused of counterfeiting *knew* the relevant mark was registered. 15 U.S.C. § 1116(d)(1)(B)(i) (2006).

⁴⁴ 130 CONG. REC. 31673, 31677 (1984).

⁴⁵ *Id.* In addition, the Customs Service is empowered to seize any imported merchandise bearing a copy of a registered trademark, unless the trademark holder consents to its importation. 19 U.S.C. § 1526(a) (2006). The statute provides that such merchandise is “subject to seizure and forfeiture, @ *Id.*, unless it bears a counterfeit mark, in which case seizure and forfeiture are mandatory, 19 U.S.C. § 1526(e) (2006); 19 C.F.R. § 133.21(b) (2007). Customs regulations further provide that a “copying or simulating @ trademark (as opposed to a counterfeit one) may be released from detention if A[t]he objectionable mark is removed or obliterated . . . in such a manner as to be illegible and incapable of being reconstituted . . . @ 19 C.F.R. § 133.22(c)(1) (2007). Goods bearing counterfeit marks, however, must be forfeited and destroyed, unless the Customs Service determines that the goods are not unsafe, and the trademark owner consents to the goods being donated to the government or a charitable institution, after the trademark has been removed. 19 U.S.C. § 1526(e) (2006); 19 C.F.R. § 133.22(d) (2007); 19 C.F.R. § 133.52(c) (2007).

⁴⁶ 18 U.S.C. § 2320(a) (2006); 18 U.S.C. § 2320(e)(1)(A)(iii) (2006). Prior to the 2005 amendments, the TCA applied only to counterfeit goods or services; some courts held that the Act did not apply to a defendant who trafficked in counterfeit labels that were not affixed to goods or services. *See, e.g.,* United States v. Giles, 213 F.3d 1247 (10th Cir. 2000) (holding that TCA did not prohibit trafficking in counterfeit labels or patches unconnected to any goods); *see also* 152 CONG. REC. S1367, S1367 (daily ed. February 15, 2006) (statement of Sen. Specter) (discussing the need to close this “loophole @ in the TCA).

⁴⁷ United States v. Sultan, 115 F.3d 321, 325 (5th Cir. 1997) (reversing conviction

convicted, the defendant may be fined up to \$2 million and/or sentenced to a maximum of ten years in prison.⁴⁸ If defendant is an entity rather than an individual person, the maximum fine increases to \$5 million.⁴⁹ If defendant is a repeat offender (*i.e.*, if his conviction occurs after he has been convicted of another offense under the TCA), he may be fined up to \$5 million and imprisoned up to twenty years; if defendant is an entity, the maximum fine for repeat offenders increases to \$15 million.⁵⁰

B. The Lukewarm Legal Regime Protecting the Public against Counterfeit Drugs

In comparison to the civil damages, criminal fines and prison time that may be levied against those who engage in *trademark* counterfeiting, the laws protecting the public from the importation of *pharmaceutical* counterfeits are positively anemic. Although some instances of pharmaceutical counterfeiting would also constitute counterfeiting under the Lanham Act and/or the TCA (*e.g.*, if the drug being copied is sold under a counterfeit trademark),⁵¹ others would not. Due to the extreme danger posed by counterfeit pharmaceuticals, these penalties are inadequate.

1. The laws protecting the public against importation of counterfeit drugs

for trafficking in counterfeit goods due to insufficient proof that defendant knew the automobile parts he was selling were counterfeit); *see also* United States v. Hon, 904 F.2d 803, 806 (2d Cir. 1990) (quoting S. REP. NO. 98-526, at 11 (1984), *as reprinted in* 1984 U.S.C.C.A.N. 3627, 3637); United States v. Gantos, 817 F.2d 41, 43 (8th Cir. 1987); United States v. Baker, 807 F.2d 427, 429 (5th Cir. 1986).

⁴⁸ 18 U.S.C. § 2320(a) (2006).

⁴⁹ *Id.*

⁵⁰ *Id.*

⁵¹ However, when Congress enacted the TCA and amended the Lanham Act to strengthen penalties against counterfeiters, it specified that generic drugs sold under labels that potentially infringed a registered trademark should not be considered “counterfeit.” *See* THE COMMITTEE ON THE JUDICIARY, U.S. CONG., REPORT TO ACCOMPANY H.R. 6071, REPORT ON TRADEMARK COUNTERFEITING ACT OF 1984 7, *available at* http://ipmall.info/hosted_resources/lipa/trademarks/PreLanhamAct_071_A_Report_04.pdf (“The Committee leaves it to the courts to determine when pharmaceuticals that are similar in appearance and are functionally equivalent to other, trademarked drugs, constitute trademark infringements. It does not intend that generic drugs be considered counterfeit for purposes of this legislation.”) (citing *Inwood Labs, Inc. v. Ives Labs, Inc.*, 456 U.S. 844 (1982)).

The Federal Food, Drug and Cosmetic Act (FDCA) defines the term “counterfeit drug” as a drug (or the container or labeling of a drug) that bears some mark, including a trademark, misidentifying its “manufacturer, processor, packer, or distributor.”⁵² Therefore, some – but not all – counterfeit drugs, as defined by the FDCA, should also be considered counterfeits under the Lanham Act and the TCA.⁵³ The question turns on whether the mark placed upon the drug is “substantially indistinguishable” from a federally registered trademark.⁵⁴ If the drug is generic and labeled as such – that is, the name placed on the drug purports to describe the type of drug, rather than the source of the drug⁵⁵ – then it would fall outside the scope of the trademark definition of counterfeit.

The FDCA criminalizes “any act which causes a drug to be a counterfeit drug, or the sale or dispensing. . . of a counterfeit drug.”⁵⁶ Similarly, the Act also criminalizes the “adulteration or misbranding” of drugs.⁵⁷ However, the penalties imposed for misbranding drugs or dispensing counterfeit drugs pale in comparison to the penalties for trafficking in trademark counterfeits. The FDCA punishes those who violate these prohibitions with a maximum \$1,000 fine and no more than one year in prison.⁵⁸ The maximum penalty increases to a \$10,000 fine and no more than three years in prison for those who have an “intent to defraud or mislead” or who are repeat offenders under the statute.⁵⁹

There is widespread agreement that the criminal penalties in the FDCA are insufficient to deter those who profit from counterfeit pharmaceuticals. The Food and Drug Administration itself has called for “[i]ncreased criminal penalties to deter counterfeiting and more adequately punish those convicted.”⁶⁰ Professor Brian Liang has

⁵² 21 U.S.C. § 321(g)(2) (2006).

⁵³ *But see supra* note 51.

⁵⁴ *See supra* notes 14-20 and accompanying text.

⁵⁵ *See* Deven R. Desai & Sandra L. Rierson, *Confronting the Genericism Conundrum*, 28 CARDOZO L. REV. 1789, 1820-22 (2007) (discussing Bayer aspirin and its transformation from a trademark to a generic word).

⁵⁶ 21 U.S.C. § 331(i)(3) (2006).

⁵⁷ 21 U.S.C. §§ 331(a)-(c) (2006). A drug is deemed to be misbranded when, among other things, it bears a false or misleading label. 21 U.S.C. § 352 (2006).

⁵⁸ 21 U.S.C. § 333(a)(1) (2006).

⁵⁹ 21 U.S.C. § 333(a)(2). The maximum criminal penalty and potential jail time increase significantly for “prescription drug marketing violations,” which primarily relate to regulations governing the importation of prescription drugs and the use of drug coupons and samples. 21 U.S.C. § 333(b). If defendant is found guilty of any of the prescription drug marketing violations listed in the statute, he may be fined up to \$250,000 and may spend no more than ten years in jail. *Id.*

⁶⁰ *See* Food and Drug Admin., COMBATING COUNTERFEIT DRUGS: A REPORT OF THE FOOD AND DRUG ADMINISTRATION (Feb. 18, 2004),

argued that the penalties for peddling counterfeit drugs should at least mirror those levied against criminals who sell illicit drugs such as heroin and cocaine.⁶¹ Although federal legislation was introduced in 2006 and 2007 to increase criminal penalties for drug counterfeiters, neither bill was ever voted upon by the House or Senate.⁶²

2. The problems posed by counterfeit pharmaceuticals

Much has recently been written about the dangers posed by counterfeit pharmaceuticals, both in the United States and abroad.⁶³ While the problem is much greater in developing nations that lack the resources to police their drug supplies, it exists in the United States as well. This article does not attempt to describe or analyze this problem in the same level of detail as these other sources; however, it does briefly address this issue to illustrate its seriousness.

The World Health Organization (WHO) released a report in 2006 describing counterfeit medicines as “a global public health crisis.”⁶⁴ The WHO defines counterfeit drugs as those that are “deliberately and fraudulently mislabeled with respect to identity or source.”⁶⁵ The WHO report notes that “[c]ounterfeiting occurs both

http://www.fda.gov/oc/initiatives/counterfeit/report02_04.html#report; see also Food and Drug Admin., COMBATING COUNTERFEIT DRUGS: A REPORT OF THE FOOD AND DRUG ADMINISTRATION ANNUAL UPDATE (May 18, 2005), <http://www.fda.gov/oc/initiatives/counterfeit/update2005.html> (advocating increased state efforts to adopt more stringent anti-counterfeiting laws and regulations as well as increased federal penalties for drug counterfeiting).

⁶¹ Bryan A. Liang, *Fade to Black: Importation and Counterfeit Drugs*, 32 AM. J. L. & MED. 279, 314 (2006) [hereinafter *Fade to Black*]. Professor Liang also argues that life imprisonment for perpetrators, total asset forfeiture, and treble damages should also be considered to deter drug counterfeiters, as “[p]enalties must be as severe as the potential harm that results.” *Id.*; see also Bryan A. Liang, *Parallel Trade in Pharmaceuticals: Injecting the Counterfeit Element into the Public Health*, 31 N.C. J. INT’L L. & COMM. REG. 847, 871-73 (2006) [hereinafter *Parallel Trade*] (arguing that light penalties for drug counterfeiting, in the United States and around the world, contribute to the proliferation of this practice).

⁶² See Counterfeit Drug Prevention Act of 2006, H.R. 5156, 109th Cong. (2006); Counterfeit Drug Prevention Act of 2007, H.R. 780, 110th Cong. (2007).

⁶³ See, e.g., KATHERINE EBAN, DANGEROUS DOSES: HOW COUNTERFEITERS ARE CONTAMINATING AMERICA’S DRUG SUPPLY (2005); Donald deKieffer, *Trojan Drugs: Counterfeit and Mislabeled Pharmaceuticals in the Legitimate Market*, 32 AM. J. L. & MED. 325 (2006); Liang, *Fade to Black*, *supra* note 61; Liang, *Parallel Trade*, *supra* note 61; Kevin Outterson & Ryan Smith, *Counterfeit Drugs: the Good, the Bad, and the Ugly*, 16 ALB. L.J. SCI. & TECH. 525 (2006).

⁶⁴ World Health Organization, Fact Sheet No. 275, Counterfeit Medicines (Nov. 14, 2006), <http://www.who.int/mediacentre/factsheets/fs275/en/>.

⁶⁵ *Id.*

with branded and generic products,” and may include “products with the correct ingredients but fake packaging, with the wrong ingredients, without active ingredients or with insufficient active ingredients,” or, at worst, counterfeit drugs may incorporate “random mixtures of harmful toxic substances.”⁶⁶ Although the WHO estimates that less than one percent of the drug supply in industrialized nations, including the United States, is potentially counterfeit, in countries with less legal and regulatory oversight (e.g., Cambodia, The Dominican Republic, Indonesia, and Kenya), the rate of counterfeits in the drug supply ranges from approximately ten to thirty percent.⁶⁷

Counterfeit drugs that incorporate toxic substances obviously may be lethal to the consumer. These toxic substances may be deliberately added to make the fake drugs look more like the real pharmaceuticals they are imitating, or they may be a by-product of an unsanitary manufacturing process. Toxic substances that have been discovered in counterfeit drugs include bacteria-laden water, colored dye, powdered cement, yellow road paint, floor wax, boric acid (a substance that is used to kill cockroaches), and diethylene glycol, a chemical used in antifreeze.⁶⁸ In one particularly horrifying example, counterfeit cough syrup laced with diethylene glycol killed eighty-nine children in Haiti in 1995 and thirty children in India in 1998.⁶⁹

Counterfeit drugs do not have to be literally poisonous to inflict serious harm upon the consumer. A counterfeit drug that lacks the active ingredient –i.e., a sugar pill – or a drug that contains the active ingredient but in an inaccurate amount (either too much or too little) can also kill or seriously injure a patient. The WHO reports that, according to a study conducted in 2001, thirty-eight percent of the anti-malarial drugs for sale in pharmacies in South-East Asia did not contain *any* active ingredients.⁷⁰ At the opposite end of the spectrum, a physician and professor of ophthalmology at the University of Kentucky nearly killed his patients in 2005 by injecting them with “fake” Botox that was actually a highly-concentrated, research version of the drug not intended for human use.⁷¹

The availability of drugs sold via the Internet has exponentially increased the potential for counterfeit drugs to enter the U.S.

⁶⁶ *Id.*

⁶⁷ *Id.*

⁶⁸ Liang, *Fade to Black*, *supra* note 61, at 284.

⁶⁹ World Health Organization, Fact Sheet No. 275, Counterfeit Medicines (Nov. 14, 2006), available at <http://www.who.int/mediacentre/factsheets/fs275/en/>. Veronica Diaz, a 22 year-old Argentinian woman, also became a casualty of counterfeit drugs when, in 2004, she died after receiving counterfeit iron injections that were supposed to treat her anemia but were in fact toxic. *Id.*

⁷⁰ *Id.*

⁷¹ Liang, *Fade to Black*, *supra* note 61, at 284 & n. 37.

marketplace. Many U.S. citizens attempt to purchase drugs online from Canadian pharmacies in an effort to save money on prescription costs. In fact, Congress recently considered legislation that would legitimize this practice,⁷² and some state officials have called for the loosening or abandonment of importation barriers.⁷³

Undoubtedly, many of these pharmacies are legitimate sources of prescription medications.⁷⁴ However, some of them are fronts for drug counterfeiters. The WHO has found that, when Internet pharmacies conceal their physical address, over fifty-percent of the drugs that they sell are counterfeit.⁷⁵ The consumer may have little way of knowing whether she is accessing a legitimate, on-line version of a brick-and-mortar pharmacy in Canada, or a sham with no connection to Canada or any legitimate pharmacy.

The problem of drug counterfeiting in the United States is not limited to online pharmacies and so-called lifestyle drugs such as Botox and Viagra. Although the percentage of drugs on pharmacy shelves that are potentially fake is low, particularly when compared to other parts of the world, any amount is unacceptable, given the potential consequences. Weaknesses in the U.S. pharmaceutical distribution network are well documented, as is the potential for counterfeiters to infiltrate the U.S. drug supply, wholly apart from Internet drug sales.⁷⁶ Since 2000, many types of counterfeit drugs – including drugs for treating cancer and AIDS patients – have been discovered in U.S. pharmacies and hospitals.⁷⁷

II. A Proposal for Reform of Counterfeiting Definitions and Remedies

⁷² Pharmaceutical Market Access and Drug Safety Act of 2005, H.R. 700, 109th Cong. (2005); *see also* Congressional Research Service, Prescription Drug Importation and Internet Sales: A Legal Overview (Jan. 8, 2004); *cf.* Liang, *Parallel Trade*, *supra* note 61 (arguing against allowing parallel imports of drugs into the United States).

⁷³ deKieffer, *supra* note 63, at 331.

⁷⁴ *See* Outterson & Smith, *supra* note 63, at 536-37 (arguing that Avirtually none of the Internet drugs arriving in the United States are non-functional counterfeits@ and that this practice should be regulated rather than criminalized); *see also* In re Canadian Import Antitrust Litigation, 470 F.3d 785 (8th Cir. 2006) (affirming dismissal of complaint filed against drug manufacturers alleging antitrust conspiracy to suppress import of prescription drugs from Canada).

⁷⁵ World Health Organization, Fact Sheet No. 275, Counterfeit Medicines (Nov. 14, 2006), *available on-line at* <http://www.who.int/mediacentre/factsheets/fs275/en/>.

⁷⁶ *See generally* deKieffer, *supra* note 63.

⁷⁷ *See generally* EBAN, *supra* note 63.

When Congress criminalized trademark counterfeiting via the TCA and stiffened penalties against counterfeiting under the Lanham Act, it did so because it perceived that counterfeits posed a danger to American consumers.⁷⁸ However, under the current system, stiff criminal penalties are levied in cases that present little if any potential to harm the consumer, while remedies and penalties for those who deal in counterfeit drugs – which may in fact kill the consumer – pale in comparison. This article advocates reform of the law regarding “counterfeiting,” so that the most harmful forms of this activity will be more adequately deterred. While these reforms would not solve the problem of drug counterfeiting in the U.S. or anywhere else, they would be a step in the right direction.

A. Policies Supporting Stiff Criminal Penalties and Civil Remedies under the Lanham Act and the TCA

When Congress criminalized trademark counterfeiting, its *primary* reason for doing so was not to save the nation from a flood of fake Gucci purses. Instead, the legislative history indicates that Congress focused on counterfeits that pose a danger to American consumers.

As explained *supra*, a defendant convicted of trafficking in trademark counterfeits may be sent to prison for up to twenty years and forced to pay millions of dollars in criminal fines.⁷⁹ In addition, he may be liable in a civil action filed by the trademark owner and forced to pay hundreds of thousands of dollars in statutory or treble damages.⁸⁰ When Congress enacted the TCA, it recognized that these penalties were “extremely high,” but determined that they were necessary “given the grave risk to health and safety that such conduct may present, or the egregious nature of a defendant’s conduct.”⁸¹ More recent amendments strengthening the TCA have similarly cited low-quality counterfeits that pose a danger to consumers (e.g., automotive parts, cosmetics, fertilizers, chemicals, sporting goods, electronic equipment, and medical devices) as evidence that such heightened penalties are warranted.⁸²

⁷⁸ See *infra* notes 79-84 and accompanying text.

⁷⁹ See *supra* notes 46-50 and accompanying text.

⁸⁰ See *supra* notes 38-42 and accompanying text.

⁸¹ Report to Accompany H.R. 6071, The Committee on the Judiciary, Report on Trademark Counterfeiting Act of 1984, at page 11, available online at http://ipmall.info/hosted_resources/lipa/trademarks/PreLanhamAct_071_A_Report_04.pdf.

⁸² See 151 CONG. REC. S12714 (daily ed. Nov. 10, 2005) (statements of Sen. Leahy and Sen. Specter); see also 152 CONG. REC. H593 (daily ed. Mar. 7, 2006)

As discussed previously, the TCA and the Lanham Act have been interpreted to encompass the post-sale confusion doctrine, under which counterfeiting or trademark infringement may be actionable even though the consumer is not confused at the point of sale.⁸³ When Congress passed the TCA, it also looked beyond direct consumers to identify the harms posed by counterfeit goods. However, it did so in considering the effect of counterfeiting on *other consumers* who might be harmed by the relevant goods, not the reputational effects on trademark holders. Congress noted that innocent third parties may be harmed by counterfeit goods, such as passengers in an airline equipped with counterfeit mechanical parts; the coronary patient whose physician implants a counterfeit heart pump, and parents who give their children counterfeit infant formula.⁸⁴ In all of these examples, the counterfeit good at issue poses a significant risk of harm to the consuming public.

B. Redefining the Term “Counterfeit” under the TCA and the Lanham Act

As currently written and interpreted, the Lanham Act and the TCA broadly define the term “counterfeit” and do not attempt to distinguish between the defendant who sells a fake pen and the defendant who passes off sugar pills as Lipitor. These Acts should be amended to focus more strongly on the most dangerous forms of counterfeiting. Criminal punishment, in particular, should be reserved for those who truly deserve it: defendants who endanger the lives of others in order to profit by counterfeiting.

1. Factors courts should consider in determining whether a mark is counterfeit

Under the Lanham Act and the TCA, whether a mark is deemed a “counterfeit” of a registered trademark largely depends on the closeness or degree of similarity between the plaintiff’s and defendant’s marks.⁸⁵ While the degree of similarity between the marks is (and should be) extremely relevant to whether a mark is

(statements of Rep. Sensenbrenner and Rep. Knollenberg); 152 CONG. REC. S1367 (daily ed. Feb. 15, 2006) (statements of Sen. Leahy and Sen. Specter).

⁸³ See *supra* notes 21- 32 and accompanying text.

⁸⁴ See S. REP. NO. 98-526, at 4 (1984); see also H.R. REP. NO. 104-556, at 3 (1996).

⁸⁵ See *supra* note 20 and accompanying text.

counterfeit *or* infringing, resting the entire analysis on this factor seems misguided.

Defendant's intent in selecting and using a particular mark should also be considered in determining whether a mark is counterfeit. Proof of intent is required to obtain a conviction under the TCA,⁸⁶ but the Lanham Act does not mandate that courts consider intent when ascertaining civil liability for counterfeiting. However, the Lanham Act defines a "counterfeit" mark as one that is "spurious," or not genuine or inauthentic,⁸⁷ thereby suggesting conduct that goes beyond merely imitating a trademark. This language supports consideration of intent when drawing the line between marks that merely infringe and those that are counterfeit.

Courts almost uniformly consider defendant's intent when determining whether a likelihood of confusion exists in the trademark infringement context.⁸⁸ Objectively, whether a consumer (or even a mere observer) is likely to be confused by the defendant's use of plaintiff's trademark is not likely impacted by defendant's intent, which may be unknown to anyone but the defendant.⁸⁹ However, courts consider intent an important factor in making this determination. Consideration of intent seems even more appropriate when determining whether to subject a defendant to the harsh civil penalties associated with counterfeiting.

2. Criminal liability should be reserved for counterfeits that deceive the consumer

As discussed *supra*, courts have held that both civil and criminal liability for counterfeiting may derive from post-sale

⁸⁶ See *supra* note 47 and accompanying text.

⁸⁷ See *supra* notes 7, 10.

⁸⁸ See, e.g., *Sullivan v. CBS Corp.*, 385 F.3d 772, 776 (7th Cir. 2004) (listing seven factors to be considered in analyzing likelihood of confusion in the context of a trademark infringement claim, including "the defendant's intent to palm off its goods as those of the plaintiff"); *AMF, Inc. v. Sleekcraft Boats*, 599 F.2d 341, 348-49 (9th Cir. 1979) (listing eight factors to be considered in analyzing likelihood of confusion in the context of a trademark infringement claim, including "defendant's intent in selecting the mark"); cf. *Beebe*, *supra* note 20 (arguing, based on empirical analysis, that, while a finding of bad faith intent is not necessary to support a claim of trademark infringement, such a finding effectively creates an almost irrebuttable presumption of infringement).

⁸⁹ See *Virgin Enter. v. Nawab*, 335 F.3d 141, 151 (2d Cir. 2003) (Bad faith "does not bear directly on whether consumers are likely to be confused."); *Chrysler Corp. v. Silva*, 118 F.3d 56, 59 n.3 (1st Cir. 1997) ("Strictly, intent, or lack thereof, does not affect the eyes of the viewer. . .") (citation omitted); *Lois Sportswear, U.S.A., Inc. v. Levi Strauss & Co.*, 799 F.2d 867, 875 (2d Cir. 1986) ("intent is largely irrelevant in determining if consumers likely will be confused as to source").

likelihood of confusion. That is, even if the consumer knows exactly what she is buying (often a cheap imitation of a luxury good), defendant may still be liable for counterfeiting, because others viewing the merchandise after the sale may be led to believe that it is associated with the trademark holder.⁹⁰ Regardless of whether this theory of liability should support a civil claim for trademark infringement or counterfeiting, the severe criminal penalties associated with counterfeiting should not extend to this type of behavior.

The phenomenon of post-sale confusion, at least with regard to counterfeiting, presents itself primarily in the context of luxury goods. The direct consumer of the good (*e.g.*, the person who buys a thirty-five dollar purse with a Gucci label) wishes to attain some of the prestige or goodwill associated with the trademark, without paying the price demanded by the trademark holder. The goodwill associated with the trademark may be primarily embodied in the trademark itself, rather than the goods to which it is typically attached.⁹¹ For example, the person who buys the fake Gucci purse described above probably does not expect to receive a purse that is equal in quality to a genuine Gucci. However, she is willing to pay thirty-five dollars for a purse of inferior quality that nevertheless allows her to attain at least some of the goodwill or status associated with owning a “Gucci” handbag. By contrast, people typically do not buy Lipitor (or any other prescription medication) because they want the prestige associated with the drug; generally, they want and need the medication itself.

For various reasons, trademark holders are harmed by defendants who sell fake luxury goods, even when the loss is not in the form of a direct sale.⁹² The person who is willing to buy a thirty-five dollar fake Gucci purse is probably not in the market for the real thing, which would cost hundreds of dollars (at least). Nevertheless, the trademark holder’s reputation may be harmed when someone sees the fake Gucci, looking rather tattered, and thinks less of Gucci as a result. Whether the defendant who harms the trademark holder in this manner needs to be imprisoned, however, is another matter.

If trademark holders are being injured by defendants who sell fake versions of their products – under circumstances in which consumers are aware that they are purchasing fakes – then the trademark holder should use the civil remedies provided in the Lanham Act to stop this activity. Trademark holders can and do obtain *ex parte* seizure orders to confiscate counterfeit goods in civil

⁹⁰ See *supra* notes 27-29 and accompanying text.

⁹¹ See Desai & Rierson, *supra* note 55, at 1794-96 (discussing ways in which brands attain value and symbolic or expressive significance to consumers).

⁹² See *supra* note 29 and accompanying text.

cases filed under the Lanham Act, and they may be awarded significant statutory damages – up to \$100,000 per mark, per type of goods sold – without proving a dime in lost profits.⁹³ These remedies should be sufficient to deter this type of counterfeiting. The use of federal law enforcement and federal prisons to deter and punish conduct that primarily harms the reputation of trademark holders, rather than consumers, seems to be an unwise allocation of a limited public resource.⁹⁴

3. The Lanham Act and the TCA should be amended to increase penalties for counterfeits that may harm the public

As noted above, a defendant found liable for counterfeiting under the Lanham Act and/or convicted of trafficking in counterfeit goods under the TCA may be required to pay thousands if not millions of dollars in damages and/or fines, and may be sent to prison. However, neither statute explicitly considers the nature of defendant's counterfeiting – *e.g.*, the type of goods being passed off – in fashioning his punishment or the extent of his liability. They should do so, to better reflect the degree of moral culpability and danger to the public associated with such conduct.

The current version of the Lanham Act provides for enhanced statutory damages – a tenfold increase – in cases of “willful” counterfeiting. As discussed *supra*, if defendant's misuse of plaintiff's trademark is not intentional or willful, in most cases it probably should not be deemed counterfeiting at all. In the typical counterfeiting case, willfulness will be present. If, for example, defendant manufactures and sells relatively inexpensive watches inscribed with an emblem that looks like the Rolex trademark, it should be fairly easy to prove that defendant willfully or intentionally sold counterfeits. Moreover, the degree of defendant's willfulness or intent can and should be considered by the court in fashioning an appropriate sentence in a given case. Therefore, creating a separate category of damages for “willful” conduct seems duplicative and unnecessary.

However, when defendant peddles a counterfeit good that could kill someone – whether it be an airplane propeller or a

⁹³ See *supra* notes 38-45 and accompanying text.

⁹⁴ Moreover, reading the TCA narrowly – to exclude criminal liability for counterfeiting based on a post-sale confusion theory – would be consistent with the rule of lenity, or “canon of strict construction of criminal statutes,” which “ensures fair warning by so resolving ambiguity in a criminal statute as to apply it only to conduct clearly covered.” *United States v. Lanier*, 520 U.S. 259, 266 (1997) (citations omitted); see also *United States v. Bass*, 404 U.S. 336, 347-48 (1971).

prescription medication – the severity of that offense should be directly reflected in the statutes, both in the context of civil and criminal liability. Statutory damages of \$1 million per mark (or greater) are not excessive when attached to the sale of counterfeit, and potentially substandard, brake pads or a lifesaving medication. Likewise, enhanced criminal penalties are appropriate when counterfeiting may contribute to or cause death or bodily injury. Both the Lanham Act and the TCA should be amended to provide for enhanced damages and penalties when the good or service defendant is attempting to “pass off” to the public is one which is designed for human consumption or which has the potential to endanger human life if it is of low or substandard quality. The punishment should fit the crime.⁹⁵

C. Detering the Sale and Distribution of Counterfeit Pharmaceuticals

Enhanced civil and criminal penalties under the Lanham Act and the TCA as described above could have a deterrent effect. However, these reforms suffer from two major constraints that limit their applicability and efficacy in the counterfeit pharmaceutical context: (1) they would impact counterfeits of drugs with registered trademarks only, not generics; and (2) enforcement is likewise limited to the efforts of trademark holders and the government. Congress should enact a statute that allows for a consumer right of action against

⁹⁵ When Congress enacted the TCA, it expressly contemplated that courts would exercise their discretion to impose penalties that were “appropriate under the circumstances” to take into account the varying degrees of harm perpetrated by counterfeiters. THE COMMITTEE ON THE JUDICIARY, REPORT ON TRADEMARK COUNTERFEITING ACT OF 1984, REPORT TO ACCOMPANY H.R. 6071, http://ipmall.info/hosted_resources/lipa/trademarks/PreLanhamAct_071_A_Report_04.pdf at page 11. However, the disparities discussed here are too great to be addressed solely by deference to judicial discretion.

⁹⁶ See *supra* notes 56-62 and accompanying text.

⁹⁷ See John L. Watts, *To Tell the Truth: A Qui Tam Action for Perjury in a Civil Proceeding is Necessary to Protect the Integrity of the Civil Judicial System*, 79 TEMP. L. REV. 773, 782-85 (2006) (discussing the impact of low prosecution rates on the deterrent effect of anti-perjury statutes); Richard A. Posner, *An Economic Theory of the Criminal Law*, 85 COLUM. L. REV. 1193, 1205 n. 25 (noting that increasing the probability of apprehension deters crime more effectively than increasing the length of the prison sentence).

those who sell or distribute misbranded or counterfeit drugs, with statutory damages and/or strict liability as a basis for recovery.

1. The limits of relying on criminal law enforcement to deter drug counterfeiting

As described *supra*, the FDCA criminalizes drug counterfeiting, although its penalties are widely perceived to be inadequate.⁹⁶ These penalties should be increased, but even if they are, they should not be expected to deter drug counterfeiting by themselves. The ability of the FDA and federal law enforcement to effectively deter drug counterfeiting is questionable, given the scope of the problem and the resources available to combat it.

Criminal penalties under the FDCA should be equal to those that are imposed for violation of the TCA. Enhanced criminal penalties should be created for counterfeit pharmaceuticals that contain toxic substances. When counterfeiting is really a form of patent infringement – defendant produces a perfect copy, not only of defendant's trademark, but also the underlying drug – enhanced penalties would not be appropriate.

No matter how great the punishment, deterrence is difficult to achieve if the criminal's fear of being prosecuted is low.⁹⁷ The FDA reports that, in 2000, it opened six counterfeit drug cases; that number has steadily increased, with fifty-eight counterfeit drug cases being opened in 2004.⁹⁸ While the FDA is presumably doing extremely well with the resources it has at its disposal, it is not equipped to investigate and prosecute every instance of drug counterfeiting or misbranding (or even a significant percentage of them). By one estimate, U.S. citizens are spending approximately \$1 billion annually on Internet pharmacy purchases alone.⁹⁹ Given the volume of drugs being sold, particularly in the online medium, it seems unlikely that the fifty-eight reported cases in 2004 represents a significant percentage of the actual number of cases of counterfeiting. Increased criminal penalties probably would not have a significant impact without corresponding increased resources to ensure that the law was enforced.

2. Creating a consumer right of action

Criminal fines, under either the FDCA or the TCA, are paid to the government. Statutory damages are paid to trademark holders. None of these statutes provides any relief, or even a private right of action, for the consumer who has been harmed by a counterfeit

pharmaceutical. Either the existing statutes should be amended or a new statute should be created that would do so. Consumers should control their own destiny.

Consumers who are given the opportunity to sue for damages, based on their purchase or consumption of counterfeit pharmaceuticals, should be given the option of proving compensatory damages or, in the alternative, electing to receive statutory damages. They should have access to the same *ex parte* seizure provisions provided to trademark holders under the Lanham Act. The inclusion of a statutory damage option would at least potentially open the door to class action litigation against retailers or distributors who sell counterfeit drugs to consumers.¹⁰⁰ Establishing strict liability on behalf of those who dispense and distribute the nation's drug supply would eliminate many of the difficulties of proof that may deter filing such lawsuits under state law.

The goal of these types of reforms would be twofold: (1) to ensure that consumers who are harmed by counterfeit drugs have a means of obtaining compensation and relief, and (2) to introduce greater accountability into the system of drug distribution in the United States. Coupled with increased criminal penalties and enforcement, these reforms should have a combined deterrent effect that constitutes an improvement over the status quo.

Conclusion

The legal regime that exists to punish "counterfeiters" in the U.S. needs to be reformed. Too many resources are currently devoted to criminal prosecution of those who do not pose a danger to society (or at least have given no indication of doing so, based on the nature of their counterfeiting). To date, no one has been killed by a fake Gucci purse. On the other hand, the penalties and remedies available to deter and punish those who risk the lives of others as a result of their counterfeiting activity should increase. The law should reflect that not all counterfeits are created equal.

⁹⁸ See COMBATING COUNTERFEIT DRUGS: A REPORT OF THE FOOD AND DRUG ADMINISTRATION ANNUAL UPDATE (2005).

<http://www.fda.gov/oc/initiatives/counterfeit/update2005.html>.

⁹⁹ Liang, *Fade to Black*, *supra* note 61, at 309.

¹⁰⁰ At least some consumer plaintiffs have already tried to file class-action lawsuits based on the sale of counterfeit drugs, with limited success. See, e.g., *Dimich v. Med-Pro, Inc.*, 304 F. Supp. 2d 517 (S.D.N.Y. 2004); *Fagan v. AmerisourceBergen Corp.*, 356 F. Supp. 2d 198 (E.D.N.Y. 2004).