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What's in Your Bottle?: *Shire US Inc. v. Barr Laboratories Inc.* and Its Effect on Prescription Drug Trade Dress Protection in the Third Circuit

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I. Introduction

The pharmaceutical industry may have lost its ability to differentiate prescription drug tablets from generic imitations in light of the Third Circuit's decision in *Shire US Inc. v. Barr Laboratories Inc*.[1] Traditional trade dress jurisprudence has long recognized a cause of action whereby a national brand-name manufacturer can sue to protect its product's identity from a generically manufactured facsimile. Such an action normally arises when a generic manufacturer copies the appearance of a brand-name product, thereby gaining instant product recognition based on the brand-name manufacturer's established marketing and accumulated goodwill.[2] Trademark common law and the Lanham Act protect brand-name manufacturers from such unfair trade practices.[3] Over-the-counter drugs are packaged in containers bearing manufacturers' names and markings, enabling consumers to differentiate between, for example, Ecotrin™ aspirin and generic CVS store brand aspirin.[4] When a generic manufacturer's label is sufficiently similar to that of an established product, the Lanham Act dictates that the generic

[1] Shire US Inc. v. Barr Labs. Inc., 329 F.3d 348 (3d Cir. 2003).
[2] *E.g.*, Two Pesos, Inc. v. Taco Cabana, Inc., 505 U.S. 763, 765-68 (1992).
[3] Lanham Act § 43(a), 15 U.S.C. § 1125(a) (1999).
[4] Smithkline Beckman Corp. v. Pennex Prods. Co., 605 F. Supp. 746, 753 (E.D. Pa. 1985).

manufacturer must cease selling its product.[5] Even when products, i.e., tablets, are physically identical, packaging labels serve as sufficient identification of their source.

Prescription drugs manufacturers, however, do not enjoy the same array of product differentiating techniques, mostly because of the regulated manner in which prescription medications are dispensed.[6] Unlike over-the-counter drugs, "[i]t is the physician, not the consumer, who selects the [prescription drug]. The drugs are repackaged by a pharmacist in clear vials which contain no easily identifiable designation of source, unique packaging or individual labeling trade dress to distinguish it."[7] Thus, trade dress, i.e., the size, shape and, color of the tablet itself, is the only indication of source available to a patient, who is the ultimate consumer of prescription medication.

After the Third Circuit's decision in *SK&F, Co. v. Premo Pharmaceutical Laboratories, Inc.*, prescription drug companies clearly retained the capability to protect their drug tablet's trade dress, i.e., the tablet's color, size and shape.[8] However, the court's holding in *Shire* has potentially cracked the foundation of the prescription drug trade dress protection it set out in *SK&F*.[9] Facing facts similar to those in *SK&F*, the *Shire* court decided to divest the brand-name manufacturer of all rights in its product's trade dress, thereby opening the door for generic drug producers to trade on the reputation built by brand-name drug manufacturers.[10] The remaining method of protecting prescription drug trade dress after *Shire* requires that companies extensively advertise their product. As an unintended effect of the holding in *Shire*, brand-name drug companies must spend a great deal more on advertising costs than they otherwise would have, an increase that will only be passed off to consumers through raising drug prices.

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[5] 15 U.S.C. § 1125(a).
[6] *See Smithkline Beckman Corp.*, 605 F. Supp. at 753.
[7] *Id.*
[8] SK&F, Co. v. Premo Pharm. Labs., Inc., 625 F.2d 1055 (3d Cir. 1980).
[9] *Shire*, 329 F.3d at 356.
[10] *Id.*

Part II of this Note will review the statutory purpose of the Lanham Act and discuss the application of trade dress protection under the Act. Part III will consider the Third Circuit's construction of trade dress law in the *SK&F* decision. Finally, Part IV of this Note will address the questions raised by the holding in *Shire US, Inc. v Barr Laboratories, Inc.*, namely: (1) whether prescription drug trade dress should be analyzed under traditional notions of trade dress law, and if not, (2) whether the Lanham Act is the appropriate vehicle for protecting a prescription drug tablet's trade dress, or (3) in the alternative, whether prescription drug tablets should be analyzed under a modified trade dress framework. Such an alternative will be proposed.

II. The Lanham Act and Trade Dress Protection

The Lanham Act was intended to make "actionable the deceptive and misleading use of marks" and to "protect persons engaged in . . . commerce against unfair competition."[11] A trademark under the Act is defined as "any word, name, symbol, or device or any combination thereof . . . [used] to identify and distinguish . . . goods, including a unique product, from those manufactured or sold by others and to indicate the source of the goods . . . ."[12] The Lanham Act does not require that *the specific source* of the product be identifiable from the trademark; rather, the trademark must simply enable a consumer to identify that the product came from *a single source*.[13]

In addition to protecting registered trademarks, § 43(a) of the Lanham Act creates a federal cause of action for trade dress infringement.[14] The Supreme Court has interpreted the language of this section broadly, expanding the realm of protectable trade dress to anything

[11] Lanham Act § 45, 15 U.S.C. § 1127 (1999).
[12] *Id.*
[13] *See id.*
[14] 15 U.S.C. § 1125(a); Wal-Mart Stores, Inc. v. Samara Bros., 529 U.S. 205, 209 (2000).

"human beings might use as a 'symbol' or 'device' . . . that is capable of carrying meaning."[15] Therefore, trade dress "involves the total image of a product and may include features such as size, shape, color or color combinations, texture, graphics, or even particular sales techniques."[16]

As the Court set out in *Wal-Mart Stores, Inc. v. Samara Bros.*, for a product's trade dress to fall within the purview of the Lanham Act's protections, the producer must show: (1) that the trade dress is either inherently distinctive, or is said to be distinctive as a result of acquiring "secondary meaning;" (2) that there is a likelihood of consumer confusion; and (3) that the alleged infringing feature is nonfunctional.[17]

A. The Requirement of Distinctiveness

In *Abercrombie & Fitch Co. v. Hunting World, Inc.*, Judge Friendly introduced the four accepted classes of distinctiveness: generic, descriptive, suggestive, and arbitrary or fanciful.[18] Generic and descriptive marks cannot gain trademark protections because they merely refer to "the genus of which a particular product is a species."[19] Generally, they are the common names of products that convey "an immediate idea of the ingredients, qualities or characteristics of the goods."[20] Courts recognize an exception to this general rule, allowing merely descriptive marks to gain distinctiveness by acquiring secondary meaning.[21] "To establish secondary meaning, a manufacturer must show that, in the minds of the public, the primary significance of a product feature or term is to identify the source of the product rather than the product itself."[22] Put slightly differently, a mark acquires secondary meaning when consumers can identify the source

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[15] *Wal-Mart*, 529 U.S. at 209-10 (citation omitted).
[16] Two Pesos, Inc. v. Taco Cabana, Inc., 505 U.S. 763, 765 n.1 (1992) (quoting John H. Harland Co. v. Clark Checks, Inc., 711 F.2d 966, 980 (11th Cir. 1983)).
[17] *Wal-Mart*, 529 U.S. at 210.
[18] Abercrombie & Fitch Co. v. Hunting World, Inc., 537 F.2d 4, 9 (2d Cir. 1976).
[19] *Id.*
[20] Id. at 11 (quoting Stix Prds., Inc. v. United Merchs. and Mfrs. Inc., 295 F. Supp. 479, 488 (S.D.N.Y. 1968)).
[21] *Id.* at 9.
[22] Inwood Labs., Inc. v. Ives Labs., Inc., 456 U.S. 844, 851 n.11 (1982) (citing Kellogg Co. v. Nat'l Biscuit Co., 305 U.S. 111, 118 (1938)).

of the product from the mark, alone. The most common means of gaining secondary meaning is through extensive advertising, which creates an association between products and their respective marks.[23]

At the other end of the spectrum, suggestive and arbitrary or fanciful marks are inherently distinctive. They are considered inherently distinctive because their "intrinsic nature serves to identify a particular source."[24] Kodak and Exxon are well-known examples of such marks.[25] Currently, these marks receive all of the rights allowed under the Lanham Act without a showing of secondary meaning, but this was not always so clear.[26] Prior to 1992, the circuit courts were split regarding the applicability of this framework for classifying trademark distinctiveness to trade dress law.[27] Whereas the Second Circuit consistently held that trade dress protection was unavailable absent proof of secondary meaning,[28] in the Fifth Circuit, no showing of secondary meaning was required if a trade dress was considered inherently distinctive.

In the landmark case of *Two Pesos, Inc. v. Taco Cabana, Inc.*, the Supreme Court quelled this circuit split.[29] The respondent sought protection of the décor of its Mexican themed restaurant under the Lanham Act's trade dress law.[30] Agreeing with the Fifth Circuit, the Court held that if a product's trade dress is inherently distinctive, it is capable of identifying the source of its product, thereby rendering unnecessary the requirement of establishing secondary meaning.[31] The Court reasoned that if it interpreted § 43(a) as requiring secondary meaning,

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[23] Scott Paper Co. v. Scott's Liquid Gold, Inc., 589 F.2d 1225, 1228 (3d Cir. 1978).
[24] *Two Pesos*, 505 U.S. at 768.
[25] Little Caesar Enters., Inc., v. Pizza Caesar, Inc., 834 F.2d 568, 571 (6th Cir. 1987).
[26] *Abercrombie*, 537 F.2d at 11.
[27] *Two Pesos*, 505 U.S. at 772-74.
[28] *Id.*
[29] *Id.* at 767.
[30] *Id.* at 765-66.
[31] *Id.* at 776.

then Congress' purpose in promulgating the Lanham Act would be undermined.[32] The stated purpose of the Lanham Act is to:

> secure to the owner of the mark the goodwill of his business and to protect the ability of the consumers to distinguish among competing producers. National protection of trademarks is desirable . . . because trademarks foster competition and the maintenance of quality by securing to the producer the benefits of good reputation.[33]

If it were more difficult to gain protection on inherently distinctive trade dress, competition between producers would be hindered because copycats could enter the market under the same trade dress, thereby nullifying the Lanham Act's policies of ensuring quality and fostering competition. Therefore, to comport with Congress' intent, the Supreme Court construed § 43(a)'s distinctiveness element as requiring a an initial inquiry into whether a product is inherently distinctive , allowing for the possibility that a product can receive protection even absent proof of secondary meaning.[34]

B. Likelihood of Consumer Confusion

Because a market economy requires competition to remain functional and healthy, it is permissible and desirable for a new business to produce products similar to ones already in existence. However, the Lanham Act precludes the later-arriving producer from gaining its market share through the use of another manufacturer's trade dress. This restriction is premised on one of the Act's underlying policies - alleviating consumer confusion.[35]

Prior to 2000, the Third Circuit analyzed "likelihood of confusion" differently depending upon whether the alleged trade dress infringer was dealing in competing or noncompeting

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[32] *Id.* at 774.
[33] *Id.* (citing S. REP. NO. 79-1333, at 3-5 (1946)).
[34] *Id.* at 773.
[35] Interpace Corp. v. Lapp, Inc., 721 F.2d 460, 462 (3d Cir. 1983).

goods.[36] "Where the [trade dress] owner and the alleged infringer deal in competing goods . . . , the court need rarely look beyond the mark[s]."[37] To determine the likelihood of confusion in noncompeting goods, however, the court has depended upon factors set out in *Interpace Corp. v. Lapp, Inc.*[38] The *Lapp* factors include:

(1) the degree of similarity between the owner's mark [or trade dress] and the alleged infringing mark;

(2) the strength of the owner's mark;

(3) the price of the goods and other factors indicative of the care and attention expected of consumers when making a purchase;

(4) the length of time the defendant has used the mark without evidence of actual confusion arising;

(5) the intent of the defendant in adopting the mark;

(6) the evidence of actual confusion;

(7) whether the goods, though not competing, are marketed through the same channels of trade and advertised through the same media;

(8) the extent to which the targets of the parties' sales efforts are the same;

(9) the relationship of the goods in the minds of consumers, whether because of the near-identity of the products, the similarity of function, or other factors; and

(10) other facts suggesting that the consuming public might expect the prior owner to manufacture a product in the defendant's market, or that he is likely to expand into that market.[39]

In *A&H Sportswear, Inc. v. Victoria's Secret Stores, Inc.*, the Third Circuit changed course, holding that the *Lapp* factors should be applied in all trade dress infringement actions, even in cases involving only non-competing goods.[40] The court clarified its position by

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[36] *Id.*
[37] *Id.*
[38] *E.g.*, A&H Sportswear, Inc. v. Victoria's Secret Stores, Inc., 237 F.3d 198, 211 (3d Cir. 2000) (citing *Lapp*, 721 F.2d at 460-63).
[39] *Lapp*, 721 F.2d at 463.
[40] *Victoria's Secret*, 237 F.3d at 214.

differentiating between the standard and the test of likelihood of confusion. When dealing with competing goods, the standard, the similarity of the products takes on increased importance; because products in the former group are sold side-by-side, they are more likely to be confused if their trade dresses are similar.[41] Though similarity may become the most important factor in determining whether competing goods are likely to be confused, it is not the only consideration.[42] For support, the court pointed to the fact that the Lapp factors "considers the competitive and potential competition of the products in the market place."[43] As a result, the court held that the test for determining likelihood of confusion, i.e., the *Lapp* factors, would apply to both competing and non-competing goods in order to determine if the trade dress reaches the appropriate standard.

C. Functionality

Even when a brand-name manufacturer can establish that its trade dress is distinctive and that there is no likelihood of consumer confusion, the allegedly infringing trade dress cannot be protected if it possesses a functional characteristic. [44] In *TrafFix Devices, Inc. v. Marketing Displays, Inc.*, the United States Supreme Court recognized two tests for determining the functionality of trade dress. Under the traditional test, "a product is functional . . . if it is essential to the use or purpose of the article or if it affects the cost or quality of the article."[45] The second test classifies a product's feature as functional if its "exclusive use . . . would put competitors at a significant non-reputation-related disadvantage."[46]

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[41] *Id.*
[42] *Id.*
[43] *Id.*
[44] Lanham Act § 43(a)(3), 15 U.S.C. § 1125(a)(3) (1999) ("The person who asserts trade dress protection has the burden of proving that the matter sought to be protected is not functional.").
[45] *TrafFix Devices, Inc. v. Mktg. Displays, Inc.*, 532 U.S. 23, 32 (2001) (internal citations omitted).
[46] *Id.*

The policies behind the functionality requirement are twofold. The first is to ensure "that competition will not be stifled by the exhaustion of a limited number of trade dresses."[47] Requiring functionality recognizes the differences between trademark law and federal patent law. Whereas trademarks are given perpetual protection, protection is afforded to the functional components of a product for only a limited time under federal patent law, allowing competitors to freely use the functional components thereafter.[48] Accordingly, by limiting protection to product features that are non-functional, trade dress law does not overstep its intended usefulness. Additionally, functionality protects brand-name manufacturers from the copying of product-identifying features by generic manufacturers.[49]

III. Prescription Pharmaceutical Tablet Trade Dress Protection in the Third Circuit after *SK&F, Co. v. Premo Pharmaceutical Laboratories, Inc.*

In *SK&F, Co. v. Premo Pharmaceutical Laboratories, Inc.*, SK&F, Company ("SKF"), a brand-name prescription drug producer, manufactured an oral diuretic in hard gelatin capsules with a maroon and white color combination.[50] After the expiration of the capsule's patent, a generic prescription drug producer, Premo Pharmaceutical Laboratories, Inc. ("Premo"), manufactured an oral diuretic and adopted the same maroon and white color scheme as SKF's product but with Premo's logo stamped on the gelatin capsule.[51] SKF filed a complaint consisting of several counts, including one for trade dress infringement in violation of § 43(a) of the Lanham Act.[52] In granting SKF a preliminary injunction, the trial court relied on its findings that SKF had expended large amounts of money promoting its product's trade dress, that doctors

[47] Two Pesos, Inc. v. Taco Cabana, Inc., 505 U.S. 763, 775 (1992).
[48] Patent Act, 35 U.S.C. § 101 (2000).
[49] Shire US Inc. v. Barr Labs. Inc., 329 F.3d 348, 353 (3d Cir. 2003).
[50] SK&F, Co. v. Premo Pharm. Labs., Inc., 625 F.2d 1055, 1057 (3d Cir. 1980).
[51] *Id.* at 1058.
[52] *Id.*

had prescribed the SKF product for 15 years to millions of patients, and that SKF's was the only product in the diuretic market using the maroon and white color scheme.[53]

On appeal to the Third Circuit, Premo reiterated several arguments in favor of permitting copying SKF's trade dress. First, Premo suggested that making generic products look like brand-name counterparts was desirable "to facilitate identification of a particular medication of a particular strength . . . ."[54] Next, Premo argued that the standardization of color, size, and shape is important to both ensure that the proper drug is dispensed and to assist in rapid identification of medications in emergency situations.[55] Premo also predicted that physicians would be confused when trying to visually identify a prescription drug.[56] Finally, Premo suggested that patients feel more confident taking a generic product when its chemical make-up is the same as that of its brand-name counterpart.[57]

The appellate court rejected these arguments in short order. As to the assertions regarding identification of drugs, the court relied on testimony of physicians who stated that they would never rely upon trade dress as the sole means of identifying a prescription drug.[58] The court rejected the argument that patients would lose confidence in generic drugs that don't resemble brand-name counterparts because most states require that a patient be informed of a generic substitution.[59] Moreover, the court reasoned that even if standardization of the color scheme for the purpose of easing patient anxiety was a viable argument, Premo's generic drug was not composed of the same amount of each ingredient as SKF's brand-name drug.[60] The

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[53] *Id.* at 1059.
[54] *Id.* at 1060.
[55] *Id.*
[56] *Id.*
[57] *Id.* at 1061.
[58] *Id.* at 1060.
[59] *Id.* at 1061.
[60] *Id.*

court determined that while the generic drug may be chemically similar to the brand-name drug, the variation in ingredients could lead to dangerously different reactions in a given patient.[61]

The Third Circuit relied on the traditional trade dress infringement analysis. The court gave deference to the trial court's finding that the trade dress was distinctive.[62] In considering the likelihood of confusion, the court found that the products would confuse consumers because the tablets were colored similarly and the logos were so small that they were ineffective.[63] Finally, the court found that the color, shape, and size of the tablet were nonfunctional because "[t]he adoption of that trade dress was arbitrary, having nothing to do with the purpose or performance of the drug, or with its processing."[64] Having found all of the elements for the cause of action to be present, the court affirmed the lower court's determination that Premo infringed SKF's trade dress under § 43(a) of the Lanham Act.[65]

In *SK&F*, the Third Circuit broadly construed the Lanham Act, thereby granting prescription drugs a wide range of protection for the trade dress of their tablets. In addition to the reasons stated herein, the court also likely considered that, unlike over-the-counter drugs, a prescription drug manufacturer relies on its product's trade dress as the only visible, source-identifying feature within its control. Accordingly, the court found that prescription drug trade dress deserves heightened protection.

IV. The Third Circuit's Change of Heart in *Shire US Inc. v. Barr Laboratories Inc.*

In May 2003, the Third Circuit clouded the parameters of prescription drug trade dress protection when it handed down its decision in *Shire US Inc. v. Barr Laboratories Inc.* The plaintiff in the case, Shire U.S., Inc. ("Shire"), manufactured the brand-name drug Adderall for

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[61] *Id.* at 1061, 1061 n.4.
[62] *Id.* at 1061.
[63] *Id.*
[64] *Id.* at 1064.
[65] *Id.* at 1068.

the treatment of attention-deficit/hyperactivity disorder (ADHD).[66] For years, Shire produced and sold its tablets in two colors, a blue 10mg tablet and an orange 20mg tablet, both stamped with an "AD" on one side and the dosage on the other.[67] Shire promoted its product through literature, featuring colored pictures of the drug, which was distributed to physicians.[68]

Barr Laboratories, Inc. ("Barr"), began selling a generic version of Adderall in 2002.[69] It adopted a color scheme very similar to Shire's, in which lower dosage tablets were blue and higher dosage tablets were orange. Both were stamped with a "b" on one side and a serial number on the other.[70] The trial court found that Shire's Adderall and Barr's generic product were of the same coloring and were "similar but not identical."[71] Further, the court considered Shire's assertion that the ingredients of the generic substitute were not identical: Barr's generic drug contained the inactive ingredient saccharin, a once controversial substance.[72]

In denying Shire's request for preliminary injunction, the Third Circuit attempted to distinguish its 1980 *SK&F* decision from the facts presented in *Shire*. Ultimately, all of the methods employed by the court to do so failed. First, the court asserted that the evidence in *SK&F* indicated that actual "passing off" had occurred within pharmacies.[73] However, the *SK&F* court construed New Jersey common law, not the Lanham Act, in making its finding of passing off.[74] Moreover, the court did not find that actual passing off had occurred in the earlier case, but rather that it could "reasonably anticipate" that passing off may occur.[75] Thus, the

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[66] Shire US Inc. v. Barr Labs. Inc., 329 F.3d 348, 349 (3d Cir. 2003).
[67] *Id.* at 350.
[68] *Id.*
[69] *Id.*
[70] *Id.* at 351.
[71] *Id.*
[72] *Id.* at 350.
[73] *Id.* at 356 (citing SK&F, Co. v. Premo Pharm. Labs., Inc., 625 F.2d 1055, 1063 (3d Cir. 1980)). Passing off is common law tort that involves fraudulently markets one's goods as those of another. *SK&F*, 625 F.2d at 1062.
[74] *SK&F*, 625 F.2d at 1062-65.
[75] *Id.* at 1062-63.

Shire court that passing off was a distinguishing factor was unpersuasive, as the court certainly could have "reasonably anticipated" that pharmacies may pass off the similarly colored tablets present in *Shire*.

Next, the court attempted to justify its departure from precedent by finding that the tablet's trade dress in *Shire* was functional, while the *SK&F* court considered a non-functional product features.[76] In so doing, the court considered, but failed to give sufficient weight to, the fact that the functionality arguments raised in *Shire* were very similar to those in *SK&F*. In *Shire*, the evidence of functionality relied on by the court consisted of affidavits from physicians stating that generic manufacturers should be permitted to use similar color schemes to those of brand name tablets because color coding would lead to: (1) less patient confusion, (2) proper patient adjustment from one medicinal strength to another, (3) proper dosing for children whose medications are administered by non-medical personnel, and (4) increased acceptance and comfort for patients using generic medication.[77] Although these assertions seem logical, they are the very arguments that the Third Circuit rejected as evidence of functionality in *SK&F*.[78] Instead of establishing a bright line rule for whether color, size, and shape of prescription tablets are functional elements of trade dress, the court merely deferred to the trial court's finding of functionality.[79]

So what changed in the twenty-three years after *SK&F* that caused the Third Circuit to restrict the trade dress protection that it had once afforded? The likely answer is linked to the

[76] *Shire*, 329 F.3d at 356.
[77] *Id.* at 354-55.
[78] *See supra* Part III.
[79] *Shire*, 329 F.3d at 356.

United States Supreme Court's decision in *Wal-Mart Stores, Inc. v. Samara Bros.*, which was handed down in 2000.[80]

In *Wal-Mart*, Samara Brothers, Inc. ("Samara"), brought a trade dress infringement action against Wal-Mart Stores, Inc. ("Wal-Mart"), for copying its line of children's clothing designs.[81] Samara asserted that its designs, including color scheme, geometric patterns, and symbols on the garments themselves, created a protectable trade dress under § 43(a) of the Lanham Act.[82] In finding that the clothing did not deserve protection, the Court held that "courts should err on the side of caution and classify ambiguous trade dress as product design," making it impossible for designs to be inherently distinctive.[83] Thus, the designs could only gain trade dress protection by acquiring secondary meaning.[84] The Court reasoned that a literal reading of the unrestrictive language of § 43 of the Lanham Act would entitle anything capable of carrying meaning to protection.[85] To provide such broad protection would deprive consumers "of the benefits of competition with regard to the utilitarian and esthetic purposes that product design ordinarily serves by . . . [facilitating] plausible threats of suit against [competitors] based upon alleged inherent distinctiveness."[86] The *Wal-Mart* holding revealed the Supreme Court's concern that the circuit courts had overly broadened trade dress protection in past years; this case reads like an attempt to constrict the protection before it extended too far out of control.[87]

In *Shire*, the Third Circuit refers to the Supreme Court's desire to constrict trade dress protection. The court stated, "[m]oreover, we have the benefit of the Supreme Court's most

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[80] Wal-Mart Stores, Inc. v. Samara Bros., 529 U.S. 205 (2000).
[81] *Id.* at 207-08.
[82] *Id.* at 208.
[83] *Id.* at 215.
[84] *Id.*
[85] *Id.* at 210.
[86] *Id.* at 213.
[87] *See id.* at 209.

recent trade dress decisions which caution against the over-extension of trade dress protection."[88] Accordingly, the Third Circuit turned away from the values it endorsed in *SK&F*, denying Shire the trade dress protection it would have previously received. But even taking as true the courts' premise that trade dress protection is over-extended, an unconsidered question remains: Should prescription pharmaceutical tablets seeking trade dress protection be subjected to the same analyses as traditional product design goods?

V. Prescription Pharmaceutical Tablets and Traditional Trade Dress Protection

As discussed above, *Wal-Mart* instructs the circuit courts to constrict the trade dress protection afforded to product design goods.[89] The Supreme Court was primarily concerned with the effect that granting trade dress protection to designs of such products would have on competition.[90] In determining that product design should never be inherently distinctive, the Court cited both the deterrent effect of a "plausible threat of [a] successful suit" involving an allegedly inherent design on hindrances to competition, and its finding that design could not likely inherently identify the source of a good.[91] Furthermore, the Court reasoned that any inherently distinctive design could certainly obtain a design patent or be protected by copyright laws.[92]

Likely underlying the court's assertions was the knowledge that manufacturers of such products also had the ability to create source-identifying product packaging.[93] Regrettably, the court's premise fails when applied to the discreet class of prescription drug tablets. The

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[88] *Shire*, 329 F.3d at 358.

[89] For an example of a court affording trade dress protection to a traditional product design due to its inherent distinctiveness, see Ashley Furniture Indus., Inc. v. Sangiacomo N. A., Ltd., 187 F.3d 363 (4th Cir. 1999) (protecting bedroom furniture).

[90] *Wal-Mart*, 529 U.S. at 213.

[91] *Id.* at 214.

[92] *Id.*

[93] For example, furniture may be shipped in boxes that carry the name and logo of its manufacturer, thereby identifying the source of the product. *See Ashley Furniture Indus., Inc.*, 187 F.3d at 363.

producers of these products do not have the same source-identifying product packaging available to them as do other types of products. The tablets are packaged in bottles capped with white lids. White labels on the side of the container indicate patient information, dosage, the prescribing doctor, and the type of drug. These labels are provided by the pharmacist; the manufacturer has no control over the aesthetics of the labels. Thus, the tablet design itself is the only real source-identifying characteristic available to the manufacturer. To take advantage of the protections granted to inherently distinctive trade dress, drug producers have accordingly developed unique color schemes, shapes, and sizes for their tablets.

Under *Shire*, these unique tablet designs have lost any protection they may have possessed under trade dress law, absent a showing of secondary meaning. While restricting trade dress protection of prescription drug tablets may seem to be justified in light of the large profits drug manufacturers amass through available patent protections, it will likely prove to be an inefficient means of curtailing a drug manufacturer's protections. Restriction could have a widespread and adverse financial impact on an already overpriced pharmaceutical market. *Shire* and *Wal-Mart* effectively hold that the only way pharmaceutical companies can acquire trade dress protection for prescription drug tablets is to gain distinctiveness through secondary meaning. Secondary meaning is primarily gained through expending millions of dollars on advertising in various media so that consumers will recognize the manufacturer as the source of the drug.[94] Unintended though the result may be, pharmaceutical companies will be forced to increase their advertising budgets to obtain any degree of assurance of protection.

It is reasonable to assume that at least a portion of any increase in the cost of production will in turn be assigned to the consuming public. That the consumer class cannot afford to pay these continually rising and unnecessary advertising costs was made evident by recent events in

[94] Scott Paper Co. v. Scott's Liquid Gold, Inc., 589 F.2d 1225, 1228 (3d Cir. 1978).

Springfield, Massachusetts. In order to take advantage of reduced cross-border prices, the city government struck a deal with Canadian drug producers whereby the city agreed to purchase its prescription drugs from the Canadian producers instead of American companies.[95] This action not only eased the cost of health care but also relieved the city's significant deficit.[96] The border crossing of prescription drugs will continue to occur, as consumers will seek alternative sources of medication until the prices of prescription drugs in the United States are reduced. Eliminating the requirement that drug manufacturers saturate the media with advertisements would be an obvious step toward easing prices.

Significant financial cuts could also be achieved by granting protections to drug producers who direct their advertisements to medical practitioners, instead of consumers. Historically, prescription drugs were only advertised to the drug prescribers, since they alone decided which drugs were prescribed.[97] As patients became more active in their own health care, pharmaceutical companies began to attempt to indirectly influence prescribers' drug choices by mounting advertising campaigns that educated consumers about available pharmaceutical options.[98] Since 2001, the pharmaceutical industry has increased its advertising directed at consumers to almost $2.5 billion, almost 200 times the amount spent on the same type of advertising in 1989.[99]

While many commentators have attributed this increase in advertising to the Federal Drug Administration's construction of an ambiguous paragraph in regulations relating to

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[95] Pete Alfano, *Online Drugs Are a Health Risk, Officials Warn,* FORT WORTH STAR-TELEGRAM, Jan. 6, 2004.
[96] *Id.*
[97] Francis B. Palumbo & C. Daniel Mullins, *The Development of Direct-to-Consumer Prescription Drug Advertising Regulation,* 57 FOOD DRUG L.J. 423, 424 (2002); *see* Patrick A. Moore & Michael D. Newton, *Prescription Drug Advertising on the Internet: A Proposal for Regulation,* 2 W. VA. J. L. & TECH. 1.1, ¶ 2 (Feb. 14, 1998), *at* http://www.wvu.edu/~law/wvjolt/Arch/Moore/Moore.htm.
[98] Palumbo & Mullins, *supra* note 97, at 424.
[99] *Id.* at 423 tbl.1.

consumer-directed prescription drug advertising,[100] the restrictions placed on trade dress protection have also likely contributed to the surge. In fact, the period between 1999 and 2001 represented the single largest increase in spending on consumer-directed advertising.[101] It cannot merely be coincidence that *Wal-Mart* was decided during this same period. Under the case's reasoning, pharmaceutical companies must increase product awareness among the consuming public before they can gain trade dress protection. To accomplish this goal, manufacturers are forced to increase their budgets for consumer-directed advertising. This phenomenon can only result in heightened spending on consumer-directed advertising in order to receive trade dress protection. In turn, the consuming public will pay higher and higher prices for prescription drugs. To the extent that manufacturers are influenced by this unintended effect of the *Shire* and *Wal-Mart* holdings, removing the effective prerequisite of increased advertising would lessen the financial burden on both manufacturers and, indirectly, on consumers.

VI. The Possible Resolution

To resolve the potential problems created by *Shire*, the Third Circuit might follow one of two approaches. First, the court could eliminate trade dress protection for pharmaceuticals entirely. This action would alleviate the burden on manufacturers to extensively advertise while still satisfying the court's desire to restrict trade dress protections. By completely removing prescription drug tablets from the realm of trade dress protection, pharmaceutical manufacturers would be less inclined to advertise to consumers, since secondary meaning would no longer be a path to distinctiveness. This approach would also allow generic manufacturers to use brand-name trade dress without fear of prosecution under the Lanham Act, which was the Supreme

[100] Moore & Michael Newton, *supra* note 97, ¶ 2 (citing FDA Prescription Drug Advertising, 21 C.F.R. § 202.1 (1997)).
[101] *See* Palumbo & Mullins, *supra* note 97, at 423 tbl.1.

Court's primary concern in *Wal-Mart*.[102] While this option seems to satisfy the main objections of the *Shire* and *Wal-Mart* courts, it is unlikely that the Third Circuit would take such a drastic step.

More plausibly, the court could entirely exclude prescription drugs from traditional trade dress analysis and create a new approach specifically tailored for the idiosyncrasies of the prescription drug industry. As discussed above, traditional trade dress analysis assumes product packaging by which the manufacturer can be identified as the source of the good. Prescription drugs lack such packaging. To account for these major discrepancies, the court should establish new criteria for determining whether a prescription drug tablet's trade dress has been infringed.

A. Distinctiveness

Distinctiveness should no longer be considered when determining trade dress infringement for prescription drug tablets. Under the patent system, most pharmaceuticals companies have a twenty-year period in which they are allowed monopolistic control over their drugs.[103] As a result, the majority of the consuming public will recognize a drug by its color, shape and size of the tablet. Even if this recognition would fail to qualify as secondary meaning under the traditional trade analysis, it would be sufficient to establish distinctiveness under this proposed analysis. Accordingly, the need for pharmaceutical companies to expend excess money on advertising to gain secondary meaning, as is required under the traditional system, would be eliminated. The resulting reduction in spending would help to ease the financial tension that currently burdens the pharmaceutical market.

B. Functionality

[102] *See* Wal-Mart Stores, Inc. v. Samara Bros., 529 U.S. 205, 213 (2000).
[103] 35 U.S.C. § 154(a)(2) (1999).

Functionality should play a less significant role in the determination of trade dress infringement. In fact, this element should only apply where the functionality of the tablet itself is sufficient to earn it a design patent. For example, an improved coating that would allow capsules to be swallowed more easily, or could provide more control over the time-release of medication, may be sufficient to obtain such a patent. Liming the applicability of the functionality requirement in this fashion would obviate the Third Circuit's construction in *Shire* and re-establish the tests for functionality set out by the Supreme Court in *TrafFix*.[104] "A product is functional . . . if it is essential to the use or purpose of the article or if it affects the cost or quality of the article"; further, a product's feature is functional if its "exclusive use . . . would put competitors at a significant non-reputation-related disadvantage."[105] The arguments accepted in *Shire* regarding the functionality of a tablet's trade dress do not fall within either of these definitions espoused in *TrafFix*. The *Shire* court reasoned that no protection should be afforded to the tablet's trade dress because a patient may be more comfortable taking a drug that uses the brand-name trade dress. However, the trade dress adopted for Shire's tablet was chosen arbitrarily; it had nothing to do with the purpose or performance of the drug, or with its processing.[106] This is the type of reputation-based disadvantage that trade dress law was designed to protect.

C. Likelihood of Consumer Confusion

The final element, likelihood of confusion, would become the central and defining element under the new approach. However, the traditional *Lapp* factors would have to be

[104] *TrafFix Devices, Inc. v. Mktg. Displays, Inc.*, 532 U.S. 23, 32 (2001).
[105] *Id.*
[106] *See SK&F*, 625 F.2d at 1064 (holding that a product feature is not functional when its adoption is "arbitrary, having nothing to do with the purpose or performance of the drug, or its processing").

slightly modified to accommodate the unique concerns present in a prescription drug trade dress analysis:

1. *The Similarity of the Prescription Drug Tablets*

This factor would remain relatively intact from the traditional analysis. Courts would have to compare the allegedly infringing tablet with the brand-name tablet to determine the degree of similarity between them. However, they would apply a new standard, inquiring whether a reasonable consumer of a particular medication could differentiate between the brand-name drug tablet and the allegedly infringing generic drug tablet. A negative finding would be a strong indication that the generic manufacturer has infringed the brand-name manufacturer's trade dress. This factor would serve to encourage generic drug producers to choose distinct appearances for their products, thereby minimizing consumer confusion. Furthermore, disallowing identical tablets would lessen the threat of passing off or capsule switching, because consumers would be better able to distinguish between various types of pills.[107]

If trade dresses are similar but not identical then the following subfactors should also be considered:

a. Bioavailability

The bioavailability of a drug is the quantity of active ingredients that are released into the bloodstream per unit dosage.[108] Under the proposed analysis, courts would look to laboratory analyses to determine whether the bioavailability of the brand-name drug tablet and the generic drug tablet are identical. The importance of bioavailability cannot be understated because a consumer may not realize that a substitution has been made if the trade dress of two types of medication is very similar. A patient's health could be seriously at risk if two pills appear alike

[107] *See supra* Part III.
[108] *SK&F*, 625 F.2d at 1061.

but have different bioavailability. No consumer should be subjected to such serious confusion and potential harm when taking prescription medication. Accordingly, under the new framework, if a court was to find that the bioavailability of a brand-name tablet and a generic product were the same, it would hold that the generic tablet does not confuse consumers. Although the significance of a drug's bioavailability has been greatly reduced by the FDA's current regulations of generic drugs, it should certainly continue to be considered when determining the likelihood of consumer confusion.[109]

b. Availability of Inactive Ingredients

In *Shire*, the Court recognized, but failed to give adequate weight to, the fact that Barr's generic drug contained the inactive ingredient saccharin.[110] Until recently, saccharin was banned by the FDA as a suspected carcinogen.[111] Many people would still prefer to avoid ingesting the substance, regardless of its FDA classification. For this reason, this factor retains its significance. Thus, a court should take into account the list of inactive ingredients when determining whether a tablet's trade dress is infringing. If the lists of inactive ingredients were found to be identical or equivalent, then the tablet's trade dress would not confuse consumers.

2. *Intent of the Generic Drug Manufacturer*

Courts should also consider the intent of the generic drug manufacturer in adopting the similar or identical trade dress. As mentioned above, passing off, or capsule switching, is one of the reoccurring problems that the courts encounter in the pharmaceutical industry.[112] If a court was to find that a generic drug manufacturer purposefully copied a brand-name trade dress for

[109] Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j) (1984).
[110] *Shire*, 329 F.3d at 350.
[111] *Id.*
[112] *See supra* Part IV.

the purpose of passing off or intentionally confusing consumers in any way, then such a finding would strongly indicate a likelihood of confusion.

3. *State Law Regarding Disclosure of Generic Substitutions*

Most states permitting generic substitutions require that purchasers be notified when a brand-name drug has been substituted by a generic equivalent.[113] Notification under the proposed approach would require a consumer to sign a document explaining that such a substitution of a brand-name drug has been made. Pharmacists would be charged with the duty of explaining the document to consumers. As a result of this requirement, generic drugs that look similar to their brand-name counterparts would be less likely to cause confusion among consumers. A properly executed notification would indicate to a court that there was no likelihood of confusion in a given case.

VII. Conclusion

Today, brand-name prescription drug manufacturers are unable to protect good will and product recognition. These competitive advantages, which are gained only through years' worth of investment, can be quickly wiped out if a generic drug manufacturer decides to imitate a brand-name product. The Third Circuit's opinion in *Shire* has dealt yet another blow to this already weak area of protection. As a result of that decision, brand-name prescription drug companies will be required to spend even more money in advertising and marketing to regain the protection that was once afforded to them under *SK&F*. The manufacturers' increased operating costs will ultimately be passed along to consumers of prescription drugs, as is evidenced by United States citizens purchasing their prescription medication in Canada at lower prices. Weakening prescription drug trade dress will only further complicate these interrelated problems. Although the changes to prescription drug trade dress law proposed in this Note do not cure these

[113] *SK&F*, 625 F.2d at 1061.

problems, they would mitigate the rising costs of drugs. The Third Circuit should reevaluate its decision in *Shire*, striving to alleviate the negative effects that its announced policy changes could have on the prescription drug market.