

FREE RIDERS AT THE DRUGSTORE: GENERICS, CONSUMER CONFUSION, AND THE PUBLIC GOOD

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INTRODUCTION

If success is said to breed imitation, then to the business person imitation is the highest form of flattery.¹ Or is it?

The enactment of the Hatch-Waxman Act of 1984² radically changed the opportunities for market entry by generic drug manufacturers. By allowing generic companies to seek Food and Drug Administration (FDA) approval for their products prior to the expiration of the brand-name drug's patent,³ it became possible for the generic alternative to be made available to consumers the very day the pioneer drug's patent expires.⁴ While this accelerated market entry has achieved the intended consequence of providing reduced-cost drug options for consumers at the earliest possible time, the financial ramifications for the

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¹ *SmithKline Beckman Corp. v. Pennex Prods. Co., Inc.*, 605 F. Supp. 746, 748 (E.D. Pa. 1985).

² Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified at 15 U.S.C. §§ 68b–68c, 70b (2012); 21 U.S.C. §§ 301 note, 355, 360cc (2006); 28 U.S.C. § 2201 (2006); 35 U.S.C. §§ 156, 271, 282 (2006)).

³ The Hatch-Waxman Act created the Abbreviated New Drug Application (ANDA) process, which allows a generic manufacturer to rely on efficacy data provided by the branded manufacturer before bringing its product to market and greatly reduces the time to market. *Id.*

⁴ Sarah E. Eurek, *Hatch-Waxman Reform and Accelerated Market Entry of Generic Drugs: Is Faster Necessarily Better?*, 2003 DUKE L. & TECH. REV. 18, 18–19 (2003); see also Shawn Tully, *Why Drug Prices Will Go Lower*, FORTUNE, May 3, 1993, at 56.

research pharmaceutical companies that develop the branded drugs has been inestimable.⁵ By losing market exclusivity so soon after patent expiration,⁶ research pharmaceutical companies must employ other strategies, such as building brand recognition, to protect their market position and perpetuate a particular drug's profitability. By developing the reputation and goodwill of a national brand, these companies are able to capitalize on consumer loyalty and patients' desires for consistency and quality in their medications.

Protecting and perpetuating profits is essential to a pharmaceutical company's economic health and survival. These profits help provide the requisite capital for future research and development efforts, allowing pharmaceutical companies to continue developing pioneer drugs. However, even after overcoming the barriers to profitability involved in bringing drugs to market, many national brand drugs fail to become profitable.⁷ To mitigate the impact of generic competition, these research companies rely on the success of national direct-to-consumer advertising campaigns and branding strategies to build goodwill and earn consumer loyalty toward their branded drugs.⁸ As part of this strategy, pharmaceutical companies more frequently seek to build source-identifying significance in various properties of the drugs themselves, such as the color, shape, and texture, rather than merely promote the manufacturing source of the drug.

As an example of the significance of these properties, although Procter & Gamble Co.'s identity as the manufacturer of Pepto-Bismol® may not be generally known to the public, consumers readily associate a pink-colored liquid for stomach relief with the brand Pepto-Bismol®.⁹ Likewise, AstraZeneca markets Nexium® (a successor medication to Prilosec®) as "The Purple Pill."¹⁰ The entire branding strategy for Nexium®, a treatment for acid reflux disease, is built around the purple color of the pill.¹¹ Arguably, it is the recognition and association of these properties with a particular product—as opposed to the

⁵ Stacey L. Schreiber, *Dollars and Senses: Pharmaceutical Product Design is Becoming Vivid* (Apr. 2003), (unpublished, Harvard University DASH repository) (on file with the ckjip), http://dash.harvard.edu/bitstream/handle/1/8846778/Dollars_and_Senses.pdf ("A 1998 Congressional Budget Office Study found that since the enactment of Hatch-Waxman, the generic market share rose from 18.6% to 42.6%.") "This study examined drugs that comprise approximately 70% of prescription drug sales through retail pharmacies and considered drugs in the form of 'easily countable units.'" *Id.* at 4 n.4 (quoting Melissa C. Popolillo, *Government Study Reveals Generics' Impact on Industry*, DRUG STORE NEWS, Oct. 19, 1998, at CP20).

⁶ See Eureka, *supra* note 4, at 18–19.

⁷ Lynn M. Jordan, *Naming A Drug in Just One Colour: Trademark Protection for Organoleptic Properties of Pharmaceuticals*, TRADEMARK WORLD, Mar. 2001, at 28.

⁸ *Id.*

⁹ See *Norwich Pharmacal Co. v. Sterling Drug, Inc.*, 271 F.2d 569, 572 (2d Cir. 1959); PEPTO BISMOL, <http://www.pepto-bismol.com/> (last visited Feb. 26, 2013).

¹⁰ See PURPLE PILL, <http://www.purplepill.com/> (last visited Feb. 26, 2013).

¹¹ *Id.*

recognition and association of the product with a particular manufacturer—that has the primary impact in building the brand.

The long-term success of marketing strategies like these depends largely on these brands' ability to enforce proprietary rights in these particular properties, individually or collectively, under trademark and unfair competition laws.¹² However, in the context of prescription pharmaceuticals, various judicial decisions have eviscerated the scope of available protection for branded drugs in favor of permissible marketing of generic "look-alikes."¹³ There appears to be an overriding social concern that the public may be implicitly deceived as to the quality or efficacy of a generic alternative if it does not mimic the appearance of the branded prescription drug. The difficulty lies in striking a balance between the competing interests of national brands to trademark protection for source-identifiers on their products and the rights of generic labels to bring publicly accepted substitute drugs to market that earn the public's trust and confidence. Absent a stable and reliable body of law, both branded and generic manufacturers may be left with inadequate security or guidance for effective business planning with respect to advertising and branding schemes, a situation that will inevitably result in costly litigation and contribute to the rising cost of drugs.

This article explores the legal and social tension between the rights of national brand research companies to trade dress protection for their pioneer prescription drugs and the rights of private label, or generic, brands to market "look-alike" drugs once patents for the brands expire. Part I explores the impact of a generic brand's market entry on a national brand and the legal and social arguments for and against generic "look-alikes." Part II discusses the current legal standard for achieving exclusive protection for non-traditional source identifiers and for enforcing those rights. Part III discusses possible resolutions to the generic drug versus brand-name drug conflict.

¹² See generally *Qualitex Co. v. Jacobson Prods. Co.*, 514 U.S. 159, 165 (1995) (trademark protection extended to color provided it is nonfunctional and has acquired secondary meaning); *In re Morton-Norwich Prods., Inc.*, 671 F.2d 1332, 1335 (C.C.P.A. 1982) (trademark protection extends to shape and other product configurations provided they are nonfunctional); *In re N.V. Organon*, 79 U.S.P.Q.2d 1639 (T.T.A.B. 2006) (in case of first impression, TTAB found trademark protection extends to flavor provided it is nonfunctional and has acquired secondary meaning).

¹³ See *Shire US Inc. v. Barr Labs., Inc.*, 329 F.3d 348, 357 (3d Cir. 2003); see also, *TraFFix Devices, Inc. v. Mktg. Displays, Inc.*, 532 U.S. 23 (2001) (broadening the reach of the functionality doctrine and exempting a larger number of possible trade dresses from trademark protection); *Wal-Mart Stores Inc. v. Samara Bros.*, 529 U.S. 205, 215 (2000) (holding that product-design trade dress cannot be inherently distinctive but must acquire secondary meaning).

I. MARKET ENTRY OF GENERIC DRUGS AND ISSUES OF TRADE IDENTITY

“Congress passed the Hatch-Waxman Act of 1984 in an effort to promote innovation and competition in the pharmaceutical industry.”¹⁴ The Act seeks to facilitate market entry for generic copies of brand name pharmaceuticals, once the branded drug comes off patent protection.¹⁵ Under the Act’s Abbreviated New Drug Application (ANDA) process, “a generic manufacturer can begin experimenting on a patented drug before its expiration and seek to market a generic version of the patented drug.”¹⁶ The ANDA allows “generic manufacturers ‘to piggyback on the proprietary safety and effectiveness data submitted by the innovator to obtain approval from the [FDA] for the pioneer drug’,”¹⁷ which significantly reduces the required capital investment by generic manufacturers before bringing a “lower-cost alternative” to market.¹⁸ In bypassing the requirement to develop “safety and efficacy data,” generic manufacturers are able to compete more effectively.¹⁹ While the purpose of the Act is to provide lower-cost alternatives to consumers, the financial impact on research companies has been inestimable.²⁰

Since the passage of the Act, these research companies, who recover their research and development (R&D) costs through drug sales, are forced to compete against “the proliferation of generic drugs [that] has eroded sales in the very market they created.”²¹ To maintain commercial success and recover their R&D costs after generic entry,²² research companies must rely on consumer loyalty toward a particular brand given its reputation for quality and consistency. To build this brand loyalty, companies spend billions of dollars on marketing programs and promotional strategies.²³ Therefore, when a generic alternative

¹⁴ Brian Porter, Comment, *Stopping The Practice Of Authorized Generics: Mylan’s Effort To Close The Gaping Black Hole In The Hatch-Waxman Act*, 22 J. CONTEMP. HEALTH L. & POL’Y 177, 178 (2005).

¹⁵ *Id.* at 178.

¹⁶ *Id.* at 179.

¹⁷ *Id.*

¹⁸ *Id.* at 179–80.

¹⁹ *Id.* at 179.

²⁰ Schreiber, *supra* note 5, at 4 (discussing impact on brand-name market share upon generic entry to market).

²¹ Jordan, *supra* note 7, at 28. Consumer demand for generic drugs results from the assumption that they represent an equally effective, but less expensive, version of the national brand. It is the consumer’s association of a generic drug with the brand identity of the pharmaceutical drug that compels its purchase. In fact, consumers often purchase generics on the mistaken belief they are manufactured by the pharmaceutical brand itself. *See id.*

²² *Id.*

²³ Schreiber, *supra* note 5 (“In the year 2000, pharmaceutical companies spent \$2.5 billion on such marketing in the United States, and several promotional strategies aimed at the public have focused on appearance as well as function.”).

mimics the branded drug's appearance, research companies believe the generic product "free rides" on the national brand's hard-earned reputation and goodwill. It is precisely this circumstance that the trademark and unfair competition laws were designed to prevent.

Conversely, generic manufacturers argue that disallowing their products to mimic their branded counterparts is detrimental to patients and frustrates the purpose of the Hatch-Waxman Act. In *SK&F, Co. v. Premo Pharmaceutical Labs.*, the generic manufacturer argued in favor of producing products that mimic brand-name drugs as they are desirable "to facilitate identification of a particular medication of a particular strength";²⁴ "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";²⁵ that physicians may become "confused when trying to visually identify a prescription drug";²⁶ and that patients feel more confident taking a generic product when they believe it is chemically identical to the brand-name counterpart.²⁷ In essence, if the generic substitute does not look like the branded drug, then "patient confusion, resistance and anxiety will result."²⁸

SK&F's counter-arguments are illustrative of the position pharmaceutical companies generally take on this issue. As for the identification of drugs, SK&F submitted "testimony of physicians who stated that they would never rely upon trade dress as the sole means of identifying a prescription drug";²⁹ that patients would not reject generic drugs that do not mimic their brand-name counterparts as inferior because "most states require that a patient be informed of a generic substitution";³⁰ and finally, that because generic drugs may not be chemically identical to the national brand, assuming the same trade dress may send a deceptive message to the consumer.³¹ Because generic substitutes may differ in efficacy and absorption rates, to permit virtually indistinguishable generic "look-alikes" on the market runs the risk that a patient may unwittingly ingest a drug of potentially lower quality, one that has a different absorption rate in the bloodstream, or one that has different inactive ingredients that could potentially

²⁴ Aaron M. Pile, *What's in Your Bottle?: Shire US Inc. v. Barr Laboratories Inc. and its Effect of Prescription Drug Trade Dress Protection in the Third Circuit*, 5 U. PITT. J. TECH. L. & POL'Y 1, 10 (2004) (quoting *SK&F, Co. v. Premo Pharm. Labs., Inc.*, 625 F.2d 1055, 1060 (3d Cir. 1980)).

²⁵ *Id.*

²⁶ *Id.*

²⁷ *Id.*

²⁸ J. THOMAS MCCARTHY, MCCARTHY ON TRADEMARKS AND UNFAIR COMPETITION § 7:50 (4th ed. 2001).

²⁹ Pile, *supra* note 24, at 10.

³⁰ *Id.*

³¹ *Id.*

harm the consumer.³² Further, when product features have nothing to do with the utilitarian performance of the product (they have no biological, scientific, or medicinal value to the underlying product and do not contribute to the workability of the medication), they should always be available for commercial exploitation and protected under existing laws.

Indisputably, market entry of a generic drug profoundly impacts the pharmaceutical brand's market share. Given Congress' and the FDA's efforts to facilitate consumer trust and confidence in generic substitutions, the question of permissible "look-alikes" is laden with legal and public policy concerns. Both generic manufacturers and branded-drug manufacturers have numerous arguments in support of and against trade dress identity for generic drugs, and neither side appears to be retreating from its position any time soon.

II. LEGAL PROTECTION FOR ORGANOLEPTIC PROPERTIES OF PHARMACEUTICAL PRODUCTS

"Every drug that goes to market has organoleptic properties."³³ Organoleptic properties comprise those product features that may be perceived by the senses, such as color, shape, taste, and aroma.³⁴ Because these product features may be legally protectable by trademark and unfair competition laws,³⁵ pharmaceutical companies are able to exploit them as product source identifiers and build branding schemes around them.³⁶ However, this protection is not without limitation. As with more traditional source identifiers, organoleptic properties may receive federal trademark protection only if "they are both nonfunctional and distinctive of the applicant's goods."³⁷

³² The FDA requires generic drugs be "identical -- or bioequivalent -- to a brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use." *Generic Drugs: Questions and Answers*, U.S. FOOD AND DRUG ADMINISTRATION, <http://www.fda.gov/drugs/resourcesforyou/consumers/questionsanswers/ucm100100.htm> (last visited Feb. 14, 2013). According to the Supreme Court, generic drugs are bioequivalent "if, when administered in equal amounts to the same individual, they reach general circulation at the same relative rate and to the same relative extent." *Inwood Labs., Inc. v. Ives Labs., Inc.*, 456 U.S. 844, 848 n.5 (1982) (citing *REMINGTON'S PHARMACEUTICAL SCIENCES* 1368 (Arthur Osol & John E. Hoover eds., 15th ed. 1975)). Nonetheless, "name brand pharmaceutical companies may claim that their products remain superior due to an even higher quality standard than required by the government regulator." Schreiber, *supra* note 5, at 3 n.1 (citing *Am. Home Prods. Corp. v. Chelsea Labs., Inc.*, 572 F. Supp. 278, 280 (D.N.J. 1982)).

³³ Jordan, *supra* note 7.

³⁴ See *Organoleptic Definition*, DICTIONARY.COM, <http://dictionary.reference.com/browse/organoleptic> (last visited Feb. 14, 2013).

³⁵ Jordan, *supra* note 7; see *Organoleptic*, *supra* note 34.

³⁶ Jordan, *supra* note 7; see *Organoleptic*, *supra* note 34.

³⁷ Jordan, *supra* note 7; see *Organoleptic*, *supra* note 34.

Product manufacturers may seek trademark protection for individual product features *per se*, such as color³⁸ or flavor,³⁹ or alternatively, they may seek protection for the overall product configuration, which encompasses a product's trade dress.⁴⁰ Generally, a product's trade dress refers to the overall product design or packaging which serves to identify the product's source.⁴¹ The Supreme Court has broadly construed the realm of protectability as anything "human beings might use as a 'symbol' or 'device' ... that is capable of carrying meaning."⁴² Trade dress, according to the Court, "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."⁴³ As mentioned, however, to qualify for legal protection, the Court has stated (1) that a particular trade dress must be either inherently distinctive, or distinctive as a result of acquiring "secondary meaning;" (2) that there must be a likelihood of consumer confusion between the original producer's trade dress and the later producer's trade dress; and (3) that the original producer's trade dress must be nonfunctional.⁴⁴

Product trade dress plays a uniquely important role in the commercial success of pharmaceutical products, and particularly for prescription drugs. A consumer may easily distinguish between over-the-counter brand-name drugs and the generic alternatives at the point of purchase, because they are sold directly to consumers in unique packaging bearing the manufacturer's marks and designs.

However, the same is not true for prescription drugs. Pharmacists dispense the drugs to consumers in vials or packages without any unique markings, so the product design is the only means by which a patient may distinguish one medication from another. Similarly, numerous courts have distinguished prescription and over-the-counter drugs on the ground that a consumer makes a conscious choice between the national brand and the generic alternative based on packaging alone, well before inspecting the product itself.⁴⁵ With respect to prescription medications, the specific properties of the actual pill—size, shape, color, and texture—are "the only indication of source available to a patient, who is the ultimate consumer of prescription medication."⁴⁶ As such, protecting these source-identifying features in their

³⁸ *Qualitex Co. v. Jacobson Prods. Co.*, 514 U.S. 159, 161 (1995).

³⁹ *In re N.V. Organon*, 79 U.S.P.Q.2d 1639, 1648 (T.T.A.B. 2006).

⁴⁰ *Wal-Mart Stores Inc. v. Samara Bros.*, 529 U.S. 205, 205, 209 (2000).

⁴¹ *Id.*; see also Lanham Act § 43, 15 U.S.C. § 1125(a) (2012); Jordan, *supra* note 7.

⁴² *Wal-Mart*, 529 U.S. at 209.

⁴³ Pile, *supra* note 24 (citing *Two Pesos, Inc. v. Taco Cabana, Inc.*, 505 U.S. 763, 765 n.1 (1992)).

⁴⁴ *Wal-Mart*, 529 U.S. at 209.

⁴⁵ Whether point-of-consumption confusion or post-sale confusion may be an issue in the context of over-the-counter drugs is beyond the scope of this paper.

⁴⁶ Pile, *supra* note 24.

prescription drug products is very important to pharmaceutical companies, particularly to combat unfair competition from generic manufacturers who enter the market under deceptively similar trade dress.

Federal unfair competition law, codified in the Lanham Act, creates a private cause of action for various forms of infringement of trade identity, including traditional trademark and trade dress infringement.⁴⁷ Notably, Section 43(a)(1) of the Lanham Act states:

Any person who, on or in connection with any goods or services, or any container for goods, uses in commerce any word, term, name, symbol, or device, or any combination thereof, or any false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which—

(A) is likely to cause confusion, or to cause mistake, or to deceive as to the affiliation, connection, or association of such person with another person, or as to the origin, sponsorship, or approval of his or her goods, services, or commercial activities by another person, or

(B) in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities,

shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such act.⁴⁸

Section 43(a)(3) clarifies the reach of 43(a) to include a private cause of action for unauthorized third-party use of trade dress.⁴⁹

A. The Element of Distinctiveness: Inherent or Acquired

Marks are organized into a classification system, ranging from weakest to strongest. Protectable marks may be inherently distinctive of a particular product, or they may acquire distinctiveness, or secondary meaning, through consumer recognition.⁵⁰ Trademark law only grants protection to those source identifiers that are distinctive of the underlying goods or services,⁵¹ unlike generic terms, or those that actually identify the product, which are the weakest of all marks and are not protectable by trademark. Marks that have no meaning other than that of a source-identifier, where their “intrinsic nature serves to identify a particular source,”⁵² are deemed inherently distinctive and accorded the broadest scope of protection. Such marks are classified as suggestive, arbitrary or fanciful.

⁴⁷ Lanham Act, § 43(a), 15 U.S.C. § 1125(a) (2012).

⁴⁸ *Id.*

⁴⁹ *Id.*

⁵⁰ *Id.*

⁵¹ Pile, *supra* note 24 (introducing categories of distinctiveness (citing *Abercrombie & Fitch Co. v. Hunting World, Inc.*, 537 F.2d 4, 9 (2d Cir. 1976))).

⁵² *Two Pesos, Inc. v. Taco Cabana, Inc.*, 505 U.S. 763, 768 (1992).

Suggestive marks merely “suggest” a quality of the underlying goods or services, but do not readily invoke the image of the product in the mind of the consumer without the imagination.⁵³ Well-known suggestive marks include The North Face® for outerwear and The Home Depot® for home improvement products and services. Arbitrary marks are known words used in a purely arbitrary manner, such as Amazon® for a bookstore and Camel® for cigarettes. Fanciful marks, the strongest of all trademarks, are coined words having no-meaning other than that of a product name. Examples include ExxonMobil® for petroleum and Kodak® for photography goods and services.

Alternatively, descriptive marks, which convey “an immediate idea of the ingredients, qualities or characteristics of the goods,” are not inherently distinctive.⁵⁴ They may, however, achieve protectability upon acquiring secondary meaning by showing that the consumer associates the mark with a particular source,⁵⁵ though this level of protection is of a narrower scope. Secondary meaning may be proved by submitting evidence relating to the following four (4) factors: “(1) [t]he length and manner of use; (2) the nature and extent of advertising and promotion; (3) the efforts made by the plaintiff to promote a conscious connection in the public’s mind between the name and the plaintiff’s ... business; and (4) the extent to which the public actually identifies the name with the plaintiff’s [goods or] service[s].”⁵⁶

Unlike traditional word marks, product features and trade dress are not as easily categorized according to this classification system. As evidence of this difficulty, the courts were split for many years as to whether trade dress could ever be inherently distinctive or protected only upon achieving secondary meaning. In 1992, the Supreme Court resolved the question in *Two Pesos, Inc. v. Taco Cabana* by construing the distinctiveness element of Section 43(a) of the Lanham Act to allow for the possibility of a product’s trade dress to be inherently distinctive and thus “capable of identifying the source of the product, thereby rendering unnecessary the requirement of establishing secondary meaning.”⁵⁷ The court reasoned this to be the proper holding because

“[e]ngrafting onto § 43(a) a requirement of secondary meaning for inherently distinctive trade dress ... would undermine the purposes of the Lanham Act given Congress’ intent in passing the Lanham Act. Protection of trade dress, no less than of trademarks, serves the Act’s purpose to secure

⁵³ MCCARTHY, *supra* note 28, §11:67; *Playtex Prods., Inc. v. Georgia-Pacific Corp.*, 390 F.3d 158, 163, (2d Cir. 2004) (“A suggestive mark is one that suggests that product, though it may take imagination to grasp the nature of the product.”).

⁵⁴ MCCARTHY, *supra* note 28, § 11:67 (quoting *Stix Prods., Inc. v. United Merchs. & Mfrs., Inc.*, 295 F. Supp. 479, 488 (S.D.N.Y. 1968)).

⁵⁵ See Lanham Act § 43(a), 15 U.S.C.A. § 1125(a) (2012); see also *Investacorp, Inc. v. Arabian Investment Banking Corp.*, 931 F.2d 1519, 1523 (11th Cir. 1991).

⁵⁶ *Investacorp*, 931 F.2d at 1525 (quoting *Conagra, Inc. v. Singleton*, 743 F.2d 1508, 1513, (11th Cir.1984)).

⁵⁷ *Two Pesos*, 505 U.S. at 775.

to the owner of the mark the goodwill of his business and to protect the ability of consumers to distinguish among competing producers. National protection of trademarks is desirable, Congress concluded, because trademarks foster competition and the maintenance of quality by securing to the producer the benefits of good reputation.”⁵⁸

In 2000, eight (8) years after *Two Pesos*, the Court revisited the distinctiveness element of trade dress in *Wal-Mart v. Samara Bros.*⁵⁹ In considering an infringement action for unregistered trade dress⁶⁰ covering clothing designs, the *Wal-Mart* court distinguished the *Two Pesos* holding on the ground that although *Two Pesos* “unquestionably establishe[d] the legal principle that trade dress can be inherently distinctive,” it did not establish that every species of trade dress, and specifically product-design trade dress, can be inherently distinctive.⁶¹ Because the trade dress at issue in *Two Pesos*, restaurant décor, did not constitute product-design trade dress, the Court held that product-design trade dress cannot be inherently distinctive, but must acquire secondary meaning to qualify for trade dress protection.⁶²

Trade dress protection with regard to prescription drugs is limited to the organoleptic properties of the pills, themselves, as they generally lack unique product packaging. Applying *Two Pesos* to prescription drugs, courts have considered numerous factors in determining whether products have acquired secondary meaning.⁶³ To assess whether a drug’s unique appearance has achieved secondary meaning,⁶⁴ courts have considered “factors such as

⁵⁸ *Id.* at 774.

⁵⁹ *Wal-Mart Stores Inc. v. Samara Bros.*, 529 U.S. 205, 205 (2000).

⁶⁰ Unregistered marks may serve as the basis for a § 43(a) claim for trademark or trade dress infringement. 15 U.S.C. § 1125(a) (2012). However, “plaintiff using §43(a) as a basis for a claim of infringement of an unregistered mark is unaided by any presumption of validity attaching to a federally registered mark.” MCCARTHY, *supra* note 28, § 27.18.

⁶¹ *Wal-Mart*, 529 U.S. at 205.

⁶² *Id.* See generally *Two Pesos, Inc. v. Taco Cabana, Inc.*, 505 U.S. 763, 763 (1992).

⁶³ This standard is inapplicable in the context of over-the-counter medications since they are generally sold in specific packaging, which is separate and distinct from the product itself.

⁶⁴ *Schreiber*, *supra* note 5; see *Florida Breckenridge, Inc. v. Solvay Pharm., Inc.*, 1997 U.S. Dist. LEXIS 17574, at *11–15, 43 U.S.P.Q.2D (BNA) 1878 (S.D. Fla. July 3, 1997) (finding that while the overall appearance is distinctive and arbitrary, third party use of similar combinations weighs against a finding of inherently distinctive trade dress).

extensive sales of a product with a particular trade dress,⁶⁵ extensive marketing,⁶⁶ widespread distribution of starter kits,⁶⁷ and consumer surveys.”⁶⁸ Courts have also found that competitor copying of the branded drug’s trade dress may provide sufficient or strong evidence of secondary meaning. In *Ciba-Geigy v. Bolar Pharm. Co.*, the “district court reasoned that a product’s appearance would not be copied if it had no value, and it is this value that translates into secondary meaning.”⁶⁹ In *Par Pharmaceutical v. Searle Pharmaceuticals*, the court stated that copying alone may be insufficient to show secondary meaning, albeit constituting strong evidence thereof.⁷⁰

B. Likelihood of Confusion

The cornerstone of trademark infringement is whether consumers are likely to be confused or deceived as to the source or sponsorship of a particular product in the marketplace.⁷¹ Like other product designers, research pharmaceutical companies find themselves in a perpetual battle with generic manufacturers who sell “look-alike,” or confusingly similar, products and undercut their market share. Because consumers tend to draw conclusions regarding the source of products from the “producers’ marks and packaging ... [and] ... through the appearance of the products themselves,”⁷² when a third-

⁶⁵ Schreiber, *supra* note 5, at 7; *see also* Am. Home Prods. Corp. v. Chelsea Labs., Inc., 572 F. Supp. 278, 281 (D.N.J. 1982) (finding that unique trade dress plus long usage, alone, can establish secondary meaning); *Ciba-Geigy Corp. v. Bolar Pharm. Co., Inc.*, 547 F. Supp. 1095, 1113 (D.N.J. 1982) (finding that the blue and white opaque capsules and pink and white opaque capsules were sufficiently recognizable and had attained secondary meaning (citing *Processed Plastic Co. v. Warner Commc’ns, Inc.*, 675 F.2d 852, 856 (7th Cir. 1982))).

⁶⁶ Schreiber, *supra* note 5, at 8; *see* Boehringer Ingelheim G.m.b.H. v. Pharmadyne Labs., 532 F. Supp. 1040, 1056 (D.N.J. 1980) (ruling that marketing expenses of over \$15 million promoting both the drug’s trademark and orange-colored, smoothly rounded biconvex trade dress was “highly persuasive evidence” of secondary meaning); *Par Pharm., Inc. v. Searle Pharm., Inc.*, 1985 U.S. Dist. LEXIS 16648, at *7–8, 227 U.S.P.Q. (BNA) 1024, (N.D. Ill. Aug. 20, 1985) (holding that evidence of a \$2,000,000 spent of marketing of a particular blue-colored tablet was one of several factors which made a claim of secondary meaning likely to succeed at trial).

⁶⁷ *See* *McNeil-PPC, Inc. v. Granutec, Inc.*, 919 F. Supp. 198, 202 (E.D.N.C. 1995).

⁶⁸ Schreiber, *supra* note 5.

⁶⁹ *Ciba-Geigy Corp. v. Bolar Pharm. Co., Inc.*, 747 F.2d 844, 856–57 (3d Cir. 1984) (demonstrating the temporal legal argument that secondary meaning may be evinced when a valuable product appearance is copied).

⁷⁰ Schreiber, *supra* note 5, at 9; *see Par Pharm.*, 1985 U.S. Dist. LEXIS 16648, at *9–10; *see also* *McNeil-PPC*, 919 F. Supp. at 202 (holding that copying alone leads only to a presumption of secondary meaning, but evidence of copying plus a survey of secondary meaning would likely succeed to show secondary meaning in a trial on the merits).

⁷¹ Lanham Act § 2(d), 15 U.S.C. § 1052(d) (2012).

⁷² Schreiber, *supra* note 5.

party producer copies the appearance, or trade dress, of the original producer's product, the imitation is likely to cause consumer confusion as to its source or "cause consumers falsely to assume an affiliation between the producers. [It is t]his potential consumer confusion ... that the Lanham Act ... seeks to prevent."⁷³ Whether due to medical conditions, such as poor eyesight, or merely due to inadequate consumer sophistication, it is reasonable to conclude that some consumers purchase generics on the mistaken belief they are actually manufactured by the same company that produces the pioneer drug.⁷⁴

Nearly every judicial circuit has developed a test to decide the confusion question, based in most part on the thirteen (13) factors set forth by the Federal Circuit in *In re E.I. Du Pont de Nemours & Co.*⁷⁵ Some factors of this confusion test include the similarity or dissimilarity of the marks or source-identifiers, the similarity or dissimilarity of the goods or services on which the marks or source-identifiers are used, and the similarity or dissimilarity of trade channels for the

⁷³ *Id.* at 15, 17.

⁷⁴ Jordan, *supra* note 7.

⁷⁵ *In re E. I. DuPont DeNemours & Co.*, 476 F.2d 1357, 1361 (C.C.P.A. 1973). The thirteen (13) factors are:

- 1) The similarity or dissimilarity of the marks in their entireties as to appearance, sound, connotation and commercial impression.
- 2) The similarity or dissimilarity and nature of the goods or services as described in an application or registration or in connection with which a prior mark is in use.
- 3) The similarity or dissimilarity of established, likely-to-continue trade channels.
- 4) The conditions under which and buyer to whom sales are made, i.e., "impulse" vs. careful, sophisticated purchasing.
- 5) The fame of the prior mark (sales, advertising, length of use).
- 6) The number and nature of similar marks in use on similar goods.
- 7) The nature and extent of any actual confusion.
- 8) The length of time during and conditions under which there has been concurrent use without evidence of actual confusion.
- 9) The variety of goods on which a mark is or is not used (house mark, "family" mark, product mark).
- 10) The market interface between applicant and the owner of a prior mark:
 - a) a mere "consent" to register or use.
 - b) agreement provisions designed to preclude confusion, i.e., limitation on continued use of the marks by each party.
 - c) assignment of mark, application, registration and good will of the related business.
 - d) laches and estoppel attributable to owner of prior mark and indicative of lack of confusion.
- 11) The extent to which applicant has a right to exclude others from use of its mark on its goods.
- 12) The extent of potential confusion, i.e., whether *de minimis* or substantial.
- 13) Any other established fact probative of the effect of use.

goods or services.⁷⁶ As a general rule, the more similar the marks, the more similar the goods, and the more similar the trade channels, the greater the chances a court will find a likelihood of confusion.

Not surprisingly, courts have often found that a likelihood of confusion exists when the generic alternative is identical or highly similar to the national brand.⁷⁷ Under this standard, a generic “look-alike” will nearly always infringe the pioneer drug’s trade dress, provided it is both distinctive and nonfunctional. When generic brands are brought to market, the underlying products are intentionally identical or nearly identical⁷⁸ to the pioneer brand. In fact, federal regulations require therapeutic identity of the products before the generic brand can obtain market entry.⁷⁹ Therefore, when applying the confusion test to branded drugs and generic drugs, because the underlying goods (drugs) and trade channels (dispensed by pharmacists) are the same, when the products have identical or highly similar distinctive trade dresses, the test necessarily demands a finding of a likelihood of confusion.⁸⁰

This inevitability poses an interesting issue unique to the prescription drug industry. Generic manufacturers have asserted several arguments that the medicinal identity of the generic substitute should extend beyond bioequivalence to the overall appearance of the pill, because there is a material public benefit to “look-alike” products⁸¹ when the consumer associates the pill’s appearance with that medicinal identity. First, if national brand manufacturers are permitted to monopolize (potentially in perpetuity) the appearance of any one particular drug, the generic brand could be barred from copying those features. This may be problematic in those instances where there is arguably a salutary effect on consumers when generics replicate the look and feel of the national brand. Absent an identity of trade dress, consumers may be implicitly deceived into believing the generic alternative is inferior, which could undermine a patient’s “psychological acceptance” of a generic substitute, thereby frustrating the purpose of facilitating public access to generic medications.⁸²

For example, in *Boehringer Ingelheim G.m.b.H. v. Pharmadyne Labs.*,⁸³ the generic manufacturer argued that its product must be similar in appearance to the brand-name product in order to avoid patient anxiety arising from

⁷⁶ *Id.*

⁷⁷ Schreiber, *supra* note 5.

⁷⁸ *See* Jordan, *supra* note 7.

⁷⁹ *Id.*

⁸⁰ Schreiber, *supra* note 5, at 17 (distinguishing point-of-consumption and point-of-purchase confusion).

⁸¹ *SK&F, Co. v. Premo Pharm. Labs., Inc.*, 625 F.2d 1055, 1067 (3d Cir. 1980).

⁸² *See generally* The Hatch-Waxman Act, *supra* note 3 and accompanying text.

⁸³ *Boehringer Ingelheim G.m.b.H. v. Pharmadyne Labs.*, 532 F. Supp. 1040, 1046 (D.N.J. 1980).

substituting a generic drug for the brand-name drug.⁸⁴ Such similarities would enable patients who take numerous medications to discriminate between them based on size, shape, color, and texture. This organoleptic equivalence would also facilitate identification of a particular drug in an emergency situation.⁸⁵

Given the public interest factor, the relevant question may be the converse of the traditional confusion case: whether consumers may be implicitly deceived into believing the generic brand is inferior in quality to the national brand unless it looks like the original brand, versus whether the generic brand is seeking to free-ride on the branded drug's goodwill or pass itself off as the original brand. An affirmative answer may erode the public's confidence in the less expensive generic alternative, an outcome contrary to the public interest. Because the likelihood of confusion analysis does not consider this patient acceptance argument, in order to avoid a finding of likelihood of confusion, sympathetic courts appear to be broadening the application of the functionality doctrine, which necessarily reduces the scope of rights national brands may assert in their respective trade dresses.⁸⁶ By finding a wider range of trade dresses functional and therefore not protectable under the Lanham Act, fewer generic "look-alikes" will be deemed confusingly similar to their corresponding branded drugs and may therefore permissibly co-exist with the national brands at market.

C. Functionality

In addition to establishing acquired distinctiveness and a likelihood of confusion, companies must show their product designs are nonfunctional to achieve statutory protection.⁸⁷ Only nonfunctional product features may be protected by trademark or trade dress.⁸⁸ The functionality doctrine seeks to prevent monopolization by manufacturers of useful and publicly desirable features, thus pushing these features into the realm of patent protection.⁸⁹ The theory presupposes that allowing one producer to monopolize a useful product feature would be tantamount to unfair competition.⁹⁰

What constitutes a nonfunctional product feature, however, has become a great source of juridical debate. The Supreme Court has handed down few decisions on product functionality and none provide a particularly clear roadmap

⁸⁴ *Id.* at 1046–47; *see also* MCCARTHY, *supra* note 28. *See generally* Inwood Labs., Inc., v. Ives Labs., Inc., 456 U.S. 844, 847 n.4 (1982).

⁸⁵ *Boehringer*, 532 F. Supp. at 1046–47.

⁸⁶ *See* TrafFix Devices, Inc. v. Mktg. Displays, Inc., 532 U.S. 23, 33 (2001); *see also* Shire US Inc. v. Barr Labs., Inc., 329 F.3d 348, 358–59 (3d Cir. 2003).

⁸⁷ *See* Valu Eng'g, Inc. v. Rexnord Corp., 278 F.3d 1268, 1278–79 (Fed. Cir. 2002).

⁸⁸ For a discussion of the theories of this doctrine *see generally* Margreth Barrett, *Consolidating the Diffuse Paths to Trade Dress Functionality: Encountering TrafFix on the Way to Sears*, 61 WASH. & LEE L. REV. 79 (2004).

⁸⁹ *See* Valu Eng'g, 278 F.3d at 1273.

⁹⁰ *Id.*

for the lower courts.⁹¹ Some courts have held that a nonfunctional product feature is one that serves no purpose other than source identification,⁹² while others posit a product feature is nonfunctional if it does not need to be used by competitors to compete effectively.⁹³ Additionally, some courts have found a product feature nonfunctional provided it is not vital to the commercial success of the product.⁹⁴ Moreover, the mixed bag of functionality standards applied in district and appellate court decisions is further evidence of this legal minefield.⁹⁵ While these various decisions have historically favored branded manufacturers,⁹⁶ recent decisions reveal an increased judicial hesitation to granting overly broad protection to trade dress.

In 2001, the Supreme Court's famous *TrafFix Devices, Inc. v. Mktg. Displays, Inc.* decision greatly reined in an ever-broadening view of trade dress protection for product features and product design by expanding the reach of the

⁹¹ See *TrafFix*, 532 U.S. at 33 (court adopted a two-step approach to functionality by reaffirming the "traditional rule" of *Inwood* that a product feature is "functional when it is essential to the use or purpose of the device or when it affects the cost or quality of the device," and then, if nonfunctional under the traditional rule, a product may still be functional if excluding copying would have an anti-competitive effect); *Qualitex Co. v. Jacobson Prods. Co.*, 514 U.S. 159, 165 (1995) (in determining whether color per se is functional, court expanded the "traditional rule" set forth in *Inwood* and re-characterized it by stating that "'a product feature 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,' that is, if exclusive use of the feature would put competitors at a significant non-reputation-related disadvantage"); *Inwood Labs., Inc., v. Ives Labs., Inc.*, 456 U.S. 844, 850 n.10 (1982) (although court did not reach functionality issue, it stated that "a product feature 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," later characterized by the court as the "traditional rule" of functionality); *Kellogg Co. v. Nat'l Biscuit Co.*, 305 U.S. 111, 122 (1938) (feature must affect the cost or quality of the product to be functional); Barrett, *supra* note 88, at 85–110.

⁹² Barrett, *supra* note 88, at 96.

⁹³ *Id.* at 102.

⁹⁴ See *Inwood*, 456 U.S. at 863 (White, J., concurring).

⁹⁵ See *supra* notes 91–94.

⁹⁶ See, e.g., *SK&F, Co. v. Premo Pharm. Labs., Inc.*, 625 F.2d 1055, 1060 (3d Cir. 1980) (adoption of maroon-and-white capsule was arbitrary, having nothing to do with the purpose of performance of the drug, or with its processing); *A.H. Robins Co. v. Med. Chest Corp.*, 1980 U.S. Dist. LEXIS 14412, at *3–6, 206 U.S.P.Q. (BNA) 1015, 1018 (E.D. Mo. 1980) (a round, light-blue tablet, convex on both sides and shiny in appearance, is an arbitrary configuration and nonfunctional); *Hoffman La Roche, Inc., v. Premo Pharm. Lab., Inc.*, 1980 U.S. Dist. LEXIS 16851, at *40–41, 210 U.S.P.Q. (BNA) 374, 386 (D.N.J. 1980) (the trade dress consisting of the use of a capsule in the distinctive color of light green is nonfunctional and does not enhance the efficacy of the medication); see also *Merck & Co. v. Par Pharm., Inc.*, 770 F.2d 1072 (3d Cir.) (unpublished), *cert. denied*, 474 U.S. 981 (1985) (blue-and-white drug capsule is nonfunctional). *But see Ives Labs., Inc. v. Darby Drug Co.*, 601 F.2d 631, 643 (2d Cir. 1979).

functionality doctrine.⁹⁷ Invoking its decision in *Wal-Mart v. Samara Bros.* the prior year, the court cautioned that “product design almost invariably serves purposes other than source identification.”⁹⁸ In fact, one commentator has summarized the Court’s holding as follows:

“Trade dress protection must subsist with the recognition that in many instances there is no prohibition against copying goods and products. In general, unless an intellectual property right such as patent or copyright protects an item, it will be subject to copying. As the Court has explained, copying is not always discouraged or disfavored by the laws which preserve our competitive economy ... Allowing competitors to copy will have salutary effects in many instances.”⁹⁹

Prior to *TrafFix*, courts generally applied one or more of three (3) general standards to determine product feature functionality: the “role of the feature” standard, the “practical effect” standard, and the “important ingredient” standard.¹⁰⁰ The “role of the feature” standard examines the actual role the feature plays within the product.¹⁰¹ The strictest approach, this standard finds a feature to be functional if it plays a material or important role in the use or purpose of the product, or affects the product’s cost or quality.¹⁰² As a result, only arbitrary or incidental features that serve as source identifiers may be protected.¹⁰³

The “practical effect” standard differs by precluding the recognition of trademark rights only when the particular design at issue affords benefits that are not practically available to third-parties through alternative designs.¹⁰⁴ This standard, which is much more liberal than the “role of the feature” approach, evaluates the likely anticompetitive impact of product trade dress protection in any given case.¹⁰⁵ Courts will deny protection only if it will significantly impair competition.¹⁰⁶ As a result, features that play a material or important role may still be protected by trade dress under this standard, provided no competitive impairment arises as a result of prohibiting competitors from copying the product feature.

Historically, the majority of appellate courts and the United States Patent and Trademark Office adopted the “practical effect” approach using various

⁹⁷ See *TrafFix Devices, Inc. v. Mktg. Displays, Inc.*, 532 U.S. 23, 30 (2001) (discussing the Sixth Circuit’s expansive view of trade dress); see also Barrett, *supra* note 88, at 82–83.

⁹⁸ *TrafFix*, 532 U.S. at 29.

⁹⁹ *Id.*

¹⁰⁰ Barrett, *supra* note 88, at 83.

¹⁰¹ *Id.* at 95.

¹⁰² *Id.* at 97.

¹⁰³ *Id.* at 93.

¹⁰⁴ *Id.* at 95.

¹⁰⁵ *Id.* at 93–94.

¹⁰⁶ *Id.* at 95.

formulations for measuring what constitutes “practical effect.”¹⁰⁷ With this standard, there appears to be a large emphasis on availability of alternate product features that would provide competitors with an equally effective product. The famed *In re Morton-Norwich Products, Inc.* case is among the “practical effect” cases.¹⁰⁸

In *Morton-Norwich*, the court set forth the distinction between *de facto* functionality and *de jure* functionality.¹⁰⁹ If a product feature is *de facto* functional, although it may have some utility other than source identification, e.g. it has some function, it may still be deemed legally nonfunctional and therefore protectable.¹¹⁰ However, if a product feature is *de jure* functional, it means that the product has a particular design because it actually works better with that design, and as such is deemed legally functional and not protectable.¹¹¹ Under *Morton-Norwich*, to determine whether a product feature is *de jure* functional, a court may apply the following factors:

- (1) the existence of a utility patent disclosing the utilitarian advantages of the design;
- (2) advertising materials in which the originator of the design touts the design’s utilitarian advantages;
- (3) the availability of competitors of functionally equivalent designs; and
- (4) facts indicating that the design results in a comparatively simple or cheap method of manufacturing the product.¹¹²

The “important ingredient” standard inquires whether “the product feature at issue is an important ingredient in the commercial success of the product.”¹¹³ This standard is stricter than the “practical effect” standard, and may or may not be stricter than the “role of the feature” standard. It is the least used and has been highly criticized by numerous courts.¹¹⁴ It places an emphasis on a consumer’s perceptions and motivation in purchasing the product at issue rather than analyzing the interrelationship of the feature with the product as a whole.

Despite the majority trend to adopt the “practical effect” standard, the *TrafFix* court adopted the “role of the feature” standard, with a “practical effect” analysis to be used as a back-up inquiry to further exclude some product features from trade dress protection.¹¹⁵ The court ignores the “important ingredient” standard as a reason for a finding of nonfunctionality. This hybrid approach

¹⁰⁷ *Id.* at 99.

¹⁰⁸ *Id.*

¹⁰⁹ *Id.* at 100.

¹¹⁰ *Id.* at 101.

¹¹¹ *In re Morton-Norwich Prods., Inc.*, 671 F.2d 1332, 1341 (C.C.P.A. 1982).

¹¹² *Valu Eng’g, Inc. v. Rexnord Corp.*, 278 F.3d 1268, 1274 (Fed. Cir. 2002) (citing *Morton-Norwich*, 671 F.2d at 1340–41).

¹¹³ Barrett, *supra* note 88, at 105 (quoting *Pagliero v. Wallace China Co.*, 198 F.2d 339, 343 (9th Cir. 1952)).

¹¹⁴ *Id.* at 104–06.

¹¹⁵ See *TrafFix Devices, Inc. v. Mktg. Displays, Inc.*, 532 U.S. 23, 34 (2001).

favors weak trade dress protection and greatly expands the reach of the functionality doctrine. Unfortunately, the court's inconsistent interpretation of product functionality has inevitably caused frustration, confusion, and unpredictability with respect to protection of pharmaceutical trade dress.

The Third Circuit's 2003 decision in *Shire US Inc. v. Barr Laboratories, Inc.* exemplifies this unpredictability.¹¹⁶ In *Shire*, the Third Circuit distinguished its prior precedent for showing the nonfunctionality of pharmaceutical trade dress.¹¹⁷ In affirming the district court's denial of a preliminary injunction against a generic drug's "imitative" coloring of Adderall®,¹¹⁸ the court significantly broadened the reach of the functionality doctrine, making it increasingly difficult to achieve proprietary rights in pharmaceutical trade dress.¹¹⁹ To support its holding that the blue and orange colors of the branded-drugs "were functional in identifying correct dosage and promoting patient acceptance of a generic substitution,"¹²⁰ the court cited U.S. Supreme Court decisions which "caution against the over-extension of trade dress protection"¹²¹ as well as recent FDA amendments that promote the marketing of generic substitutions.¹²² Strangely, the court's holding, which reversed its prior decision in *SK&F*,¹²³ appears to rest more on its opinion that the physical similarities between the generic and brand-name drug "materially benefitted the patient population" by promoting patient acceptance rather than an application of the legal standard for functionality announced in *Traffix*.¹²⁴ The court's opinion seems to read as if the court wrote to a desired conclusion rather than follow an established legal path to a just result.

This decision significantly undermined the reliability and predictability of trade dress jurisprudence. Strangely, the *Shire* court appears uncharacteristically sympathetic to generic manufacturers' formerly unsuccessful arguments as to why trade dress is nearly always functional and therefore available for permissible imitation.¹²⁵ Before *Shire*, such arguments were routinely rejected.¹²⁶ With its decision, the court disrupted settled law and raised numerous legal and public policy questions regarding the competing rights and responsibilities of brand name companies and their generic bioequivalents. A decade later, these questions remain.

¹¹⁶ *Shire US Inc. v. Barr Labs., Inc.*, 329 F.3d 348, 356 (3d Cir. 2003).

¹¹⁷ *Id.*; see also MCCARTHY, *supra* note 28.

¹¹⁸ *Shire*, 329 F.3d at 359.

¹¹⁹ *Id.* at 353–54.

¹²⁰ MCCARTHY, *supra* note 28; *Shire*, 329 F.3d at 357.

¹²¹ *Shire*, 329 F.3d at 358. The court also referred to the 1999 Lanham Act amendment shifting the burden to prove nonfunctionality of unregistered trade dress to the plaintiff. *Id.* at 354 n.13 (citing 15 U.S.C. 1125(a)(3) (2000)).

¹²² *Id.*

¹²³ *SK&F, Co. v. Premo Pharm. Labs., Inc.*, 625 F.2d 1055, 1068 (3d Cir. 1980).

¹²⁴ *Shire US Inc. v. Barr Labs., Inc.*, 329 F.3d 348, 359 (3d Cir. 2003).

¹²⁵ See *id.*; see also MCCARTHY, *supra* note 28.

¹²⁶ *Shire*, 329 F.3d at 359; see also MCCARTHY, *supra* note 28.

III. POSSIBLE RESOLUTION TO THE CONFLICT

This is a classic Mexican stand-off.¹²⁷ In the post-*Shire* legal environment, generic and branded manufacturers are left without a bright-line rule or consistent legal standard regarding the scope of protection available for pharmaceutical trade dress. Although *Shire* stands alone as Third Circuit precedent, it announced a policy change that is far more antagonistic to pharmaceutical companies than prior decisions. However, given its inherent limitations,¹²⁸ generic manufacturers should be cautious before entering the market with a “look-alike” drug. A successful infringement suit could prove fatal to a particular product’s commercial viability. For example,

“[I]osing the battle over a particular color can be costly for a generic manufacturer even above the costs of legal fees and/or damage awards; if a generic manufacturer receives FDA approval for a look-alike medication with certain color dyes and is subsequently barred from manufacturing the drug in that color, then the generic must seek FDA re-approval for the drug’s different color additives before being able to reenter the market.”¹²⁹

Perhaps given the nature of the conflict in this area, traditional trade dress protection may be inadequate to ameliorate the concerns of both camps. Solutions aimed to bring more stability and predictability in this area range from the elimination of trade dress protection for pharmaceuticals altogether to customizing the trade dress framework to the prescription drug industry.¹³⁰ A modified approach would exclude prescription pharmaceuticals from the traditional trade dress rubric in favor of a *sui generis* model better suited to the prescription drug industry.¹³¹ Such a framework would eliminate the distinctiveness requirement,¹³² reduce the role of the functionality requirement,¹³³ establish a modified test for determining likelihood of consumer

¹²⁷ See *Mexican stand-off Definition*, DICTIONARY.COM, <http://dictionary.reference.com/browse/mexicanstand-off> (last visited Feb. 14, 2013).

¹²⁸ Inevitably, pharmaceutical companies will seek to distinguish *Shire* on its facts and argue its jurisdictional limitations.

¹²⁹ Schrieber, *supra* note 5, at 48 (citing Telephone Interview with Robert E. Lee, Jr., Asst. Gen. Pat. Coun., Law Div., Eli Lilly & Co. (Jan. 3, 2003)).

¹³⁰ Pile, *supra* note 24, at 7.

¹³¹ *Id.* A new framework would take into consideration the peculiarities and idiosyncrasies of the prescription drug industry.

¹³² *Id.* at 8. Given the period of exclusivity afforded a national brand during the patent period, consumers are likely to recognize a particular brand by its specific properties. Such recognition would replace the requirement to establish secondary meaning under the traditional framework.

¹³³ *Id.* Functionality would be limited to those features that qualify for design patent protection. “For example, an improved coating that would allow capsules to be swallowed more easily, or could provide more control over the time-release medication, may be sufficient to obtain such a patent.” *Id.* at 20.

confusion,¹³⁴ consider the intent of the generic manufacturer,¹³⁵ and broaden the notification requirement of generic substitutions under applicable state law.¹³⁶

While *sui generis* protection is not a panacea, it may restore balance, predictability, and consistency to trade dress jurisprudence. Both research pharmaceutical companies and generic manufacturers would have increased security and guidance for effective business planning, implementing marketing programs, making branding decisions, and considering overall strategies for commercial success.

CONCLUSION

When it comes to the pharmaceutical market, the expiration of patents on brand name drugs, coupled with the production of generic drugs, initiates a series of legal questions concerning the trade dress protection accorded established brands. If a generic drug organoleptically resembles a branded drug, does the generic “piggyback” on the reputation of the branded, creating unfair competition and constituting infringement upon the brand’s nonfunctional identifiers? If the generic is not allowed to resemble the branded, does the dissimilarity negatively impact the consumer’s impression of the generic’s efficacy, thus damaging the public good? Does the dissimilarity cause confusion in the consumer, negatively impacting a possible salutary effect? Does a strong similarity cause confusion in violation of the Lanham Act?

There are no clear-cut answers to these questions, and the hypothetical arguments posed in response to them can quickly become circular, with both sides claiming to hold superior legal and social positions. With a lack of consistent judicial decisions, further clarification, possibly through a *sui generis* model, is needed for improved predictability and balance. Without dependable guidelines, the business models of both national brand and generic manufacturers suffer from uncertainty and confusion, resulting in loss of security, profits, and quality of service to the consumer.

¹³⁴ *Id.* A new likelihood of confusion standard would distinguish between identical and similar trade dresses. Where the trade dresses are identical, the traditional analysis would apply. However, where the trade dresses are merely similar (yet, potentially confusingly so), factors such as bioavailability, or the quantity of active ingredients released into the bloodstream, and equivalence of inactive ingredients would be taken into consideration.

¹³⁵ *Id.* at 9.

¹³⁶ *Id.* In most states, the law requires consumers be notified before substituting a generic brand for a national brand drug. Under this new regime, this notification requirement would be expanded to require patients to acknowledge such notification in writing. Such a writing may establishing *prima facie* an absence of confusion.