SHOULD "THE PURPLE PILL" BY ANY OTHER DRUG COMPANY STILL BE AS PURPLE? THE CHANGING FACE OF TRADE DRESS PROTECTION FOR PHARMACEUTICAL MANUFACTURERS

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I. INTRODUCTION

Charles Caleb Colton once wrote that "imitation is the sincerest of flattery,"[1] but, in corporate America, such flattery can often lead to a lawsuit. Historically, trademark law prevented makers of generic "copycat" drugs from mimicking the unique appearance of their brand name "innovator" counterparts. Recently, however, this legal regime has begun to change. The result is that brand name pharmaceutical manufacturers face the prospect of having diminished legal protections for the unique pill colors and designs they regularly employ to distinguish their products in the minds of doctors, pharmacists, and patients in an increasingly competitive marketplace.

This article examines the application of trade dress protection to pharmaceutical manufacturers employing a unique color scheme to distinguish their prescription pill products. Part II of this article examines the prescription drug marketplace in the United States and the emergence of generic drugs as a powerful competitor to brand name innovator drugs. Part III discusses the legal framework governing trademark and trade dress protection for pharmaceutical products in the United States. Part IV discusses the historical application of trademark law to pharmaceutical pill design and the dramatic shift introduced by

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1 CHARLES CALEB COLTON, LACON: OR, MANY THINGS IN FEW WORDS, ADDRESSED TO THOSE WHO THINK 127 (rev. ed., New York, Charles Wells 1836) (1822).

the Third Circuit's decision in *Shire U.S., Inc. v. Barr Laboratories, Inc.*[2] Finally, Part V examines the social and legal underpinnings of the *Shire* decision and why the decision appears to be less of a faithful adherence to the principles of trademark law and more an expression of public policy to promote generic drug substitutions.

II. BRAND NAME VS. GENERIC DRUGS—OVERVIEW

Prescription drug costs currently account for one-third of U.S. health care expenditures.[3] Generic drugs are offered as less expensive "bioequivalent" substitutes for their brand name prescription counterparts.[4] When a brand name drug's patent protection expires, other companies can apply to the FDA to sell generic equivalents.[5]

The use of genetic pharmaceuticals as a substitute for brand name drugs has undergone explosive growth in the U.S. Prior to 1984, generic pharmaceuticals represented less than four percent of total prescriptions dispensed in the United States.[6] Today, that number exceeds 53%.[7]

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2 329 F.3d 348 (3d Cir. 2003). For a discussion of the *Shire U.S., Inc. v. Barr Laboratories, Inc.* decision, see *infra* Section V.C.

3 Sharon Terlep & Dalia Naamani-Goldman, *Insurers Push Doctors to Prescribe More Generics*, ASBURY PARK PRESS, Aug. 21, 2005 (noting pressure from insurance companies to substitute generic drugs for brand-name prescriptions), *available at* http://www.app.com/apps/pbcs.dll/article?AID=/20050821/BUSINESS/508210366/1003.

4 Ctr. for Drug Eval. and Research (CDER), Office of Generic Drugs, U.S. Food and Drug Admin., *Home Page*, http://www.fda.gov/cder/ogd/#Introduction (last visited Oct. 25, 2006).

5 *Id.* (summarizing the FDA generic drug approval process).

6 *See Examing the Administration's Proposed Health Security Act, To Establish Comprehensive Health Care For Every American: Hearings Before the S. Comm. On Labor and Human Resources*, 103d Cong. 181 (1993) [hereinafter de Vink] (statement of Lodewijk de Vink, President and CEO, Warner-Lambert Co.) (noting impact of 1984's Hatch-Waxman Act on pharmaceutical industry).

7 *See Increasing Generic Drug Utilization: Saving Money for Patients: Hearing Before the Subcomm. on Health of the H. Comm. On Energy and Commerce*, 109 Cong. (2005) [hereinafter Jaeger] (statement of Kathleen Jaeger, President and CEO, Generic Pharmaceutical Association), *available at* http://energycommerce.house.gov/108/Hearings/05182005hearing1526/Jaeger.pdf ("Generic pharmaceuticals represent more than 53 percent of all prescriptions dispensed in the United States, but they account for only 12 percent of all dollars spent on prescription drugs."). As of March, 2005, there were more than 8,637 generic versions of the approximately 11,184 FDA-approved pharmaceuticals. *See* CTR. FOR DRUG EVALUATION AND RESEARCH (CDER), U.S. FOOD AND DRUG ADMIN., APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (25th ed. Cum. Supp. 3, Mar. 2005), *available at* http://www.fda.gov/cder/orange/supplement/cspreface.htm (Section 1.4) (listing numbers of FDA approved drugs and therapeutic equivalent drugs by quarter). *See also* Terlep, *supra*

A. Cost Factors for Generic Pharmaceuticals

The skyrocketing popularity of generic pharmaceuticals is attributable to one factor—cost.[8] A generic drug can be as much as 80% cheaper than its brand name counterpart.[9] This is why generic drug use is promoted by insurance companies, health care plans, and government agencies as a cost saving alternative to brand name prescriptions.[10]

The cost savings offered by generic drugs are largely due to three important differences between a brand name drug and its generic substitute. First, brand name drugs are new "innovator" drugs. As such, they require large investments in research and development, testing, and securing FDA approval, before reaching the drug market. The pharmaceutical and biotechnology industry spent an estimated $51.3 billion dollars in research for new medicines in 2005.[11] A generic drug replicates the active ingredients in its brand name counterpart. As such, there is little up-front investment. Therefore, generics have no need to recoup the investment dollars set out by the brand name "innovator" company in researching and developing a novel drug treatment.

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note 3 ("Global sales of generic drugs are expected to increase to $49 billion in 2007 from $29 billion in 2003.").

8 *See* de Vink, *supra* note 6 (noting impact of price competition from generic drug manufacturers on pharmaceutical industry).

9 *See* Jaeger, *supra* note 7 (noting price differential between generic and brand name pharmaceuticals). "[A]ccording to the National Association of Chain Drug Stores, last year the average retail price for a brand drug was $96.01 while the average retail price of a generic was $28.74, a savings of nearly seventy percent per prescription." *Id.* "The first generic manufacturer to enter a market typically charges 70% to 80% of the brand manufacturer's price. As additional generic versions of the same drug enter the market, the price continues to drop, sometimes decreasing to a level of 50% [sic] or less of the brand price." *Competition in the Pharmaceutical Marketplace: Antitrust Implications of Patent Settlements: Hearing Before the S. Comm. on the Judiciary*, 107 Cong. (2001) [hereinafter Boast] (statement of Molly Boast, Director of the Federal Trade Commission Bureau of Competition). The FDA's Center for Drug Evaluation and Research's Office of Generic Drugs estimates that generic drugs save US consumers $8 to $10 billion a year at retail pharmacies, and billions more are saved by hospitals by using generic substitutes for brand name pharmaceuticals. *CDER, Office of Generic Drugs Home Page*, *supra* note 4.

10 *See* Terlep, *supra* note 3 (noting results of AARP survey of physicians where two-thirds felt pressured by health plans or insurance companies to prescribe generic drugs). One HMO's director of pharmacy programs noted that "increasing generic use [i]s a great and relatively easy way to decrease costs without decreasing quality." *Id.*

11 PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PHRMA), PHARMACEUTICAL INDUSTRY PROFILE 2006, 2, 45 (2006), *available at* http://www.phrma.org/files/2006%20Industry%20Profile.pdf (noting that, for PhRMA member companies, R&D investment is an estimated 15.8% of total sales).

Secondly, generic drugs do not need to go through the costly and time-consuming regulatory approval process that innovator drugs need to.[12] The FDA reviews all new drugs before they may be sold in the United States to "decid[e] whether the scientific studies submitted by the drug's sponsor adequately demonstrate the proposed drug's safety and effectiveness."[13] It costs an average of $800 million to get a new drug through the FDA's approval process, adding further to the costs needed to be recovered by makers of brand name "innovator" drugs.[14] Generic drugs, by comparison, benefit from an abbreviated approval process that saves their makers both time and money in bringing new generics to market.[15]

Finally, generic drugs don't need to make the financial investment in building brand awareness that their brand name counterparts do. Brand name pharmaceutical manufacturers spend enormous amounts of money to build market awareness and promote their products. In 2002, U.S. pharmaceutical companies spent over $21 billion to promote their products and drive prescription demand.[16] Generic drugs, however, are the "unadvertised brand."[17] They can

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12 *See infra* Section II, B for a discussion of the drug approval process.

13 David M. Fritch, *Speak No Evil, Hear No Evil, Harm the Patient? Why the FDA Needs to Seek More, Rather Than Less, Speech From Drug Manufacturers on Off-Label Drug Treatments*, 9 J. MED. & L. 315, 331 (2005).

14 Paul H. Rubin, *An Opportunity or a Threat: How to Have Safer, Less Expensive Drugs* 1 (Dec. 7, 2004) http://www.independent.org/newsroom/article.asp?id=1433.

15 *See infra* Section II.B for a discussion of the approval process required of generic drugs. *Compare* Office of the Comm'r, U.S. Food and Drug Admin., *FDA White Paper—New FDA Initiative on "Improving Access to Generic Drugs"* (June 12, 2003) http://www.fda.gov/oc/initiatives/generics/whitepaper.html [hereinafter *FDA White Paper*] (generic drugs take an average of more than 20 months to complete the FDA's approval process), *with* Alliance Pharmaceutical Group, *Drug Development and Approval Process*, http://www.allp.com/drug_dev.htm (last visited Sept. 10, 2005) (average of 12 years to approve a new drug); PHARMACEUTICAL RESEARCH AND MANUFACTURER ASSOC. (PHRMA), WHAT GOES INTO THE COST OF PRESCRIPTION DRUGS? 10 (Jun. 2005), *available at* http://www.phrma.org/files/Cost_of_Prescription_Drugs.pdf (an average of 12 to 15 years is needed to bring a new drug from pre-clinical testing to market approval).

16 BLUE CROSS BLUE SHIELD, MEDICAL COSTS REFERENCE GUIDE 34 (2005), *available at* https://secure.bcbs.com/mcrg/mcrg_pharmacy.pdf. Promotional spending can be broken down into various components, including sampling (leaving drug 'samples' with physicians), detailing (in-person calls on physicians by drug company sales representatives), direct to consumer advertising, and advertising in professional journals. *See* Fritch, *supra* note 13, at 353 n.205 (describing various types of pharmaceutical promotions). The largest component, as a percentage of spending, remains sampling, which, in 2002, was 56% of total promotional spending ($11.9 billion).

17 *See generally Generic Drugs—The Unadvertised Brand*, http://www.theunadvertised-brand.com/ (last visited Oct. 25, 2006).

capitalize on the demand generated for the brand name innovator drug without the need for extensive promotional expenditures. Consequently, this leaves less required investment for the generic manufacturer to recoup through higher market prices.

B. The FDA and the Drug Approval Process

The FDA, through their Center for Drug Evaluation and Research (CDER), acts as the "consumer watchdog in America's healthcare system."[18] Both innovator drugs and their generic counterparts must be approved by the FDA prior to being offered for sale in the United States.

1. Drug Approval of Innovator Drugs

Prior to being brought to market, new innovator drugs must go through an extensive multi-phase approval process, including:[19]

- Pre-clinical testing, using laboratory and animal studies to assess the drug's safety and biological activity.[20]
- Clinical testing – following a filing with the FDA of a Notice of Investigational New Drug (IND), clinical testing of the new drug in humans can begin.[21] Subsequent clinical testing takes place in three phases:
  - *Phase I* – testing for adverse effects on small numbers of healthy volunteers
  - *Phase II* – clinical trials on limited numbers of patients with the target disease to determine efficacy and dose-response
  - *Phase III* – large scale clinical trials on patients with the disease[22]

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18 Ctr. for Drug Evaluation and Research (CDER), U.S. Food and Drug Admin., *CDER Frequently Asked Questions*, http://www.fda.gov/cder/about/faq/default.htm#1 (last visited Oct. 25, 2006).

19 OFFICE OF PUBLIC AFFAIRS, U.S. FOOD AND DRUG ADMIN., PUBL'N. NO. FS 02-5, FDA AND THE DRUG DEVELOPMENT PROCESS: HOW THE AGENCY ENSURES THAT DRUGS ARE SAFE AND EFFECTIVE (Feb. 2002), *available at* http://www.fda.gov/opacom/factsheets/justthefacts/17drgdev.pdf (outlining the FDA's four step approval process).

20 Alliance Pharmaceutical Group, *supra* note 15 (noting that preclinical testing takes an average of three and a half years). On average, five out of every 5,000 compounds evaluated in pre-clinical testing are moved into clinical trials. *Id.*

21 *See* Center for Drug Evaluation and Research, U.S. Food and Drug Administration, *Frequently Asked Questions on Drug Development and Investigational New Drug Applications*, http://www.fda.gov/cder/about/smallbiz/faq.htm#IND (last visited Oct. 25, 2006) (an IND application follows a successful preclinical testing to advance the drug to the next phase of testing in humans).

- Filing of New Drug Application (NDA) – providing all relevant data that has been collected during the product's research and development to demonstrate that the new drug is both effective for its intended use and that the benefits of the drug (as established by prior testing) outweigh its known risks[23]
- Post-marketing surveillance (also called Phase IV) – requires manufacturers and others to maintain records and file regular reports of adverse reactions and problems discovered after initial marketing of a drug[24]

2. Drug Approval of Generic Drugs

Unlike innovator drugs, generic drugs can take advantage of an "abbreviated" approval process. Prior to 1984, generic drug companies were required to prove the safety and efficacy of their products independently, essentially mirroring the extensive testing process followed by the drug's initial developer.[25]

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22 U.S. FOOD AND DRUG ADMINISTRATION, *supra* note 18 (noting that only products that pass FDA evaluation that the trials have demonstrated "that the product's health benefits outweigh its risks" can be marketed in the US).

23 CTR. FOR DRUG EVALUATION AND RESEARCH (CDER), U.S. FOOD AND DRUG ADMIN., CDER HANDBOOK—NEW DRUG APPLICATION, http://www.fda.gov/cder/handbook/ndabox.htm (last visited Oct. 25, 2006) (outlining the history and contents of NDA submissions). The NDA describes the drug, the results of pre-clinical and clinical trials, sets forth the proposed labeling, as well as sets forth a Risk Management Plan and a description of the manufacturing and testing processes for the drug. Ctr. for Drug Evaluation and Research (CDER), U.S. Food and Drug Admin., *New Drug Application (NDA) Process*, http://www.fda.gov/cder/regulatory/applications/nda.htm (last visited Oct. 25, 2006). The purpose of the NDA is to provide sufficient information to the FDA so that they may determine: (1) if the drug is safe & effective in its proposed use(s) and whether the benefits of the drug outweigh its risks; (2) whether the proposed labeling is appropriate and what (if anything) should be changed; and (3) whether the methods used in manufacturing the drug and the controls used to maintain its quality are adequate. *Id.* If the NDA is approved, the drug may be marketed. *Id. See also* 21 U.S.C. § 371 (2006) (granting FDA authority to promulgate regulations to ensure drug safety and efficacy).

24 *See* CTR. FOR DRUG EVALUATION AND RESEARCH, U.S. FOOD AND DRUG ADMIN. (CDER), CDER HANDBOOK—POST MARKETING SURVEILLANCE, http://www.fda.gov/cder/handbook/postmark.htm (last visited Oct. 25, 2006). Significant problems with a drug may prompt revisions to the drug's "labeling." *See* 21 C.F.R. § 314.81 (2006).

25 Elizabeth L. Wright, *David vs. Goliath: A New Front in the Ongoing Battle Between Generic and Brand-Name Drug Companies*, CITIZENS AGAINST GOV'T WASTE, Dec. 4, 1998, http://www.cagw.org/site/PageServer?pagename=reports_davidgoliath.

This was all changed in 1984 with the passage of the Hatch-Waxman Act ("the Act").[26]

The Act was a compromise between the interests of drug companies, seeking to extend patent protection for their drugs, and the government, seeking to expand the availability of low cost generic pharmaceuticals.[27] The Act allowed pharmaceutical companies to add up to five additional years of patent protection on new pioneer drugs.[28] Such an extension provides one additional incentive for research and development of new drugs.[29] In exchange, the Act opened the door to generic pharmaceutical companies, giving them a faster, less expensive approval path for generic substitutes for name-brand pharmaceuticals,

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[26] 35 U.S.C. § 156 (2006). This Act also goes by the alternative name of the Drug Price Competition and Patent Restoration Act of 1984. *See id.* This Act has been credited as the start of the modern generic pharmaceutical industry, "open[ing] the floodgates for generic pharmaceutical products." *Barr Pharmaceuticals, Inc., History of the Generic Industry*, *at* http://www.barrlabs.com/generic/history.php (last visited Oct. 25, 2006).

[27] *See* Ralph G. Schroeder & Paul Papas, *Protecting the Balance of Hatch-Waxman: Understanding the Industry's New Dynamics for the 21st Century*, 56 FOOD & DRUG L.J. 19, 19 (2001) ("[Hatch-Waxman] established both an industry and a new market dynamic for the business of pharmaceuticals."). "This landmark legislation struck a difficult, but compromised balance between consumers' needs for lower priced drugs and the needs of the pharmaceutical industry to fairly protect their innovation through a predictable intellectual property framework." *Id.*

[28] Gerald J. Mossinghoff, *Striking the Right Balance Between Innovation and Drug Price Competition: Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process*, 54 FOOD & DRUG L.J. 187, 189–90 (1999) (outlining patent protection provisions of Hatch-Waxman Act). While the full provisions themselves are rather complex, Hatch-Waxman essentially allows drug companies to extend patent protection for a period equal to one-half the time of the investigational new drug period (where the drug is in clinical trials in humans) plus the period of review for their NDA. *Id.* The maximum extension available under the Act is five years, and the total exclusivity period cannot exceed fourteen years. *Id.*

> For example, Innovator Pharmaceuticals, Inc. (Innovator, Inc.) filed a patent during year one for its drug that treated high blood pressure. The patent issued in year three. Then, in year ten, the Innovator, Inc. drug was approved by the Food and Drug Administration (FDA). Innovator, Inc. has only ten years left of its patent term to prevent others from making, using, and selling its patented drug. Pursuant to the Act, Innovator, Inc. may be able to extend its period of market exclusivity by extending its patent term for up to five additional years. If Innovator, Inc. is granted a three-year patent term extension under the Act, the total time of market exclusivity will equal thirteen years.

Kristin E. Behrendt, *The Hatch-Waxman Act: Balancing Competing Interests or Survival of the Fittest?*, 57 FOOD & DRUG L.J. 247, 248 (2002).

[29] *Id.* (noting increased period of exclusivity to pharmaceutical products afforded under the Hatch-Watchman Act.)

as well as adding incentives for these generic manufacturers to challenge the extended patent protections for the original brand name drug's patent holders.[30]

Rather than requiring independent proof of a generic drug's safety and efficacy, the Act allows generic manufacturers to submit an abbreviated new drug application (ANDA) to obtain FDA approval for a generic drug.[31] To obtain approval for their ANDA, the generic company must prove that their generic drug is "bioequivalent" to its brand name counterpart.[32] Bioequivalence means that the generic must have the same effectiveness and similar "bioavailability" (the manner in which the drug is absorbed or becomes available at the site of physiological activity after administration) as the generic's already approved brand name counterpart.[33]

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30 Holly Soehnge, *The Drug Price Competition and Patent Term Restoration Act of 1984: Fine-Tuning the Balance Between the Interests of Pioneer and Generic Drug Manufacturers*, 58 FOOD & DRUG L.J. 51, 51 (2003).

31 *Id.* at 54. These abbreviated approval provisions were designed to "make available more low cost generic drugs." H.R. REP. NO. 98-857, pt. 1, at 14 (1984).

32 Soehnge, *supra* note 30, at 68. "[This Act] is a unique piece of legislation because it actually ties the hands of a regulatory agency—in the area of public health—by providing specifically that [the] FDA can require only bioavailability studies for ANDAs." Mossinghoff, *supra* note 28, at 189.

33 *See* 21 U.S.C. § 355(j)(2)(A)(iv) (2006). The ANDA "permit[s] an applicant seeking approval of a generic drug to avoid the costly and time-consuming studies required for a pioneer drug." *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990). The FDA requires that:

- Generic drugs must have the same active ingredients and the same labeled strength as the brand-name product.
- Generic drugs must have the same dosage form (for example, tablets, liquids) and must be administered in the same way.
- Generic drug manufacturers must show that a generic drug is bioequivalent to the brand-name drug, which means the generic version delivers the same amount of active ingredients into a patient's bloodstream in the same amount of time as the brand-name drug.
- Generic drug labeling must be essentially the same as the labeling of the brand-name drug.
- Generic drug manufacturers must fully document the generic drug's chemistry, manufacturing steps, and quality control measures.
- Firms must assure the FDA that the raw materials and finished product meet specifications of the U.S. Pharmacopoeia, the organization that sets standards for drug purity in the United States.
- Firms must show that a generic drug will remain potent and unchanged until the expiration date on the label before it can be sold.

Additionally, the Act created an exception to the traditional rules of patent infringement to facilitate and accelerate testing for generic pharmaceuticals. Prior to the Act, a generic company that performed the required testing to get a generic pharmaceutical approved before the patent on the brand name innovator drug expired could be liable for patent infringement.[34] As a result, the generic companies were forced to wait until the patent on the brand name equivalent drug ended before beginning approval testing.[35] Under the Act, however, generic companies are allowed to "obtain a supply of a patented drug product during the life of the patent and conduct tests using that product if the purpose of those tests is to submit an application to [the] FDA for approval."[36] This eliminates the need to wait until a brand name drug's patent expires before obtaining the needed tests and gaining the requisite approvals for a generic substitute.

III. TRADE DRESS PROTECTION AND PHARMACEUTICAL PRODUCTS

The Lanham Act defines a trademark owner's rights and provides the governing law for trademark disputes.[37] Trademarks, under the Lanham Act, can be a "word, name, symbol, or device, or any combination thereof" used by a maker or seller of goods to identify and distinguish their goods from those made or sold by others.[38]

- Firms must comply with federal regulations for good manufacturing practices and provide the FDA a full description of facilities they use to manufacture, process, test, package, and label the drug. The FDA inspects manufacturing facilities to ensure compliance.

Michelle Meadows, U.S. Food and Drug Admin., *Greater Access to Generic Drugs*, http://www.pueblo.gsa.gov/cic_text/health/access-gen-drugs/access-gen-drugs.htm#requirements (last visited Sept. 10, 2005).

34 Roche Prods, Inc. v. Bolar Pharm. Co., 733 F.2d 858, 863 (Fed. Cir. 1984) (holding experimental tests for generic approval constitute patent infringement when conducted prior to expiration of the brand name drug's patent).

35 *Id.* *See also* Behrendt, *supra* note 28 at 250 (noting how § 271(e)(1) of the Hatch-Waxmann act overturned the *Roche* decision).

36 H.R. REP. NO. 98-857, pt. 2, at 5 (1984) (amending 35 U.S.C. § 271(e)(1) (1982)).

37 15 U.S.C. §§ 1051–1127 (2006).

38 15 U.S.C. § 1127 (defining "trademark").

A. Distinguishing Pharmaceutical Products

Pharmaceutical promotional strategies have undergone a dramatic shift over the last fifteen years.[39] Drug companies have moved from promotions targeted exclusively at medical professionals to promotions targeted at consumers directly.[40] Not all segments of the prescription drug industry see this shift as beneficial.[41] However, with billions of dollars in pharmaceutical promotional expenditures per year being targeted directly at consumers, this shift is a market reality.[42]

The increased emphasis on consumer promotion has impacted drug design as well. For over-the-counter drugs, consumer confusion can extend to

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39 Carol Lewis, U.S. Food and Drug Admin., *The Impact of Direct-to-Consumer Advertising*, FDA CONSUMER MAG., Mar.–Apr. 2003, *available at* http://www.fda.gov/fdac/features/2003/203_dtc.html (noting increasing popularity of direct-to-consumer advertising for prescription drugs).

40 *Id.* (attributing promotional shift to increase in number of patients making their own health care decisions).

41 *See*, *e.g.*, Public Citizen's Health Research Group, *Comments on Food and Drug Administration's Draft Guidance for Industry on Direct to Consumer Advertising* (Oct. 14, 1997), http://www.citizen.org/publications/release.cfm?ID=6626&secID=1682&catID=126 (claiming DTC pharmaceutical promotion "leaves consumers naked in the viciously competitive marketplace for prescription drugs without the protection of accessible objective, independent information about risks and benefits"). Other segments, however, feel that the overall impact of direct-to-consumer promotions is beneficial. *See*, *e.g.*, Lewis, *supra* note 39 ("When it comes to advertising prescription drugs on radio and television and in magazines, doctors say that, for the most part, the ads help people more than hurt them."); PHARMACEUTICAL RESEARCH AND MANUFACTURERS ASSOCIATION (PHRMA), DIRECT-TO-CONSUMER ADVERTISING STRENGTHENS OUR HEALTH CARE SYSTEM 1 (Nov. 2002), *available at* http://international.phrma.org/publications/publications/2002-11-11.616.PDF ("Despite what some critics suggest, there is no evidence that DTCA encourages inappropriate prescribing of prescription drugs."). Despite these changes, the vast majority of prescription drug promotion remains focused on the prescribing physician. *See* KAISER FAMILY FOUNDATION, TRENDS AND INDICATORS IN THE CHANGING HEALTH CARE MARKETPLACE, 2004 UPDATE (Exhibit 1.20), *available at* http://www.kff.org/insurance/7031/ti2004-1-20.cfm (last updated Feb. 6, 2006) (noting 86% of prescription drug promotional spending in 2004 was directed at physicians). In 2004, the biggest shares of prescription drug promotional spending was directed at sampling (providing free sample prescription drugs for physicians to offer to their patients) and detailing (sales professionals calling directly on physicians) which combined for 83% of promotional spending. *Id.* (breaking down the amounts of prescription drug promotional spending).

42 For example, of the $19.2 billion in promotional spending for prescription drugs in the U.S. in 2001 (more than triple the amount spent in 1990), direct-to-consumer promotions represent 14% or $2.7 billion. *See* KAISER FAMILY FOUNDATION, *supra* note 41 (detailing promotional spending by pharmaceutical companies in the United States).

similarity in the outer packaging—such as the box, label, and pill bottle—since these elements are what are presented to the consumer at the time of purchase.[43] Prescription drugs, however, are repackaged by the dispensing pharmacy in bottles "which contain no easily identifiable designation of source, unique packaging or individual labeling trade dress to distinguish it."[44] This makes a prescription drug's unique shape and color a crucial means of identifying the drug's manufacturer and influencing consumer preference.[45]

This is why, in the fiercely competitive market for prescription drugs, "an ordinary, round white pill will not survive."[46] With increasing competition for consumer's attention and loyalty in the prescription drug market, "[c]olor has been elevated to "powerhouse" status because it is the most fundamental part of a drug's personality."[47] As one expert put it, in the area of prescription drugs, "appearance counts":

> [D]rug companies probe the consumer's subconscious mind when they select a drug's appearance. Glossy, two-tone capsules, for example, have a sophisticated look thought to appeal to younger buyers. Color is particularly impor-

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43 *See* Smithkline Beckman Corp. v. Pennex Prods. Co., 605 F. Supp. 746, 753 (E.D. Pa. 1985) (noting off-the-shelf medication "comes in many unique packaging configurations which help indicate the source of the product").

44 *Id.* (noting differences in trade dress protections between prescription and over-the-counter drugs). The design of the pill bottle itself, however, is becoming a branding differentiator for the dispensing pharmacy, rather than the pill manufacturer. *See*, *e.g.*, Gregory Bull, *Target Pill Bottles Now Convenient and Cute*, USA TODAY, Apr. 28, 2005, http://www.usatoday.com/money/industries/health/drugs/2005-04-28-target-pill_x.htm (describing design effort for new prescription pill bottle for Target pharmacies).

45 As the District of New Jersey noted:

> Most tablets, lozenges, capsules, and the like, however, are dispensed by the pharmacist out of the manufacturer's bottle and presented to the patient in an anonymous vial, usually a dark plastic, with only the pharmacist's label. The patient never sees, for these [prescription drugs], the manufacturer's bottle with what may well be a distinctive lablel. Under these conditions, with narrow exceptions to be noted, the only means available to the manufacturer to provide a means of identification of origin and source is by the trade dress of the drug itself, which is inevitably small enough to be swallowed easily (or chewed).

Biocraft Labs., Inc. v. Merck & Co., 532 F. Supp. 1068, 1074 (D.N.J. 1980).

46 Charles W. Schmidt, *Have I Got a Drug for You!*, MODERN DRUG DISCOVERY, Dec. 2001, at 41, *available at* http://pubs.acs.org/subscribe/journals/mdd/v04/i12/html/12money.html (noting importance of appearance in prescription pharmaceuticals).

47 Jill Morton, COLOR MATTERS, *Taking the Color of Medications Seriously*, http://www.colormatters.com/body_pills.html (last visited Oct. 25, 2006). Color in prescription drugs, like in other products, has the ability to create an emotional appeal to consumers, communicate the product's benefits, and help to distinguish one brand from others. *Id.*

> tant: Blue is masculine (Viagra is blue), red is bold and stimulating, pink is feminine, and AstraZeneca representatives describe purple as an "attractive yet dignified" shade.[48]

A prescription drug's appearance can serve practical purposes as well. A pill's form, shape, and color are critical elements in identifying a particular medication.[49] Color choices must also be made in such a way that proposed dyes do not interfere with a drug's active ingredients or create adverse allergic reactions in patients.[50] Including colors in a pill's design can also help eliminate dosing errors and improve patient compliance with their prescriptions.[51] Some

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48 Schmidt, *supra* note 46, at 41. There is a branding science to the design of pills, which has become more important over the last few years. *See* Brand Institute, Inc., *Dose* (May 2005), http://brandinstitute.com/NEWS/DOSE_05_05.HTM. "Colours of pills stand for things . . . . There are even ways to take the name and tie it to the color and size of the pill and what you're tryin[g t]o do: wake people up, alert them, smack them, a cold slap in the face. Your jaw drops at all the things that go into it." *Id.* "According to a professor of drug marketing, quoted in a *Boston Globe* article, 'You wouldn't make a pink Viagra. . . . Designers propose colors for a particular medicine and help make sure there are no symbolic mistakes.'" Nathan Greenslit, *Pharmaceutical Branding: Identity, Individuality, and Illness*, 2 MOLLECULAR INTERVENTIONS 342, 343 (Oct. 2002), *available at* http://molinterv.aspetjournals.org/cgi/reprint/2/6/342.pdf.

49 *See*, *e.g.*, Drugs.com *Pill Identification Wizard*, *at* http://www.drugs.com/pill_identification.html (last visited Oct. 25, 2006) (allowing consumers to match size, shape, and color of a prescription drug pill to identify a particular drug). This can be useful to allow the dispensing pharmacist to properly identify the drug and dosage to fill a patient's prescription. *See* SK&F, Co. v. Premo Pharm. Labs., Inc., 625 F.2d 1055, 1060 (3d Cir. 1980) (noting importance of color and shape in identifying prescription drugs). These features also facilitate identification of the drug to patients, especially in emergency situations where rapid identification is needed. *Id.* Even in non-emergency situations, color can play an important role in patient's properly identifying their medications, especially for elderly patients who take an average of seventeen to twenty four prescriptions a year. *See Reducing Medical Errors: A Review of Innovative Strategies to Improve Patient Safety: Before the Subcomm. on Health, Comm. on Energy and Commerce*, 107th Cong. (2002) [hereinafter Hethcox] (statement of James M. Hethcox, Vice President, Pharmacy Practice Cardinal Health), *available at* http://energycommerce.house.gov/107/hearings/05082002Hearing557/print.htm. "Researchers have also found that patients who took more drugs on a daily basis preferred bright pill colors. Consequently, color and color combinations are a powerful way to create emotional appeal and reduce medical errors." Morton, *supra* note 47.

50 *See* Patricia Wen, *Designer Pills Aimed at the Consumer's Subconscious*, BOSTON GLOBE, May 20, 2001, at D1, *available at* http://www.intelihealth.com/IH/ihtIH/WSIHW000/8124/21291/322037.html (noting importance of pill design in prescription drug marketing).

51 Capsugel, *The Importance of Color Selection & Imprints, and How They Effect Compliance*, DOSE RESPONSE, Fall 2002, at 3, *available at* http://www.capsugel.com/pdf/dose_response_fall_2002.pdf.

prescription drugs, for example, color code according to dosage.[52] Research shows that patients who take drugs on a daily basis prefer bright colored pills and that the right color combinations can create an emotional appeal with the patient.[53] Such effects can reduce errors and improve patient compliance with their prescription medication regimen.[54]

B. Trade Dress Infringement

Under section 32 of the Lanham Act, it is illegal to use "any reproduction, counterfeit, copy, or colorable imitation" of a protected mark in commerce where "such use is likely to cause confusion, or to cause mistake, or to deceive."[55] The public policy goal served by trademark protection, however, has little to do with the owner of the trademark.[56] The Lanham Act serves to protect the *consumer*, not the trademark owner from possible confusion arising from trademark misuse.[57]

Infringement claims have historically been designed to protect purchasers of goods from confusion about the source of the goods that they are buying.[58] Modern courts, however, protect a much broader catalog of rights under infringement claims. Currently, infringement claims can be used to provide pro-

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52 For example, the anti-depressant Paxil, is distributed in color-coded pills where color is used to identify the pill's dosage. *See* GlaxoSmithKline, *Paxil, Prescribing Information*, at 2, *available at* http://us.gsk.com/products/assets/us_paxil.pdf (last updated July 2006) (noting dosage and color of Paxil pills). For example, yellow pills are 10mg, pink pills are 20mg, blue pills are 30mg, etc. *Id.*

53 *See* Morton, *supra* note 47 ("[C]olor and color combinations are a powerful way to create emotional appeal and reduce medical errors.").

54 Hethcox, *supra* note 49 ("An AARP survey showed that 58 percent of the elderly population makes errors when taking medications, and nearly 10 percent of all Medicare hospital admissions are the result of medication noncompliance."). "The growing variety of colors and shapes also has practical value for people, especially the elderly, who may be taking many pills a day and need visual cues about which is which." Wen, *supra* note 50.

55 15 U.S.C. § 1114(1)(a) (2006) (defining trademark infringement).

56 *See* David M. Fritch, *Searching for Initial Interest Confusion and Trademark Protection in Cyberspace*, 9 PGH. J. TECH. L. & POL'Y 4, at *3 (2005), *available at* http://tlp.law.pitt.edu/articles/Vol_9_Fritch.pdf (outlining policy goals of trademark protection).

57 *Id.* The right at issue in trademark law is not the ownership rights of the trademark owner, but protecting "the consuming public from confusion, concomitantly protecting the trademark owner's right to a non-confused public." Gregory Shea, *Trademarks and Keyword Banner Advertising*, 75 S. CAL. L. REV. 529, 535–36 (2002).

58 *See* Official Airline Guides, Inc. v. Goss, 6 F.3d 1385, 1391 (9th Cir. 1993) ("The core element of trademark infringement is the likelihood of confusion, i.e.[,] whether the similarity of the marks is likely to confuse customers about the source of the products.")

tection against confusion relating not only to the source of a product, but also as to a product's affiliation, connection, or sponsorship.[59]

C. Trade Dress Protection

Protected marks under the Lanham Act include not only trade*marks*, but also trade *dress*.[60] Trade dress encompasses "a combination of any elements in which a product or service is presented to the buyer."[61] Trade dress can be likened to a form of consumer shorthand, identifying a product's manufacturer to the consumer through visual queues like unique packaging or product design.[62] Trade dress can cover a broad range of features, including "size, shape, color or color combinations, texture, graphics, [or] even particular sales techniques" used to market a product.[63] Examples of protectable trade dress can include the

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59 *See* Lindy Pen Co. v. Bic Pen Corp., 725 F.2d 1240, 1246 (9th Cir. 1984) (noting trademark infringement protection "embrac[es] confusion as to the association between the goods or sponsorship of the allegedly infringing goods.").

60 15 U.S.C. § 1125(a)(3) (2006). *See also* Wal-Mart Stores, Inc. v. Samara Bros., 529 U.S. 205, 209 (2000) ("trade dress constitutes a 'symbol' or 'device'" for Lanham Act purposes); Two Pesos, Inc. v. Taco Cabana, Inc., 505 U.S. 763, 773 (1992) ("§ 43(a) provides no basis for distinguishing between trademark and trade dress.").

61 1 J. THOMAS MCCARTHY, MCCARTHY ON TRADEMARKS AND UNFAIR COMPETITION § 8:1 (4th ed. 2005).

62 *Wal-Mart Stores*, 529 U.S. at 209 (noting expansive use of trade dress protection). Historically, trade dress was limited to "the manner in which a product was 'dressed up' to go to market with a label, package, display card and similar packaging elements." Jeffery Milstien, Inc. v. Greger, Lawler, Roth, Inc., 58 F.3d 27, 31 (2d Cir. 1995). The more modern view of trade tress, however, "includes the design and appearance of the product as well as that of the container and all elements making up the total visual image by which the product is presented to customers." *Id.* (citing Le Sportsac, Inc. v. K Mart Corp., 754 F.2d 71, 75 (2d Cir. 1985)). *See*, *e.g.*, Ashley Furniture Indus., Inc. v. Sangiacomo N.A., Ltd., 187 F.3d 363, 374 (4th Cir. 1999) (holding design of bedroom furniture protectable trade dress); Knitwaves, Inc. v. Lollytogs, Ltd., 71 F.3d 996, 1006 (2d Cir. 1995) (holding sweater design protected as trade dress); Stuart Hall Co. v. Ampad Corp., 51 F.3d 780, 791 (8th Cir. 1995) (holding design for notebooks and writing pads protected as trade dress).

63 John H. Harland Co. v. Clarke Checks, Inc., 711 F.2d 966, 980 (11th Cir. 1983) (citing examples of protectable trade dress). As the Eleventh Circuit noted:

> Most trade dress infringement actions involve the packaging or labeling of goods. *See*, *e.g.*, *Chevron Chemical Co. v. Voluntary Purchasing Groups, Inc*., 659 F.2d 695 (5th Cir.1981) (Unit A) (packaging of lawn and garden chemical products), *cert. denied*, 457 U.S. 1126 (1982); *Sun-Fun Products, Inc. v. Suntan Research & Development Inc.*, *supra*, (packaging of sun tan preparations); *Perfect Fit Industries, Inc. v. Acme Quilting Co.*, 618 F.2d 950 (2d Cir.1980) (packaging of mattress pads), *cert. denied*, 459 U.S. 832 (1982). Recently, however, courts have recognized that the design of a product itself

design and décor of a restaurant,[64] adoption procedures for a "Cabbage Patch" doll,[65] layout of a clothing catalog,[66] or even the "Marlboro Man" themed cigarette advertising.[67]

To protect trade dress from infringement, the owner must demonstrate that the allegedly infringing feature is: (1) not "functional;"[68] (2) likely to cause

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> may constitute protectable trade dress under § 43(a) of the Lanham Act. *See*, *e.g.*, *Warner Bros., Inc. v. Gay Toys, Inc.*, 658 F.2d 76 (2d Cir.1981) (distinctive color and symbols on toy car protected under § 43(a)); *Harlequin Enters. Ltd. v. Gulf & W. Corp*., 644 F.2d 946 (2d Cir.1981) (distinctive book covers protected against trade dress infringement); *Truck Equip. Serv. Co. v. Fruehauf Corp.*, 536 F.2d 1210 (8th Cir.) (unique exterior design of twin hopper bottomed grain semi-trailer protected under § 43(a)), *cert. denied*, 429 U.S. 861 (1976).

Id.

64 *See*, *e.g.*, Prufrock, Ltd. v. Lasater, 781 F.2d 129, 132 (8th Cir. 1986) ("A restaurant's trade dress can include the shape and general appearance of the exterior of the restaurant, the identifying sign, the interior floor plan, the appointments and décor items, the equipment used to serve the food, and the servers' uniforms.") (citations omitted).

65 *See* Original Appalachian Artworks, Inc. v. Toy Loft, Inc., 684 F.2d 821, 831 (11th Cir. 1982) (finding unique marketing technique part of product's packaging, and thus, protectable trade dress).

66 *See* Abercrombie & Fitch Stores, Inc. v. Am. Eagle Outfitters, Inc., 280 F.3d 619, 632–33 (6th Cir. 2002) (finding "configuration of the [Abercrombie & Fitch] catalog as trade dress" because it is "an objectively observable 'particular sales technique' used to sell clothing, or packaging of the products it depicts.").

67 *See* Phillip Morris, Inc. v. Star Tobacco Corp., 879 F. Supp. 379, 383 (S.D.N.Y. 1995) (protecting trade dress in advertisements of Marlboro cigarettes evoking "Marlboro Man" and "Marlboro Country" images, as inherently distinctive and protectable).

68 *See* Brunswick Corp. v. Spinit Reel Co., 832 F.2d 513, 517 (10th Cir. 1987) (noting that, "to be eligible for protection, the product's 'trade dress' must be nonfunctional"). As Judge Posner noted:

> [A] seller should not be allowed to obtain in the name of trade dress a monopoly over the elements of a product's appearance that either are not associated with a particular producer or that have value to consumers that is independent of identification. In the lingo of unfair competition, elements of the latter type—elements whose value is not merely signification—are a product's "functional" features; they can be either utilitarian in the narrow sense of that word, or aesthetic. Wine is sold corked. The cork is a functional feature of the product, because it enables the wine to age properly; and so the first seller of wine could not claim that the cork was his trade dress. Mink coats are normally sold dyed. The dye does not make the coat any warmer, but it makes it more beautiful, and, once again, it could not be claimed as trade dress by the first furrier to have hit on the idea. Functional improvements may be patentable, or protected as trade secrets, but they cannot be appropriated in the name of trade dress even if they are distinctive.

confusion in consumers regarding the protected product if it is copied by another manufacturer;[69] and (3) distinctive.[70] The distinctiveness requirement is not explicitly required within the text of the Lanham Act, but, as the Supreme Court noted, without it, imitating another's trade dress would not cause the required confusion as to the product's origin and would not be protectable.[71]

Trade dress may be distinctive in one of two ways. Trade dress can be inherently distinctive if its "intrinsic nature serves to identify a particular source."[72] A product's packaging can be inherently distinctive, as can the unique design of a restaurant chain.[73] A product's color[74] or design, however, is

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Publ'ns Int'l, Ltd. v. Landoll, Inc., 164 F.3d 337, 339 (7th Cir. 1998) (citations omitted).

69 *See Brunswick Corp.*, 832 F.2d at 517 ("If the trade dress is eligible for protection, to recover under the Lanham Act the plaintiff must further establish that there is a likelihood of confusion between the products.").

70 Wal-Mart Stores v. Samarra Bros., 529 U.S. 205, 205 (2000) ("Although § 43(a) does not explicitly require a producer to show that its trade dress is distinctive, courts have universally imposed that requirement. . . .").

71 *Id.* "The courts have struggled to articulate a standard for when a trade dress is sufficiently distinctive to be entitled to the prima facie protection of the Lanham Act." *Publ'ns Int'l, Ltd.*, 164 F.3d at 338. The difficulty is in striking a balance between competing public policies of encouraging innovation through protection of intellectual property and discouraging monopolies. "[A] seller should be encouraged to make his products recognizable by consumers at a glance as *his* product and not that of another seller." *Id.* at 339. However, a seller should not be able to use trade dress and obtain a monopoly over elements that are not associated with a single producer or do not indicate source. *Id.*

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

73 Felicia J. Boyd, *Supreme Court Narrows Trade Dress Protections*, http://library.findlaw.com/2000/Apr/1/127704.html (last visited Oct. 25, 2006). If the trade dress is found to be inherently distinctive, then secondary meaning is not required for it to be protected. *Two Pesos*, 505 U.S. at 773. In *Two Pesos*, the restaurant chain successfully defended their restaurant design as trade dress. *Id.* at 784. This design was described as:

> [A] festive eating atmosphere having interior dining and patio areas decorated with artifacts, bright colors, paintings and murals. The patio includes interior and exterior areas with the interior patio capable of being sealed off from the outside patio by overhead garage doors. The stepped exterior of the building is a festive and vivid color scheme using top border paint and neon stripes. Bright awnings and umbrellas continue the theme.

Id. at 765 (quoting Circuit Court decision).

74 *Wal-Mart Stores*, 529 U.S. at 206 ("This Court has held, however, that applications of at least one category of mark—color—can *never* be inherently distinctive, although they can be protected upon a showing of secondary meaning.") (emphasis in original) (citing Qualitex Co. v. Jacobson Prods. Co., 514 U.S. 159, 162–63 (1995)). For color to be protectable, it must operate in conjunction with other characteristics of the product. *See*, *e.g.*, Ideal Toy Corp. v. Plawner Toy Mfg. Corp., 685 F.2d 78, 82 (3d Cir. 1982) (finding color scheme of "Rubick's Cube" puzzle obtained sufficient secondary meaning to constitute protectable trade dress).

not inherently distinctive.[75] If a product's trade dress is not inherently distinctive, it can only be protected if it develops secondary meaning.[76] Secondary meaning means that the trade dress has achieved such consumer recognition of the manufacturer that, in the minds of the consuming public, its primary significance "is to identify the source of the product rather than the product itself."[77] A manufacturer generally establishes secondary meaning "through extensive advertising which creates in the mind of consumers an association between different products bearing the same mark."[78]

IV. PROTECTING UNIQUE PILL COLORING

As noted *supra*, a product's color, no matter how unique or eye-catching, is not inherently distinctive and is not automatically entitled to trade dress protection.[79] Color can, however, take on a secondary meaning in the marketplace when consumers begin to regard a particular color on a product as signifying a specific brand.[80] This fact has not been lost on the makers of prescription drugs. Drug makers, in an effort to drive prescriptions, spend billions of dollars on consumer marketing to develop brand loyalty for their products and, in the process, often create secondary meaning for their pill color scheme.[81]

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75 *Wal-Mart Stores*, 529 U.S. at 216 ("[I]n an action for infringement of unregistered trade dress under § 43(a) of the Lanham Act, a product's design is distinctive, and therefore protectable, only upon a showing of secondary meaning.").

76 *Id.* at 211 (explaining secondary meaning).

77 Inwood Labs., Inc. v. Ives Labs., Inc., 456 U.S. 844, 851 n.11 (1982).

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

79 *See* Qualitex Co. v. Jacobson Prods. Co., 514 U.S. 159, 163 (1995) (noting that product color is not inherently distinctive).

80 *Id.* As the Supreme Court noted:

> [O]ver time, customers may come to treat a particular color on a product or its packaging (say, a color that in context seems unusual, such as pink on a firm's insulating material or red on the head of a large industrical bolt) as signifying a brand. . . . [C]olor alone, at least sometimes, can meet the basic legal requirements for use as a trademark. It can act as a symbol that distinguishes a firm's goods and identifies their source, without serving any other significant function.

Id. at 163, 166.

81 *See* Wen, *supra* note 50 (noting that, while "there didn't used to be any brand personality around pills, . . . [n]ow there is.").

A. A Prescription Pill's Color Scheme as Trade Dress

A manufacturer's selection of a pill's color can often play a key role in a prescription drug product's promotional efforts. Possibly the most famous example of this is the marketing success of AstraZeneca's prescription drug Prilosec®, which is probably best known in the marketplace as the "Purple Pill."[82] In 1997, relaxation of FDA restrictions on direct-to-consumer prescription drug promotions led to an all-out marketing blitz, where promotions for the "Purple Pill" appeared everywhere—on TV, the Internet, and in print ads.[83] The pill's signature color, purple, was at the heart of this effort. When prospective patients found their way to their doctor's office, "they didn't even have to recall the drug's name. All they had to do was remember its color."[84]

This marketing push paid off. Prilosec was the first drug ever to hit $5 billion a year in worldwide sales.[85] By 2000, as many as one in ten Americans were using Prilosec, and annual sales exceeded $6 billion.[86] In October 2001, however, the patent for Prilosec expired.[87] AstraZeneca then switched its marketing push to a new "purple pill," Nexium®, as a new prescription-only replacement for Prilosec®.[88] The program worked. In the first year, 42% of existing Prilosec® prescriptions were converted to Nexium®.[89] By 2004, Nexium®

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82 *See* Associated Press, *'Purple Pill' Going OTC*, CBS NEWS, June 21, 2003, http://www.cbsnews.com/stories/2003/06/21/health/main559770.shtml (noting Priolosec® is "better known in TV ads as 'the purple pill'").

83 Neil Swidey, *The Costly Case of the Purple Pill—The Story of One Blockbuster Heartburn Drug Tells You Everything You Need To Know About the High Cost of Prescription Medicine*, BOSTON GLOBE, Nov. 17, 2002, *available at* http://www.mercola.com/2002/dec/18/nexium.htm. In 1997, the direct to consumer ("DTC") advertising spending on Prilosec was $41.9 million dollars. RICHARD FRANK ET AL., KAISER FAMILY FOUNDATION, TRENDS IN DIRECT-TO-CONSUMER ADVERTISING OF PRESCRIPTION DRUGS Exhibit 6 (Feb. 2002), *available at* http://www.kff.org/rxdrugs/loader.cfm?url=/commonspot/security/getfile.cfm&PageID=14881. By 2000, this DTC spending had grown to $107.9 million. *Id.*

84 Swidey, *supra* note 83.

85 *Id.*

86 Ann W. Latner, *Procter & Gamble Seeks OTC Status for Prilosec*, PHARMACY TODAY, June 20, 2002, *available at* http://www.pharmacist.com/articles/h_ts_0047.cfm.

87 *See* Swidey, *supra* note 83.

88 *Id.* AstraZeneca spent $478 million on the promotional campaign to launch Nexium® in 2001 and hired 1,300 new sales representatives to promote the launch. *Id.*

89 *Id.* Nexium® was being billed as "next-generation Prilosec®" and advertised as "today's purple pill." Associated Press, *supra* note 82. Despite the popularity of prescription Nexium®, many experts continue to question whether it is any more effective than the now cheaper and over-the-counter Prilosec® drug it was supposed to replace. Swidey, *supra* note

sales reached $3.9 billion and are expected to exceed $4.6 billion in 2005.[90] While prescription Nexium® has assumed Prilosec's moniker and trade dress as the new "purple pill," Prilosec® is still sold over-the-counter (OTC), but no longer bears its signature color—OTC Prilosec® pills are "salmon pink."[91]

What if a generic manufacturer, seizing upon the expiration of Prolosec's trademark, began to produce a generic version of Prilosec® using AstraZeneca's signature purple color? Given the high degree of marketing muscle behind promoting the "Purple Pill," the pill's color has clearly taken on secondary meaning in the marketplace.[92] When a patient goes to their doctor seeking a prescription for "the purple pill" to treat their heartburn, they are not looking for omeprazole[93] (the active ingredient in Prilosec®) or esomeprazole[94] (the active ingredient in Nexium®) formed into a purple capsule. They are looking for the AstraZeneca product that they saw on television or read about in a magazine. Clearly, the color scheme in this case would meet the requirements to be

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83, (noting minimal differences between Prilosec and Nexium in performance from company drug trials).

90 *See* David Seemungal, *On the Mend at AstraZeneca*, BUSINESS WEEK ONLINE, Aug. 9, 2005, http://www.businessweek.com/investor/content/aug2005/pi2005089_8918_pi008.htm, (estimating 2005 worldwide sales for Nexium®); Press Release, Astra Zeneca Int'l, *FDA Approves Intravenous Formulation for Nexium®*, (Apr. 1, 2005), http://www.astrazeneca.com/pressrelease/4975.aspx (documenting Nexium® 2004 worldwide sales). By 2003, Nexium® was the seventh biggest selling prescription drug in the world, with a 66% increase in sales over 2002. PharmaLive.com, Special Report, *Top 400 Prescription Drugs*, MED AD NEWS, May 2004, at 3, *available at* http://www.pharmalive.com/special_reports/sample.cfm?reportID=167 (ranking top 400 prescription drugs by annual worldwide sales).

91 *See* Associated Press, *supra* note 82. AstraZeneca makes both Nexium® and Prilosec®, but Procter & Gamble markets Prilosec OTC. *Id.*

92 Where customers identify color as a particular manufacturer's, and it serves no other purpose, then that color has developed a secondary meaning under the Lanham Act. Qualitex Co. v. Jacobson Prods. Co., 514 U.S. 159, 166 (1995). *See also* Scott Paper Co. v. Scott's Liquid Gold, 589 F.2d 1225, 1228 (3d Cir. 1978) ("Secondary meaning is generally established through extensive advertising which creates in the mind of consumers an association between different products bearing the same mark.") Once secondary meaning is established, then competitors are barred from using a similar mark. *Id.* "The purpose of this rule is to minimize confusion of the public as to the origin of the product and to avoid diversion of customers misled by a similar mark." *Id.*

93 *See* Ctr. for Drug Evaluation and Research (CDER), U.S. Food and Drug Admin., *Questions and Answers on Prilosec OTC*, http://www.fda.gov/cder/drug/infopage/prilosecOTC/prilosecotcQ&A.htm (last visited Oct. 25, 2006) (describing FDA approval of Prilosec® as an over-the-counter (OTC) product).

94 Drugs.com, *Nexium Information*, http://www.drugs.com/ nexium.html, (last visited Jan. 20, 2006).

considered a form of trade dress, but is it legally protectable against would-be imitators?

B. Traditional View of Protecting Pill Colors as Trade Dress

Pill colors were traditionally deemed to be part of a drug manufacturer's trade dress and were not allowed to be imitated by generic manufacturers.[95] A pill's color is usually arbitrarily selected by the manufacturer and is unrelated to the efficacy of the ingredients contained in the pill.[96] Whatever color scheme that is selected by the manufacturer is often supported by extensive promotional efforts and backed by years of monopolistic distribution by the original patent owner.[97] This can create strong associations between a pill's appearance and its maker in the minds of patients, doctors, and pharmacists.[98] Although this color-

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[95] *See*, *e.g.*, SK&F. Co. v. Premo Pharm. Labs., Inc., 625 F.2d 1055 (3d Cir. 1980) (holding unique coloring of prescription drug capsule protectable trade dress); Boehringer Ingelheim G.m.b.H. v. Pharmadyne Labs., 532 F. Supp. 1040 (D.N.J. 1980) (finding generic manufacturer copying name-brand pill's color scheme violating Lanham Act). "In the United States, trademark laws do not allow a generic drug to look exactly like the brand-name drug." Ctr. for Drug Evaluation and Research (CDER), U.S. Food and Drug Admin., *Generic Drugs: Questions and Answers*, http://www.fda.gov/cder/consumerinfo/generics_q&a.htm (last visited Oct. 25, 2006).

[96] *See* Morton, *supra* note 47 (noting how technology allows pills to be made in a variety of colors).

> The color transformation started in the '60s and accelerated in 1975 when the new technology of "softgel" capsules made colorful medications possible for the first time. Shiny primary colors such as cherry red, lime green, and tangy yellow arrived first. Today's gell caps can be tinted to any of 80,000 color combinations. As for tablets, continuous advancements in technology consistently bring new and colorful coating products to market.

Id.

[97] For example, the plaintiff in *Shire U.S., Inc. v. Barr Labs., Inc.* sought trade dress protection for their Adderall product's shape and color on the basis of the strong association between the pill's appearance and consumer identification of the pill's source. 329 F.3d 348, 350 (3d Cir. 2003). The court noted that:

> Shire's product literature, promotional materials, and mailings, which its sales staff distributed to physicians, feature color pictures of the Adderall tablets and sometimes direct patients to examine the tablets to ensure that they have received exactly the drug prescribed. Shire does not advertise its products in general consumer publications, but pictures of Adderall tablets appear in the Physician's Desk Reference and in certain consumer books.

Id.

[98] Some prescription drug products feature the pill's appearance even more prominently to reinforce the linkage in the minds of consumers. For example, AstraZeneca's prominently fea-

ing, over time, becomes a useful identifier of a pill's source and contents, this was not generally considered by courts to be a functional element.[99] The association in the minds of consumers between a pill's coloring and its source or origin has traditionally been regarded as trade dress. As such, it is entitled to legal protection.

C. Shire U.S., Inc. v. Barr Laboratories, Inc.[100]*—The Third Circuit Changes the Rules—Undercutting Protection for Brand-Name Pharmaceutical Manufacturers and Increasing Consumer Confusion*

The traditional view of protecting unique coloring of brand-name pharmaceuticals from imitation by generic companies seemed firmly established until the Third Circuit's recent ruling in *Shire U.S., Inc. v. Barr Laboratories, Inc.* This ruling appeared to reject the traditional arguments for extending

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tures their Nexium® pill's color scheme and appearance in their promotional materials. *See*, *e.g.*, AstraZeneca Corporation, *Official Nexium Site: Info on Heartburn and Acid Reflux Disease*, *at* www.purplepill.com (last visited Jan. 20, 2006) (featuring the pill's color in the website URL as well as a picture of the pill itself at the top of the website promoting Nexium).

99 *See*, *e.g.*, Ciba-Geigy Corp. v. Bolar Pharm. Co., 547 F. Supp. 1095, 1103–04 (D.N.J. 1982) (finding pill coloring that identifies dosage strength non-functional, even though it can be used to identify a particular pill.); *SK&F, Co*., 695 F.2d at 1064 (finding pill's color scheme non-functional); A.H. Robins Co. v. Med. Chest Corp., 1980 U.S. Dist. LEXIS 14412, *15 (E.D. Mo. 1980) (finding pill's color scheme non-functional); Marion Labs., Inc. v. Mich. Pharmacal Corp., 338 F. Supp. 762, 766–67 (E.D. Mich. 1972) (holding capsule color non-functional given wide array of color combinations available for gelatin capsules). *C.f.* Norwich Pharacal Co. v. Sterling Drug, Inc., 271 F.2d 569, 572 (2d Cir. 1959) (holding pink color of Pepto-Bismol functional on grounds that, while color has no healing value, it presents a pleasing appearance designed to encourage product's use). "Color—even color applied over the entire surface of the goods—is really nothing other than a type of product ornamentation. Analysis of color trademarks should, therefore, be subject to the same analysis as any other sort of ornamentation." *In re* Star Pharms., Inc., No. 319,221, 225 U.S.P.Q. 209, 210, 1985 TTAB LEXIS 128, *7 (TTAB 1985). Where a pill color is not found to create a link in consumers' minds as to the pill's origin, however, the pill color can be found a functional element able to be copied by generic imitators. *See*, *e.g.*, Inwood Labs., Inc. v. Ives Labs., Inc., 456 U.S. 844, 853 (1982). The *Inwood* Court found that the blue and blue-red colors used by Ives in their prescription pills were functional to doctors, hospitals, and patients in differentiating one pill from another. *Id.* Because Ives failed to demonstrate that the unique coloring of their pills had created an association in patients' minds as to the drug's origin, the color hadn't acquired secondary meaning entitling Ives to protection against imitators copying their pill's color scheme. *Id.*

100 329 F.3d 348 (3d Cir. 2003).

trademark protection to pharmaceutical manufacturers' pill colorings, clouding what was once a well-settled set of rules and blurring the line of what is permissible for both brand-name manufacturers and their generic imitators.

The Plaintiff in the case, Shire U.S., Inc., manufactured a drug to treat attention deficit hyperactivity disorder (ADHD) under the brand name "Adderall."[101] Adderall had been on the market since 1996, and by 2001 it commanded a 32% market share in the U.S. ADHD prescription market.[102] The pills were marketed in various strengths, and color and size of the pills varied with pill strength. For example, 5mg tablets were blue and round, 7.5 mg tablets were blue and oval, 15 mg tablets were pale orange and oval, etc.[103] All the pills were marked "AD" on one side, and the dosage size (in milligrams) were marked on the other side.[104] This color and shape scheme was featured in product literature and promotional materials, and some materials directed patients to examine their tablets to ensure they are taking the exact drug and dosage prescribed for them.[105] Like other prescription pills, pictures of the Adderall pills appeared in the *Physician's Desk Reference* and other reference books on prescription medications.[106]

In 2002, Shire stopped promoting Adderall but continued to sell the drug.[107] In February 2002, the defendant Barr Laboratories began marketing a generic version of Adderall.[108] Barr's generic drug was bioequivalent to Adderall but, like many generics, contained different inactive ingredients than its brand name counterpart.[109] Like Adderall, Barr marketed their generic equivalent in different dosages, and mirrored the color, shape, and dosage combinations of Shire's Adderall product.[110] In May 2002, Shire filed a motion seeking a preliminary injunction precluding Barr from selling their generic pills with

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101 *Id.* at 349 (summarizing facts of case).

102 *Id.*

103 *Id.* at 350 (describing Adderal pills' trade dress).

104 *Id.*

105 *Id.* (noting manufacturer's promotional efforts).

106 *Id.*

107 *Id.*

108 *Id.*

109 *Id.* Barr's tablets, for example, contained saccharin, which was once on the FDA's list of banned substances. *Id.*

110 *Id.* at 351. The sizes and shapes for Barr's tablets, like Shire's Adderall pills, were keyed to dosage. *Id.* The face of Barr's tablets, however, were stamped with a "b" mark and contained a numerical product code, while Shire's pills were stamped with an "AD" and the dosage amount. *Id.*

such a similar appearance to their Adderall tablets.[111] The District Court denied Shire's motion in August 2002, and Shire subsequently appealed to the Third Circuit in September 2002.[112]

The Third Circuit upheld the District Court's finding that "'Shire has failed to prove the requisite non-functionality [of their unique color scheme] as an initial step to gaining the desired relief . . . .'"[113] The *Shire* court found that similarity in pill appearance between Adderall and its generic counterpart both enhanced patient safety by allowing them to readily identify the pills and dosages by color and promoted a patient's psychological acceptance of the generic substitute drug.[114] This finding, however, directly contradicts the Third Circuit's earlier holding from *SK&F Co. v. Premo Pharmaceutical Laboratories, Inc.*[115] In that case, the court rejected those same arguments and found that a unique color scheme employed by a brand name pharmaceutical manufacturer for their pills could not be imitated by the manufacturer of a generic equivalent.[116]

The *SK&F* court noted, like other courts addressing the issue, that "[p]roof of nonfunctionality generally requires a showing that the element of the product serves no purpose other than identification" and that, in the case of drugs, "the allegedly nonfunctional element must not enhance efficacy."[117] The *SK&F* court, therefore, rejected Premo's arguments that pill color was functional just because it helped patients to identify and adjust to a generic counter-

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111 *Id.* (outlining procedural history of case).

112 *Id.*

113 *Id.* at 355 (quoting District Court's opinion, *Shire U.S., Inc. v. Barr Labs.*, Inc., 2002 U.S. Dist. LEXIS 27134, *18–19 (D.N.J. Aug. 26, 2002)).

114 *Id.* (recognizing that prior district court cases rejecting these arguments have been affirmed by the Third Circuit).

115 625 F.2d 1055, 1057 (3d Cir. 1980).

116 The *SK&F* Court reviewed affidavits by licensed pharmacists that were submitted by the generic pill manufacturer noting that having standardized size, shape, and color between brand-name pills and their generic counterparts is "important to ensure that the proper pharmaceutical product is dispensed[,] . . . highly desirable in emergency situations, where the color, size and shape provide rapid identification of the product to which a patient has overdosed[,] . . . [and] useful to enable a patient to advise a physician regarding the medication the patient has taken previously by describing the color, size, and shape." *Id.* at 1060. Premo Pharmaceuticals, the generic manufacturer, also presented affidavits to the *SK&F* Court that when patients are switched from the brand name drug to its less expensive generic counterpart, "the patient will feel confident that there is no change being made in the chemistry of the medication if the generic drug is in the same size, shape and color as the [brand-name medication they were previously on.]" *Id.* at 1060–61.

117 *Id.* at 1063 (citing William R. Warner & Co. v. Eli Lilly & Co., 265 U.S. 526, 529 (1924)).

part drug.[118] The *SK&F* court further noted that SK&F's choice of color scheme was arbitary and had "nothing to do with the purpose or performance of the drug, or with its processing."[119] Because the only purpose of the coloring was to identify the pills with their source, the color scheme had acquired a protectable secondary meaning and could not be copied by competitors like Premo in their generic counterpart drugs.[120]

Twenty three years later, the *Shire* court attempted to distinguish its ruling from the seemingly contradictory *SK&F* ruling by noting that the plaintiff in *SK&F* presented evidence of actual "passing off" of the generic drug for its brand name counterpart by unscrupulous pharmacies, while no such claim was made by the *Shire* plaintiff.[121] This fact, however, offers little grounds for distinguishing the two cases, since the *SK&F* court considered this as a factor in construing New Jersey state law not the Lanham Act.[122] The *Shire* court also noted that the district court credited evidence that such similarity in pill appearance enhanced patient safety by promoting psychological acceptance of generics and played a functional role in identifying the pills and their dosages.[123] This argument, however, was expressly rejected by the *SK&F* court and others prior to the *Shire* ruling.[124]

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118 *Id.* at 1064 (finding drug's color scheme had acquired secondary meaning).

119 *Id.* "[I]t is undisputed that the maroon and white color scheme of a virtually identical capsule container was adopted by Premo with the intention of associating its product, in the minds of users, physicians, and pharmacists, with [SK&F's product] DYAZIDE." *Id.* at 1063.

120 *Id.* at 1064 (declaring pill color scheme non-functional because there was "ample evidence that neither the capsule form nor the color combination reflects any industry practice for the identification of diuretics"). "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." Aaron M. Pile, *What's In Your Bottle?:* Shire U.S., Inc. v. Barr Laboratories Inc. *and its Effect on Prescription Drug Trade Dress Protection in the Third Circuit*, 8 J. PGH. J. TECH. L. & POL'Y 2, at *11 (2004), *available at* http://tlp.law.pitt.edu/articles/PileSpring2005.pdf.

121 Shire U.S., Inc. v. Barr. Labs., Inc., 329 F.3d 348, 356 (3d Cir. 2003) (noting *SK&F* "is distinguishable on its facts as in *SK&F* we found evidence of actual passing off by pharmacists . . . . Shire does not make a comparable claim in this case.").

122 *See SK&F Co.*, 625 F.2d at 1062–64 (finding likelihood of success that plaintiff could establish that defendant committed tort of 'passing off' and tort of unprivileged imitation). Furthermore, the *SK&F* court did not require a showing of actual passing off, but only that the "use of a practically identical trade dress would facilitate such passing off." *Id.* at 1063.

123 *Shire U.S., Inc.*, 329 F.3d at 358–59 (attempting to distinguish current holding from prior contrary precedents).

124 *SK&F, Co.*, 625 F.2d at 1060–61 (rejecting argument that color scheme is functional due to patient familiarity with it). In *SK&F*, the defendant presented expert testimony that marketing generics in the same size, color, and shape as their brand-name counterparts was "desir-

As noted by the *Shire* court, the Supreme Court has, in the years since the *SK&F* decision, expressly cautioned courts "against the over-extension of trade dress protection."[125] Even this, however, fails to provide a satisfactory explanation for the Third Circuit's dramatic reversal between *SK&F* and *Shire*.[126] In 2000, the Supreme Court warned against the potential harm to consumer interests by over-protection of product design features under the Lanham Act.[127] The Court in *Wal-Mart Stores v. Samara Brothers, Inc.*[128] held that, in cases of product design, courts should "err on the side of caution and classify ambiguous trade dress as product design, thereby requiring secondary meaning."[129] The *Shire* court, however, failed to acknowledge that Shire's color scheme had acquired secondary meaning and, therefore, entitled them to trademark protection.

The *Shire* court's functionality finding was based on the fact that the color scheme employed by Shire in their Adderall tablets was so familiar to patients, that adherence with this color scheme was deemed to be a therapeutic benefit.[130] Because the *Shire* court found that the color scheme for Shire's Ad-

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able to facilitate identification of a particular medication . . ." and to avoid patient confusion. *Id.* at 1060. Premo's experts also warned that "patients who have been using Dyazide [(SK&F's product)] on an extended basis would become uneasy, confused and react adversely if they received a renewal of their prescriptions with a different colored or shaped medication, even though the medication is completely identical. This could hamper the therapeutic effectiveness of the generic medication." *Id.* at 1061. The *SK&F* court, however, rejected this argument, finding that the coloring adopted by SK&F was "arbitrary, having nothing to do with the purpose or performance of the drug, or with its processing." *Id.* at 1064. The coloring adopted by SK&F was non-functional in that "[t]he only value of the trade dress was in identifying the goods with their source. . . ." *Id.* Other courts addressing this issue have similarly found a pill's coloring to be non-functional. *See*, *e.g.*, Ciba-Geigey Corp v. Bolar Pharm. Co., 547 F. Supp. 1095, 1103–04 (D.N.J. 1982) (finding pill coloring that identifies dosage strength non-functional, even though it can be used to identify a particular pill); A.H. Robins Co. v. Med. Chest Corp., 1980 U.S. Dist. LEXIS 14412, at *15 (E.D. Mo. 1980) (finding pill color non-functional); Marion Labs., Inc. v. Mich. Pharmacal Corp., 338 F. Supp. 762, 766–68 (E.D. Mich. 1972) (holding capsule color nonfunctional given wide array of color combinations available for gelatin capsules).

125 *Shire U.S., Inc.*, 329 F.3d at 358.

126 *Id.* at 353 (citing TrafFix Devices, Inc. v. Mktg Displays, Inc., 532 U.S. 23 (2001)).

127 Wal-Mart Stores, Inc. v. Samara Bros., Inc., 529 U.S. 205, 213 (2000) ("Consumers should not be deprived of the benefits of competition with regard to the utilitarian and esthetic purposes that product design ordinarily serves by a rule of law that facilitates plausible threats of suits against new entrants based upon alleged inherent distinctiveness.").

128 529 U.S. 205 (2000).

129 *Id.* at 215.

130 *Shire U.S., Inc.*, 329 F.3d at 354–55 (concurring with the District Court's decision that unique color and shape of Shire's generic pills were directly linked to the drug's efficacy).

derall tablets was functional and not entitled to trademark protection, the court did not address the question of whether or not Shire had achieved secondary meaning for the pill's color scheme.[131]

The very elements of Shire's trade dress that the *Shire* court found to give the color scheme functionality, however, are the source of the scheme's secondary meaning and trademark protection. Secondary meaning is found where a manufacturer's trade dress is so widely recognized by consumers it has the effect of identifying the source of a product in the mind of the consuming public.[132] In the case of generic drugs, any therapeutic benefit derived from the familiarity of a pill's color is because the brand name manufacturer created secondary meaning in their pill's color scheme.

When a patient takes a generic drug that looks identical to its brand-name counterpart, the purported "therapeutic benefit" from the identical color scheme is derived from the patient's strong association between the pill's color and its perceived source. For example, in the *Shire* case, patients receiving an alleged functional benefits from taking these pills, either generic or name brand, did so from the assurance (reinforced by the pill's color scheme) that they were taking "Adderall," not Amphetamine-Dextroamphetamine, the active ingredient in Adderall shared with its generic counterparts.[133] The *Shire* decision, however, blurs the lines between secondary meaning and functionality. Secondary meaning is generally used as grounds for affording legal protection to a manufacturer's trade dress. The *Shire* court, however, found the elements of secondary meaning to be a functional characteristic and grounds for denying protection for Shire's trade dress.

V. CONCLUSION

The real reasoning behind the *Shire* court's shift appears to "'have more to do with public health policy' regarding generic drug substitution 'than with trademark law.'"[134] As the court in *Smithkline Beckman Corp. v. Pennex Products Company, Inc.*[135] noted, "[i]f success is said to breed imitation, then to the

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131 *Id.* at 359 (finding no error in District Court finding that "Shire had failed to show that its product configuration was non-functional.").

132 Inwood Labs., Inc. v. Ives Labs., Inc., 456 U.S. 844, 851 (1982).

133 Amphetamine-Dextroamphetamine is the active ingredient in the brand-name drugs Adderall and Adderall XR. *See* Drugs.Com, *Drug Database*, *at* http://www.drugs.com/adderall.html (last visited Oct. 25, 2006).

134 *Shire U.S., Inc.*, 329 F.3d at 358 (quoting J. GINSBURG, D. GOLDBERG & A. GREENBAUM, TRADEMARK AND UNFAIR COMPETITION LAW 194–95 (1991)).

135 605 F. Supp. 746, 748 (E.D.Pa. 1985).

business person imitation is the highest form of flattery."[136] Successful name brand drugs breed successful generics.[137] Imitating the shape and color of a successful brand name prescription pill contributes to the success of its generic substitutes. Patients who currently subscribe to the brand-name product may be more willing to switch to a generic substitute if that generic has the same color and shape of the brand-name drug they have become accustomed to.[138] Standardization of color and shape between brand name drugs and their generic substitutes can assist doctors, pharmacists, and even patients, in quickly identifying the product and in helping to ensure that the proper drug and dosage is being dispensed.[139]

The *Shire* court, however, is not the first court presented with this set of public policy arguments. Nonetheless, it refused to allow these interests to overcome the interests of protecting the brand name innovator drug manufacturer against trade dress infringement by generic imitators. Previous cases in this area have long acknowledged a public policy interest in favor of permitting

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136 *Id.*

137 The market for a given generic is a function of the market for its brand-name counterpart. The first generic substitute introduced to the market can claim 15–30% of the market share of its branded counterpart. Fred Gebhart, *Generic Pharmaceutical Industry Growth Slows a Tad*, DRUG TOPICS, Apr. 1, 2005, http://www.drugtopics.com/drugtopics/article/articleDetail.jsp?id=152727&sk=&date=&pageID=2. As subsequent generic substitutes are introduced, generics can typically claim 90% of a brand name equivalent's original market share. *Id.*

138 *See* SK&F, Co. v. Premo Pharm. Labs., Inc., 625 F.2d 1055, 1060–61 (3d Cir. 1980) (noting expert testimony that where patients are switched from brand-name to generic drugs, they "will feel confident that there is no change being made in the chemistry of the medication if the generic drug is in the same size, shape and color as the branded [drug]"). As one expert in the *SK&F* case noted, patients who have been using brand-name drugs "on an extended basis would become uneasy, confused and react adversely if they received a renewal of their prescriptions with a different colored or shaped medication, even though the medication is completely identical." *Id.* at 1061. As Justice White noted in his concurring opinion in *Inwood*, "for the patient-user, of course, constancy of color and shape may be as psychologically reassuring and therefore as medically beneficial as the drug itself. . . ." Inwood Labs, Inc. v. Ives Labs., Inc., 456 U.S. 844, 862 (1982) (White, J., concurring).

139 *SK&F, Co.*, 625 F.2d at 1060 (noting desirability of standardizing color, size, and shape between brand name drugs and generic equivalents). There can also be a more sinister driver of generic drugs that imitate the look and feel of their name-brand counterparts. As the court in *Boehringer Ingelheim v. Pharmadyne Labratories* noted, "such copying increases sales of the[] generic [drug] because unscrupulous pharmacists will buy it to pass it off profitably as [the name-brand product]." 532 F. Supp. 1040, 1051 (D.N.J. 1980). *See also SK&F, Co.*, 625 F.2d at 1063 (noting generic's "use of a practically identical trade dress would facilitate . . . passing off" of less expensive generics for more costly name-brand drugs by "unscrupulous pharmacists").

such imitation. For example, in *SK&F Co. v. Premo Pharmaceutical Laboratories, Inc.*,[140] the Justice Department submitted an amicus curae brief to the Third Circuit urging that "the general federal policy of favoring competition . . . in the prescription drug industry . . . demand the conclusion that generic drug manufacturers should be free to copy the form and appearance of the most popular brand name prescription products."[141] Despite these seemingly compelling reasons proffered to permit generic companies to mimic the unique appearance of their brand-name counterparts, courts have traditionally held that such imitation runs afoul of the protections of the Lanham Act.[142]

The public policy landscape, and the continuing push to promote generic drugs, has, however, changed dramatically in the years between *SK&F* and *Shire*. The Hatch-Waxman Act, passed four years after the *SK&F* decision, marked an explosive growth in the use of generic pharmaceuticals. Generic pharmaceuticals currently account for 53% of all prescriptions in the U.S., compared to less than 4% prior to 1984, and that percentage continues to grow.[143] The escalating cost of prescription drugs also places additional public policy pressures on fostering more cost-effective generic substitutes for brand-name pharmaceuticals. Prescription drug spending has grown from 5.8% of U.S. health expenditures in 1997 to 10.5% in 2002.[144] During this time, U.S. prescription drug costs grew by a real (inflation-adjusted) average annual rate of 14.5%.[145]

The dramatic shift of the *Shire* court's application of trade dress protection to prescription pharmaceuticals appears to be a case of what Justice Scalia

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140 625 F.2d at 1067.

141 *Id.*

142 *Id.* (noting that this type of "business activity, while promoting competition in the short run, are in the long run apt to be destructive of competition."). The *SK&F* Court noted that such imitation also runs afoul of the "patient's interest in protection from both inadvertent confusion and deliberate illegal substitution" from look-alike generic substitute drugs. *Id.* In spite of the public policy arguments offered in support of look-alike generic drugs, the *SK&F* Court rejected the "contention that it would be somehow in the public interest to permit [generic companies] either to facilitate passing off or to appropriate a nonfunctional trade dress that has acquired a secondary meaning in the identification of [the name brand counterpart] product." *Id.*

143 *See* de Vink, *supra* note 6, at 181 (noting pre-1984 marketshare of generic prescription drugs); Jaeger, *supra* note 7 (noting current generic pharmaceutical marketshare); Terlep, *supra* note 3 (noting projected growth of generic pharmaceutical industry).

144 COLIN BAKER, CONGRESSIONAL BUDGET OFFICE, ECONOMIC BUDGET AND ISSUE BRIEF—WOULD DRUG IMPORTATION REDUCE U.S. DRUG SPENDING?, Apr. 29, 2004, *available at* http://www.cbo.gov/ftpdocs/54xx/doc5406/04-29-PrescriptionDrugs.pdf.

145 *Id.*

criticizes as judges adopting "the *attitude* of the common-law judge—the mind-set that asks, 'What is the most desirable resolution of this case, and how can any impediments to the achievement of that result be evaded?'"[146] Allowing generic pharmaceutical manufacturers to imitate the appearance of their brand-name counterparts, however, may not be as desirable a resolution as the *Shire* court's opinion appears to presume.

In addition to the traditional business reasons for extending protection under the Lanham Act, there are compelling public policy reasons for *not* allowing generic drugs to imitate the appearance of their brand-name counterparts. Generic drugs may be bioequivalent, but they aren't the same drug as their brand-name counterparts.[147] Generics are identical to their brand-name counterparts only with respect to the active ingredients. "The binders, dilutents, and excipients (filler) in the formulation, as well as the methods of manufacture, may vary."[148]

This means that a generic drug, while *bioequivalent* to its brand-name counterpart, may not always be *therapeutically* equivalent.[149] This can be especially problematic for "narrow therapeutic range" or "NTI" drugs, where small changes in dosage and/or blood concentration result in critical changes in drug efficacy or safety.[150] While the FDA maintains that generics are fully interchangeable for brand name NTI drugs,[151] various groups throughout the medical industry support the contention that these generics are not always safely inter-

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146 ANTONIN SCALIA, A MATTER OF INTERPRETATION: FEDERAL COURTS AND THE LAW 13 (Princeton University Press, 1997).

147 *See supra* notes 32–33 and accompanying text for a discussion of bioequivalence.

148 COUNCIL ON SCIENTIFIC AFFAIRS AND PUBLIC HEALTH, AMERICAN MEDICAL ASSOCIATION, FEATURED REPORT: GENERIC DRUGS, June 2002, *available at* http://www.ama-assn.org/ama/pub/category/15279.html.

149 *Id.* (noting that, while the FDA has been unable to "document a single example of therapeutic failure when an FDA designated therapeutically equivalent product" was used as a substitute for a brand name drug, the perception persists that "the current bioequivalence approach for approving generic products does not adequately account for individual variation in drug disposition."). "[I]n the 1970s it was recognized that differences in the formulation of products containing the same amount of active ingredient could result in significant differences in bioavailability, and several cases of therapeutic inequivalence involving generic products were reported." *Id.*

150 Letter from Stuart L. Nightingale, Assoc. Comm'r for Health Affairs, U.S. Food and Drug Admin., to Health Practitioners, (Jan. 28, 1998), *available at* http://www.fda.gov/cder/news/nightgenlett.htm.

151 *Id.* (claiming that no "additional clinical scrutiny is necessary when interchange [of generic equivalent for NTI drugs] ocurrs."). The FDA maintains that "generic alternatives act the same way as the brand-name drugs—that they are just as safe and effective." *FDA White Paper*, *supra* note 15.

changeable for their brand-name NTI counterparts.[152] While the debate about the safety and interchangeability of these drugs continues, it is clear that there may be some cases where it is medically helpful to be able to visually distinguish between a brand name drug and its generic counterparts. This goal would be undermined by allowing look-alike generics.

Being able to distinguish easily between generic drugs and their brand-name counterparts is also crucial to the proper functioning of a competitive prescription drug marketplace. Due to the unique nature of the prescription drug marketplace, a pill's appearance may offer the only means for a consumer to readily identify a pill's source. Prescription drugs are generally distributed to pharmacists in large original packages, which bear distinguishing labels, but, when the pills are sold to the ultimate consumer, the tablets are re-packaged in generic pharmacy bottles.[153] This creates the risk of a pharmacist "passing-off," either deliberately or inadvertently, cheaper look-alike generic drugs to patients while charging for the more expensive brand name medication. This problem is only exacerbated by generics imitating the appearance of brand-name counterparts.[154]

The inability to identify look-alike generics from their brand name counterparts also undermines the ability for consumers to exercise their prefer-

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152 *See*, *e.g.*, Peter R. Kowey, American Heart Association, *Issues in Bioequivalence and Generic Substitution for Antiarrhythmic Drugs*, Dec. 7, 2005, *at*, http://www.americanheart.org/presenter.jhtml?identifier=3015266 (last visited Sept. 7, 2006) (urging physicians to use caution in substituting generics for NTI drugs and urging the FDA to alter the approval process for NTI generic equivalents "to assure a greater sense of clinical security"); LINDA L. BARRETT, AMERICAN ASSOCIATION OF RETIRED PERSONS (AARP), PHYSICIANS' ATTITUDES AND PRACTICES REGARDING GENERIC DRUGS, 17 (Mar. 2005), *available at* http://assets.aarp.org/rgcenter/health/phys_generic.pdf ("Three in four (75%) physicians *strongly* or *somewhat agree* that there are some drugs with therapeutic indices that should not be substituted [with generics] even when required by third parties."); Wellmark BlueCross Blue Shield, *Narrow Therapeutic Index*, http://www.wellmark.com/products/pharmacy/nti.htm (last visited Oct. 25, 2006) (noting that patients will not be required to pay the difference between brand name and generic drug if the brand name drug is considered to be an NTI medication); University of Michigan Health System, *Generic and Brand-Name Drugs*, http://www.med.umich.edu/1libr/aha/aha_genbrand_sha.htm (last modified May 3, 2005) ("Sometimes brand-name drugs are preferred to generics. For example, very precise control of dose may be important, or the medicine may be hard to produce.").

153 *See* Smith, Kline & French Labs. v. Heart Pharm. Corp., 90 F. Supp. 976, 977 (S.D.N.Y. 1950) (noting how prescription drugs are generally distributed).

154 *Id.* at 978 (finding look-alike generic manufacturer's "wrong . . . in designedly enabling" unscrupulous phrmacists to palm off generic prescriptions as that of the brand name drug). *See also* SK&F, Co. v. Premo Pharm. Labs., Inc., 625 F.2d 1055, 1067 (3d Cir. 1980) (noting public interest in protecting consumers "from both inadvertent confusion and deliberate illegal substitution" of generic drugs).

ence, whether reasonable or not, for a particular manufacturer's drugs.[155] Despite the dramatic cost differential between generics and brand name drugs,[156] as well as the pressure from insurance companies to encourage generic prescriptions,[157] many consumers continue to prefer brand-name drugs, even though a generic counterpart is available.[158] Without the ability for a consumer to readily identify the source of a pill by its unique appearance, a consumer is subject to the very type of confusion that the Lanham Act is designed to prevent—confusion as to the source of the product they are purchasing.[159]

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155 The FDA maintains that "[g]eneric drugs work in the same way and in the same amount of time as brand-name drugs." CDER, *supra* note 94. Despite this position, the medical community is not in unanimous agreement with this position. *See*, *e.g.*, Kowey, *supra* note 152 (noting that not all generics are therapeutically equivalent to their brand-name counterparts); AARP, *supra* note 152 (noting that not all generics are therapeutically equivalent to their brand-name counterparts). The FDA also notes that brand-name and generic drug facilities must meet the same manufacturing standards. CDER, *supra* ("Generic firms have facilities comparable to those of brand-name firms."). "In fact, brand-name firms are linked to an estimated 50 percent of generic drug production. They frequently make copies of their own or other brand-name drugs but sell them without the brand name." *Id.*

156 "Generic drugs cost about 30 to 80 percent less than name-brand equivalents, and some estimates put the annual savings from generic drugs at $10 billion nationally. For patients with prescription drug coverage, co-payments for generic drugs usually are less than for name-brand drugs." Terlep, *supra* note 3.

157 Insurance companies utilize marketing campaigns and "educational blitzes" to encourage doctors to prescribe generic drug alternatives as well as set goals for physicians to prescribe generics at least 50% of the time. *Id.* "In a recent AARP survey of 425 physicians, two-thirds said they frequently feel pressured by health care plans or insurance companies to prescribe generic drugs." *Id.*

158 *See id.* (noting that consumers often prefer brand-name drugs to their generic counterparts). *See generally*, Natihan Sabel, *Irrational Choice: A Study of Brand-Name and Generic Drug Purchasing Patterns*, May 6, 2005, http://leda.law.harvard.edu/leda/data/708/Sabel05_redacted.html (last visited Oct. 25, 2006) (noting that, despite efforts by the FDA and insurance companies to push generic drugs, consumers continue to purchase brand-name drugs even when less expensive generics are available).

159 *See* 3 J. THOMAS MCCARTHY, MCCARTHY ON TRADEMARKS AND UNFAIR COMPETITION § 23:5 (4th ed. 2005).