

Trademarks and "Look-Alike" Drugs

I. INTRODUCTION

"Look-alike" drugs are generic products¹ which are identical in size, shape, and color to their brand-name counterparts. The problems created by look-alike drugs have arisen in several cases; however, the equities were such that the courts were never forced to decide specifically whether, absent any fundamental inequality in the products, generic drug manufacturers should be allowed to market products made identical in size, shape, and color to their brand-name counterparts. The recent case of *Ives Laboratories, Inc. v. Darby Drug Co.*,² has crystallized this issue and was heard by the United States Supreme Court during its 1981-1982 term.

The courts, aided by previously existing "anti-substitution" legislation,³ had been able to control the controversy between generic and brand-name drug manufacturers. However, with the majority of states repealing that legislation, coupled with the Food and Drug Administration's (FDA) strong support of generic drug use,⁴ the issue of look-alike drugs has exploded into high-stakes economic warfare. The generic drug companies allege that brand-name manufacturers are trying to block generic products from entering the market by creating monopolies in color combinations which would effectively extend the term of their expired patent under the guise of trademark law.⁵ The brand-name companies

¹A "drug product" is a capsule, tablet, or other dosage form which contains a specific "drug" as the active ingredient. Each drug has both a standard "chemical name" and a "non-proprietary name." The non-proprietary name is usually a shortened version of the chemical name and is often, as in this Note, referred to as the "generic name." REMINGTON'S PHARMACEUTICAL SCIENCE 1308-09 (15th ed. 1975) [hereinafter cited as REMINGTON'S]. A brand name, by contrast, is a name arbitrarily assigned to the drug by a particular manufacturer and is often protected under trademark laws as a trade-mark. As long as a generic and a brand-name product contain the same quantity of the active chemical entity, they are termed generically or chemically equivalent. REMINGTON'S, *supra*, at 1368.

²455 F. Supp. 939 (E.D.N.Y. 1978), *aff'd and remanded*, 601 F.2d 631 (2d Cir. 1979); 488 F. Supp. 394 (E.D.N.Y. 1980), *rev'd and remanded*, 638 F.2d 538 (2d Cir. 1981), *rev'd and remanded sub nom.* *Inwood Laboratories, Inc. v. Ives Laboratories, Inc.*, 50 U.S.L.W. 4592 (1982).

³"Anti-substitution laws" prohibit pharmacists from dispensing any manufacturer's drug product other than the one specifically named on the prescription. See notes 12-17 *infra* and accompanying text.

⁴See BUREAU OF CONSUMER PROTECTION, U.S. FEDERAL TRADE COMM'N, DRUG PRODUCT SELECTION, STAFF REPORT TO FTC 1-44 (1979) [hereinafter cited as FTC REPORT]; Hecht, *Generic Drugs: How Good Are They?*, FDA CONSUMER, Feb. 1978, at 17.

⁵See note 30 *infra*.

respond that they are only trying to prevent the generic companies from unfairly utilizing the innovator's advertising campaigns and to protect the good will they have earned through the promotion and use of their products.

Consumers also have interests in the issues raised by look-alike drugs. Without a means to distinguish between specific drug products, consumers will be unable to determine whether unknown or inferior quality drugs are received. In addition, consumers may fall prey to unscrupulous pharmacists who may easily substitute lower-priced generic products for more expensive brand-name products without the consumer's knowledge. Finally, the use of look-alike products provides an opportunity for the imitation of drugs with high abuse potentials thereby creating the possibility for injury or even death.

This Note will evaluate the methods used to control the look-alike drug problem and the effect of look-alikes upon various interested parties. A discussion of legislative and judicial avenues for controlling the problems will follow. Finally, a possible solution will be proposed which takes into consideration the efficiency of available systems and balances the legitimate interests of the parties.

II. BACKGROUND

For centuries merchants and consumers alike have recognized the importance of being able to differentiate among similar products.⁶ Some goods, such as clothing and raw materials, are easily distinguishable simply by touching them; others, such as perfumes or foods, are recognizable by smelling or tasting. For other goods consumers must rely upon accompanying literature, advertising, or consumer reports. Prescription drug products, however, present a unique situation because consumers have no opportunity to receive first-hand information. They must rely not only upon a physician to prescribe the appropriate medications, but also upon a pharmacist to dispense the correct product. Unlike other goods, drugs are capable of being positively identified only by technical chemical assaying; therefore, strict rules and ethics regulating the prescription and distribution of drugs have been created.⁷

Drugs are distributed from the manufacturers in distinctive packaging and with identifying literature; however, the various drugs reach the ultimate consumer in identical amber vials with

⁶H. TOULMIN, *THE TRADE-MARK ACT OF 1946* 1-2 (1946).

⁷*See, e.g.*, IND. CODE §§ 25-26-13-1 to -29 (Supp. 1981) (laws regulating licensure of pharmacists and pharmacies); *id.* §§ 16-1-28-1 to -5, -7 to -16, -19, -22 (pure food and drug legislation).

only a pharmacist's label affixed. Once a medication is removed from one of these vials, only the product's size, shape, and color can provide any hints to its identity. Although the physical appearance of a drug product can create a presumption of the product's identity, the presumption is valid only as long as the strict regulations governing the manufacture and distribution of drug products remain intact.

A. *Mechanisms Used to Further
Drug Product Identification*

The continuing goal of pharmacy laws and ethics has been to assure the patient that he will receive the medications properly prescribed by his physician and that the drugs he receives are of good quality.⁸ A physician has traditionally had the prerogative not only to prescribe an appropriate drug for his patient, but to identify a particular product and its manufacturer or source as well.⁹ Until recently the modern laws governing pharmacy, in an effort to aid in product identification, required the pharmacist to fill the prescription exactly as it was written by the physician. Forty-nine states, however, have repealed these "anti-substitution" laws¹⁰ and now permit pharmacists to substitute, within specified limits, equivalent products for the drug specified by the physician.¹¹

The role of both anti-substitution and pro-substitution laws in providing the ultimate consumer with a means of identifying drugs will be presented as a framework for analyzing the cases involving

⁸REMINGTON'S, *supra* note 1, at 24.

⁹PHARMACEUTICAL MFRS. ASS'N, THE MEDICATIONS PHYSICIANS PRESCRIBE: WHO SHALL DETERMINE THE SOURCE? 3-4 (1972) [hereinafter cited as PMA]. See Willig, *The Prosubstitution Trend in Modern Pharmacy Law*, 6 U. MICH. J.L. REF. 1, 2 & nn.3 & 4, 20 (1972).

¹⁰Indiana is the only state which has retained its substitution prohibition. *Indiana: The Only State Where RPh's Don't Play a Role in Rx Product Selection*, AM. DRUG-GIST, Dec. 1981, at 34.

¹¹For a discussion of state laws permitting substitution, see McCarey, *Generic Substitution Policy*, 34 FOOD DRUG COSM. L.J. 103 (1979); Ruggieri, *Manufacturers' View of Generic Substitution Legislation*, 34 FOOD DRUG COSM. L.J. 108 (1979); Willig, *supra* note 9; Note, *Consumer Protection and Prescription Drugs: The Generic Substitution Law*, 67 KY. L.J. 384 (1978-1979). See also Dickinson, *Substitution After a Decade: Oh, What a Tangled Web!*, DRUG TOPICS, Mar. 15, 1982, at 45, 46-47.

For a pharmaceutical discussion of these laws, see Goldberg & DeVito, *The Impact of State Generic Drug Substitution Laws*, DRUG THERAPY, Dec. 1981, at 75; *Drug Substitution Laws: A State-by-State Overview*, DRUG THERAPY, Dec. 1979, at 15 [hereinafter cited as *Overview*].

For a medical discussion, see Carr, *Potential Liabilities of Generic Drug Prescribing*, DRUG THERAPY, July 1979 at 99; Coyne, *Fear and Loathing and Generic Drugs*, PRIVATE PRAC., Sept. 1978, at 18; *Substitution: The Doctor's Dilemma*, PRIVATE PRAC., June 1980, at 47-60 (special section) [hereinafter cited as *Doctor's Dilemma*].

look-alike drugs. In addition, a familiarity with fundamental concepts concerning trademark law is necessary for an understanding of the judicial treatment of look-alike drugs.

1. *Anti-Substitution Laws.*—Although drug substitutions were occasionally necessary and tolerated during periods of commercial uncertainty and of war, the first national anti-substitution drug law can be traced back to a thirteenth century German edict.¹² Modern anti-substitution laws promulgated during the early 1950's were the result of a growing concern regarding the increased marketing of drug products of unknown quality whose appearance resembled established products.¹³ In an effort to protect consumers from unethical pharmacists who were "palming off," or substituting cheaper imitations without the knowledge or consent of either the physician or the patient, and to protect the property interests of the innovator or brand-name companies, states passed legislation prohibiting the unauthorized substitution of drug products.¹⁴ The underlying rationale appeared to be that the sanctions¹⁵ imposed by these laws against pharmacists engaging in unauthorized substitution would sufficiently curb the practice. The pharmacist, by virtue of his professional ethics,¹⁶ was trusted to refrain from illegal substitution. These laws and the pharmacist's ethics were the only means by which the patient, or ultimate consumer, could be assured

¹²According to an edict issued in 1227 by Emperor Frederic II of Germany, a substitution without the physician's consent would result in a confiscation of all the pharmacist's wares. PMA, *supra* note 9, at 3.

¹³Green, *Welfare Losses from Monopoly in the Drug Industry: The Oklahoma "Anti-Substitution" Law*, 6 ANTITRUST L. & ECON. REV. 97, 108 (1972); Note, *supra* note 11, at 389.

¹⁴See PMA, *supra* note 9, at 5-7.

¹⁵See, e.g., IND. CODE § 25-26-13-26.1(e) (Supp. 1981). One commentator has noted that:

When the consumer reposes a high level of trust and confidence in the expertise of a provider of goods and services, the law commonly treats this vendor in a fashion different from the manner in which it treats other suppliers of goods and services. Accordingly, the law regulates the professions to a greater extent than other occupations. This scrutiny stems largely from the inability of the public to protect itself adequately in a situation where its members engage the professional on the understanding that he will put their interests before his own. Because the professional is deemed to be a fiduciary, the rule of caveat emptor does not apply. This is clearly the case with the professional pharmacist. He stands as a fiduciary for most transactions, and particularly in the case of prescription drugs, the public must trust the ability of the pharmacist to dispense properly those commodities on which health and life may depend.

Willig, *supra* note 9, at 1.

¹⁶AM. PHARMACEUTICAL ASS'N, CODE OF ETHICS (1969), *reprinted in* REMINGTON'S, *supra* note 1, at 23.

of the drug product's identity because of the inherent difficulty in identifying a drug. The consumer had to believe the drug was what the pharmacist labeled it to be, otherwise he would always have to have it assayed. If look-alike products were available, the faith in the pharmacist had to be well-founded.

The sanctions imposed by the anti-substitution laws impressed upon pharmacists the magnitude of their ethical responsibilities to consumers. In addition, they imposed a standard of conduct which resulted in a high degree of predictability with respect to substitution and similar products. As long as the anti-substitution laws were in effect, *any* substitution of drug products without the physician's knowledge or consent was illegal. The patient could, thereby, reasonably rely on the pharmacist to dispense the specific product ordered by his physician without fear of an unauthorized substitution occurring.

2. *Pro-Substitution Laws.*—In the 1970's, however, a strong, and ultimately successful, movement to reverse the traditional anti-substitution attitude began to gain momentum.¹⁷ As patents held by research-oriented drug manufacturers expired, large numbers of cheaper, generic drug products became increasingly available.¹⁸ Because of the nature of the advertising strategies of the two types of drug companies,¹⁹ the brand-name companies appeared to have a substantial marketing advantage over the generic drug manufacturers.²⁰ This resulted in an alleged inability of the lower priced generic products²¹ to break competitively into the market unless substitution was allowed, thus depriving the consumer of the opportunity to receive cheaper medications.²²

¹⁷See *Generic Deceit: "Look-alike" Drugs and Your Patients*, PRIVATE PRAC., May 1978, at 61, 63. See generally note 11 *supra*.

¹⁸See FTC REPORT, *supra* note 4, at 43-45.

¹⁹See *id.* at 44-50. For a comparison of the differing approaches used by the companies, see notes 50-62 *infra* and accompanying text.

²⁰See, e.g., *Pennwalt Corp. v. Zenith Laboratories, Inc.*, 472 F. Supp. 413, 421 (E.D. Mich. 1979); Green, *supra* note 16, at 102; Latiolais, *Should the Anti-Substitution Laws Be Amended to Permit Substitution? Yes!*, PHARM. TIMES, Sept. 1972, at 32; Stetler, *Should the Anti-Substitution Laws Be Amended to Permit Substitution? No!*, PHARM. TIMES, Sept. 1972, at 33; *Look-Alike Drugs: Is This Pharmacy's Next Battle Ground?*, DRUG TOPICS, Sept. 4, 1979, at 6.

²¹Generic products are generally less expensive than their brand-name counterparts, primarily for three reasons: (1) generic drug manufacturers have no research and development costs to recoup; (2) they advertise products on a "product line" concept rather than individually promoting drugs; and, (3) they adhere primarily to minimum FDA quality control standards. See THE PHARMACEUTICAL INDUSTRY 87 (C. Lindsay ed. 1978); FTC REPORT, *supra* note 4, at 44-50. See also notes 46-62 *infra* and accompanying text.

²²But as with other commodities, a cheaper product is not always better than, or even equivalent to, similar goods. The added expense often covers the cost of increased quality. See *Brand vs. Generic Names*, 59 J. IND. ST. MED. A. 914 (1966) (editorial).

In asserting their position, proponents of substitution pointed to ongoing scientific developments as providing a rational basis for a reversal in policy. They asserted that the fear of unknown or inferior products was no longer valid in light of: (1) the increased regulation and control of drug production by the federal government and, (2) the increased training received by pharmacists which enables them to evaluate data concerning various drug products and to choose among safe and comparable products.²³ Based upon this rationale, the anti-substitution laws were repealed by all but one state,²⁴ and new laws permitting drug substitution within specified limitations were passed.²⁵

With the restraints of anti-substitution laws removed, the presumption that the drug received is the specific drug product ordered becomes weaker. Although the pharmacist is still restricted to substituting only generic equivalents,²⁶ there are many other factors affecting the specific drug products which may or may not be equivalent.²⁷ For this reason it becomes important that the consumer actively monitors the particular drug product which he receives. Without the strong presumption that the drug product is indeed the one specified by the prescription, the consumer must rely more than

²³Tyler, *Are Generics a Drug on the Market?*, 70 J. IND. ST. MED. A. 452, 454-55 (1980). The validity of these bases has been challenged and is the focus of the raging debate concerning substitution. See, e.g., Berger, *Drug Product Selection: Are All Drugs Created Equal?*, MED. MKTG. & MEDIA, Sept. 1980, at 46; Coyne, *Substitution or Switching? New Name For An Old Game*, PRIVATE PRAC., Oct. 1981, at 22-26; Davis, *Brand vs. Generic Drugs*, MED. MKTG. & MEDIA, May 1979, at 4; Dickinson, *supra* note 11, at 45; Feldmann, *Drug Product Selection—Freedom with Responsibility*, 12 J. AM. PHARM. A. (n.s.) 368 (1972); Latiolais, *supra* note 20, at 36; Stetler, *supra* note 20, at 33; *Doctor's Dilemma*, *supra* note 11, at 47-60; *Look-Alikes Can Be Trouble For All, Lawyer Says*, DRUG TOPICS, June 19, 1981, at 16-17. See also *Generic Deceit*, *supra* note 17, at 61, 63.

²⁴See note 10 *supra*; see also *Overview*, *supra* note 11, at 15.

²⁵The New York substitution law is exemplary of common substitution limitations. The physician signs the prescription on a line indicating permission for the pharmacist to substitute or not. N.Y. EDUC. LAW § 6810(6)(a) (McKinney Supp. 1981-1982). If permission to substitute is indicated, the pharmacist must select a less expensive drug product equivalent in form and dosage to the one originally prescribed. *Id.* § 6816-a(1). Often the pharmacist is required to select the product from a list specially prepared by the state. See, e.g., N.Y. PUB. HEALTH LAW § 206(1)(o) (McKinney Supp. 1981-1982). Unfortunately, cost is often the paramount criterion used to compose these lists. Tyler, *supra* note 23, at 455.

²⁶See note 1 *supra*.

²⁷Many factors are involved in the manufacture of drug products and each factor has the potential to alter the amount of actual drug which is made available to the body. For a complete discussion of these variables and their potential effects, see REMINGTON'S, *supra* note 1, at 1355-435. For a brief overview, see *Generic Deceit*, *supra* note 17, at 64.

ever on the physical appearance of the dispensed medication, the only information available to him.

It appears that the opportunity to receive less expensive drug products has shifted more responsibility onto the consumer to recognize the drug products he receives. This, in turn, should require the drug manufacturers to sufficiently distinguish their similar products in order to enable the consumer to aid the pharmacist in dispensing the same product as previously received. A degree of predictability has been lost in primarily two aspects when look-alike products are also involved because questions remain whether the specific drug product dispensed is indeed what it is labeled to be, and whether the drug dispensed was the exact product specified by the physician.

3. *Trademark Theories and Policies.*—Although the specific laws regulating trademarks developed slowly, various marks have been used since antiquity to designate the source or ownership of particular goods.²⁸ Today, trademarks serve primarily three functions: (1) as a means of assuring the consumer of a continuity of quality; (2) as a means of identifying a product's source or origin and thus distinguishing between competing products; and, (3) as a means of advertising.²⁹

Because of the fear of creating monopolies, however, these laws have always limited the scope of what can be trademarked.³⁰ In

²⁸See McClure, *Trademarks and Unfair Competition: A Critical History of Legal Thought*, 69 TRADEMARK REP. 305, 310-16 (1979). For a full discussion of early trademark history, see Diamond, *The Historical Development of Trade-marks*, 65 TRADEMARK REP. 265 (1965); Paster, *Trademarks—Their Early History* (pt. 1), 59 TRADEMARK REP. 551 (1969); Ruston, *On the Origin of Trademarks*, 45 TRADEMARK REP. 127 (1955). For a discussion of early American trademark history, see Pattishall, *Two Hundred Years of American Trademark Law*, 68 TRADEMARK REP. 121 (1978).

²⁹J. CALIMAFDE, TRADEMARKS AND UNFAIR COMPETITION 1 (1970); Diamond, *supra* note 28, at 289; Lunsford, *The Function of Trademarks in the Market Place*, 64 TRADEMARK REP. 75, 78 (1974).

³⁰See McClure, *supra* note 28, at 1.

At first blush, the decisions of *Sears, Roebuck & Co. v. Stiffel, Co.*, 376 U.S. 225 (1964), and *Compcorp. v. Day-Brite Lighting, Inc.*, 376 U.S. 334 (1964), appeared destined to grossly restrict state regulation of industrial property through unfair competition laws. See G. ALEXANDER, COMMERCIAL TORTS § 1.4 (1972); Handler, *Product Simulation: A Right or a Wrong? (Symposium)*, 64 COLUM. L. REV. 1183, 1184 (1964). More importantly, these cases appeared to restrict the application of federal trademark law to products which were the subject of an invalid or expired patent. See Kestenbaum, *The Sears and Compcorp Cases: A Federal Right to Compete by Copying*, 51 A.B.A. J. 935, 939 (1965); Spratling, *The Protectability of Package, Container and Product Configurations*, 63 TRADEMARK REP. 117, 133-34 (1973); Comment, *The Impact of Sears and Compcorp on Federal Trademark and Patent Law*, 19 BUFFALO L. REV. 91, 95-96 (1970).

The Supreme Court has, however, subsequently held that trademark principles

order to be a trademark, the identifying mark must be in continual use and capable of identifying the product.³¹ A mark which is neither distinctive nor arbitrary but is merely descriptive must also have acquired secondary meaning in the minds of the public; the public must associate the mark as representing goods from a particular, albeit anonymous, source.³² Whether a mark has acquired a secondary meaning in the public mind is always a question of fact.³³ Because of the difficulty in discerning the "public's mind," courts have generally considered three factors in determining the acquisition of secondary meaning: (1) the length of time the mark has been in use; (2) the expense and extent of promotional advertising; and, (3) the product's sale volume.³⁴

If the mark is "primarily descriptive of the qualities, ingredients, or characteristics" of the product, however, it will not be protected as a trademark because it is a "functional" feature.³⁵ For example, in *William R. Warner & Co. v. Eli Lilly & Co.*,³⁶ the plaintiff was unable to prevent competitors from marketing imitative chocolate-flavored quinine syrups. The Court held that the chocolate flavoring

and patent principles are directed at different purposes and thus one is not limited by the other. *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 491-93 (1974). *See also* *Truck Equip. Serv. Co. v. Fruehauf Corp.*, 536 F.2d 1210, 1215 (8th Cir.), *cert. denied*, 429 U.S. 861 (1976) ("Full and fair competition requires that those who invest time, money and energy into the development of goodwill and a favorable reputation be allowed to reap the advantages of their investments."); *In re Mogen David Wine Corp.*, 372 F.2d 539 (C.C.P.A. 1967) (*Mogen David II*); *In re Mogen David Wine Corp.*, 328 F.2d 925 (C.C.P.A. 1964) (*Mogen David I*); *In re Deister Concentrator Co.*, 289 F.2d 496 (C.C.P.A. 1961).

For a more thorough examination of the *Sears-Compco* doctrine, see Dannay, *The Sears-Compco Doctrine Today: Trademarks and Unfair Competition*, 67 TRADEMARK REP. 132 (1977); Zammitt, *The Ghost of Sears-Compco is Finally Laid to Rest Or Is It?*, 3 HOFSTRA L. REV. 37 (1975); Note, *Generic Drug Laws and Unfair Competition Claims Under the Lanham Act—An Uneasy Alliance: Ives Laboratories, Inc. v. Darby Drug Co.*, 33 RUTGERS L. REV. 227, 240-44 (1980).

³¹J. CALIMAFDE, *supra* note 29, at 1.

³²E. VANDENBURGH, TRADEMARK LAW AND PROCEDURE 119-23 (1968 & Supp. 1978); *Tas-T-Nut Co. v. Variety Nut & Date Co.*, 245 F.2d 3 (6th Cir. 1957). The term "secondary meaning" is actually a misnomer because it "does not mean a subordinate or rare significance. It means rather a subsequent significance added to the previous meaning of the designation and becoming in the market its usual and primary significance." RESTATEMENT OF TORTS § 716, comment b (1938).

³³J. CALIMAFDE, *supra* note 29, at 102.

³⁴*Id.* *See, e.g.*, *SK&F, Co. v. Premo Pharmaceutical Laboratories, Inc.*, 625 F.2d 1055 (3d Cir. 1980) (sales volume); *Barton v. Rex-Oil Co.*, 2 F.2d 402 (3d Cir. 1924) (length of time); *Le Blume Import Co. v. Coty, Inc.*, 293 F. 344 (2d Cir. 1923) (advertising expenses).

³⁵R. CALLMANN, 3 THE LAW OF UNFAIR COMPETITION, TRADEMARKS, AND MONOPOLIES § 70.1 (3d ed. 1969 & Supp. 1981).

³⁶265 U.S. 526 (1924).

was a functional feature of the syrup because it masked the bitter taste of the quinine, and therefore did not "merely serve the incidental use of identifying the . . . preparation."³⁷

In order to be protectable as a trademark, the identifying feature, therefore, must be both nonessential to the product and capable of being associated with the product in the public's mind. Justice Frankfurter summarized and explained the qualifications and relationships of trademarks as follows:

A trade-mark is a merchandising short-cut which induces a purchaser to select what he wants, or what he has been led to believe he wants. The owner of a mark exploits this human propensity by making every effort to impregnate the atmosphere of the market with the drawing power of a congenial symbol. Whatever the means employed, the aim is the same—to convey through the mark, in the minds of potential customers, the desirability of the commodity upon which it appears. Once this is attained, the trade-mark owner has something of value. If another poaches upon the commercial magnetism of the symbol he has created, the owner can obtain legal redress.³⁸

These requirements have caused the development of two closely related causes of action which differ primarily in the number of steps necessary to prove the existence of a trademark.³⁹ Section 32 of the Lanham Act embodies the common law test for true trademark infringement—"likely to cause confusion, or to cause mistake, or to deceive"⁴⁰—and is applicable in cases involving registered trademarks.⁴¹ Section 43(a) of the Lanham Act⁴² encompasses the broader category of unfair competition which includes actions for palming off and "unprivileged imitation."⁴³ In addition to proving the "likelihood of confusion," section 43(a) requires a

³⁷*Id.* at 531. For an argument that the use of chocolate flavoring should have been classified as nonfunctional, see Cooper, *Trademark Aspects of Pharmaceutical Product Design*, 70 TRADEMARK REP. 1, 9-11 (1980).

³⁸*Mishawaka Rubber & Woolen Mfg. Co. v. S.S. Kresge Co.*, 316 U.S. 203, 205 (1942).

³⁹McClure, *supra* note 28, at 314.

⁴⁰15 U.S.C. § 1114(1)(a) (1976). See *Sears, Roebuck & Co. v. All States Life Ins. Co.*, 246 F.2d 161 (5th Cir.) *cert. denied*, 355 U.S. 894 (1957); *Ciba Pharmaceutical Prods., Inc. v. Abbott Laboratories*, 121 F.2d 551 (C.C.P.A. 1941).

⁴¹15 U.S.C. § 1114(1)(a) (1976).

⁴²*Id.* § 1125(a).

⁴³See, e.g., *SK&F, Co. v. Premo Pharmaceutical Laboratories, Inc.*, 625 F.2d 1055 (3d Cir. 1980).

preliminary step of proving secondary meaning.⁴⁴ This prerequisite step is not necessary under section 32 because the registration of the mark creates a mandatory presumption of its secondary meaning. Section 43(a) is not limited to actions alleging infringement of unregistered trademarks, but also includes false advertising and false descriptions of products.⁴⁵

B. *The Parties' Interests*

The goal of both pharmacy laws concerning substitution and trademark laws is to protect the valid interests of as many concerned parties as possible. To understand the depth of the look-alike controversy, it is necessary to examine in more detail the various interests of the parties concerned. Because the more blatant economic effects are present at the manufacturers' level, the controversy is more sharply focused there. Nevertheless, the issue has significant effects on both distributing professionals and ultimate consumers.

1. *Manufacturers.*—The look-alike issue affects two types of drug manufacturers: brand-name, or innovator, companies which, through extensive research and development, introduce new patented drugs into the market;⁴⁶ and generic companies, which offer their products only after the brand-name companies' patents have expired. Although both parties have economic interests to safeguard, the law protects those interests only to a limited extent through the use of patents,⁴⁷ trademarks,⁴⁸ and general anti-trust principles.⁴⁹

Brand-name companies have an economic interest in protecting their investment of time and money in researching products. A 1979 FTC staff report⁵⁰ stated that drug companies not only finance their

⁴⁴See Note, *Generic Drug Laws and Unfair Competition Claims Under the Lanham Act—An Uneasy Alliance: Ives Laboratories, Inc. v. Darby Drug Co.*, 33 RUTGERS L. REV. 227, 235-38 (1980). If the mark is, however, purely arbitrary and has no descriptive property, secondary meaning is inherently present. See 3 R. CALLMANN, *supra* note 35, at § 71.4.

⁴⁵15 U.S.C. § 1125(a) (1976).

⁴⁶These manufacturers continue to market the drug even after the patent has expired, of course. In addition, some brand-name manufacturers also market various generic products. See FTC REPORT, *supra* note 4, at 48-49.

⁴⁷35 U.S.C. §§ 101-171 (1976). Patents, with the exception of design patents, are issued for periods of 17 years. Design patents are issued for the terms of 3½, 7, or 14 years, depending upon the election of the applicant. *Id.* §§ 154, 173.

⁴⁸Lanham Act of 1946, 15 U.S.C. §§ 1051-1127 (1976).

⁴⁹Sherman Act, 15 U.S.C. §§ 1-7 (1976); Clayton Act, 15 U.S.C. §§ 12-27. See McClure, *supra* note 28.

⁵⁰FTC REPORT, *supra* note 4.

own research almost exclusively, but spend more money on research and development than any other industry.⁵¹ The estimated cost of pharmaceutical research is fifty million dollars for each drug actually marketed after its approval by the FDA.⁵² Because the research and development process of the drug industry is internally funded, these dollars must be recouped if new drugs are to continue to be discovered and marketed.⁵³

Once the new drug is actually marketed, the brand-name company generally has only eight or nine remaining years of its patent-created monopoly.⁵⁴ In order to recover their costs within this period of time, the innovator companies spend large amounts of money in advertising and promoting their products.⁵⁵ Those companies typically employ large forces of "detail men" to deal directly with physicians, hospitals, and pharmacists, providing both promotional and informative literature regarding the products' physical and pharmacological attributes and properties.⁵⁶ Brand-name companies also advertise extensively in medical and pharmaceutical journals.⁵⁷ Those promotional activities not only serve an economic function as advertising, but are relied upon by both pharmacists and

⁵¹*Id.* at 22-25. The drug industry spends approximately 12% of its research budget on basic research and development as compared to the aircraft industry which spends less than 1%, and all private industry which spends an average of 3%. *Id.* at 24. Figures from the Pharmaceutical Manufacturers Association show that company-financed research and development was \$50,000,000 in 1951 and increased to \$937,500,000 in 1975. *Id.* at 22.

⁵²*Unapproved Generics*, AM. PHARM. (n.s.) Nov. 1980, at 12, 17. See also Gorrell, *Substitution: Expectations and Realizations*, MED. MKTG. & MEDIA, May 1981, at 54, 57.

⁵³*Large Drug Firms Fight Generic Substitution*, 206 SCI. 1054 (1979). See Cocks, *Economic Competition in the Ethical Pharmaceutical Industry*, TILE & TILL, Winter 1978-1979, at 19, 22; Tyler, *supra* note 23, at 455-57.

⁵⁴Although patent protection is conferred for 17 years, a slow down in the FDA's processing has created an average lag of eight years between the time a new drug is patented to the time it is marketed. This period should be compared to the time lag in patenting and marketing new electronics—eighteen months. *Large Drug Firms Fight Generic Substitution*, 206 SCI. 1054, 1056 (1979). For a discussion of prerequisites to FDA marketing approval for new drugs, see REMINGTON'S, *supra* note 1, at 1300-11.

⁵⁵See, e.g., *Pennwalt Corp. v. Zenith Laboratories, Inc.*, 472 F. Supp. 413, 416 (E.D. Mich. 1979), *appeal dismissed mem.*, 615 F.2d 1362 (6th Cir. 1980) (the plaintiff spent over \$2,000,000 in promoting its product each year since 1971); *Smith, Kline & French Laboratories v. Heart Pharmaceutical Corp.*, 90 F. Supp. 976, 977 (S.D.N.Y. 1950) (the plaintiff spent approximately \$900,000 in promoting the new color and shape of its product).

⁵⁶See *The Pharmaceutical Sales Representative: A Professional Communicator*, TILE & TILL, Summer 1978, at 8.

⁵⁷See, e.g., *Pennwalt Corp.*, 472 F. Supp. at 416; *Smith, Kline & French Laboratories*, 90 F. Supp. at 977; see generally Leffler, *Persuasion or Information? The Economics of Prescription Drug Advertising*, 24 J.L. ECON. 45 (1981).

physicians as an important source of information about new drugs.⁵⁸ Through its advertising and detailing service, a brand-name drug company establishes a reputation for quality products. Because a picture of the product is often featured in the promotional and advertising literature, its physical appearance also becomes easily recognized as an attendant consequence of this process.

The generic companies, on the other hand, offer only unpatented drugs, but can provide them at substantially lower prices.⁵⁹ The generic companies are generally able to offer the consumer lower prices for the following reasons: they do not engage in research and development; they do not engage in "detailing" or individual promotion, but rather promote drugs in "product lines"; and most generic companies adhere only to minimum FDA quality control standards.⁶⁰ Because of the brand-name companies' monopolies during their patent periods, and their extensive advertising and promotional campaigns, the generic companies contend that unless they are allowed to copy the size, color, and shape of brand-name products, they will not be able to break competitively into the market.⁶¹ They also assert that by producing a look-alike, they are promoting emergency identification, as well as making substitution easier for both pharmacists and consumers.⁶²

2. *Professionals.*—Physicians and pharmacists have an interest in product safety, a concern that has two overlapping aspects: a concern for easy identification; and a concern for bioequivalency in substituted products.⁶³

⁵⁸Because of the nature of research within the drug industry, the innovator manufacturer is often the only source of information regarding the uses and precautions, as well as the physical and pharmacological properties of a new drug. Therefore, physicians and pharmacists rely heavily upon the manufacturers, especially for initial information and clinical studies pertaining to the new drug. DRUG DEVELOPMENT AND MARKETING 124, 182-86 (R. Helms ed. 1975).

⁵⁹See FTC REPORT, *supra* note 4, at 44-50.

⁶⁰*Id.* FDA control standards are only minimum standards. See PHARMACEUTICAL MFRS. ASS'N, BRANDS, GENERICS, PRICES AND QUALITY—THE PRESCRIBING DEBATE AFTER A DECADE (1971); Willig, *supra* note 9, at 19-21. For information concerning quality control within drug manufacturing, see generally REMINGTON'S, *supra* note 1, at 519-29. For information from which to derive differences in quality control standards among various manufacturers, see Goldfinger, *Dissimilarities of Digoxin*, 285 NEW ENG. J. MED. 1376 (1971); Lindenbaum, Mellow, Blackstone & Butler, *Variations in Biologic Availability of Digoxin from Four Preparations*, NEW ENG. J. MED. at 1344; Vitti, Baner & Byers, *Bioavailability of Digoxin*, NEW ENG. J. MED. at 1433.

⁶¹See, e.g., *Pennwalt Corp.*, 472 F. Supp. at 421; *Look-Alike Drugs: Is This Pharmacy's Next Battle Ground?*, DRUG TOPICS, Sept. 4, 1979, at 6.

⁶²Letter from Milton A. Bass & George Schwartz, representatives of the National Association of Pharmaceutical Manufacturers, to FDA Commissioner Jere E. Goyan (July 14, 1980).

⁶³The bioequivalence of two drug products is a comparison between the

Distinguishing one drug from another is not always sufficient; often the manufacturer must be known as well. Although many drugs are distinctly colored, others, for various reasons, are not.⁶⁴ Neither physicians nor pharmacists positively identify a tablet or capsule by color alone.⁶⁵ Without additional information, such as the drug's name, the company's name, or distinguishing marks or numbers, it is often impossible to identify a capsule or tablet once it is removed from its bottle or vial.⁶⁶

Look-alike drug products compound this problem. Typically, physicians or pharmacists attempt to match a combination of color and distinguishing marks or numbers with ones presented in the *Physicians' Desk Reference (PDR)*.⁶⁷ However, because many generic companies do not submit monographs to the *PDR*, their products are not easily identifiable.⁶⁸ The fact that their products may be similarly colored to one in the *PDR* is of no real value because many completely different drugs may be look-alikes.⁶⁹

Bioequivalence is the second major safety concern. It is now well established that even though a drug may be chemically equivalent,

bioavailability of the two products. Bioavailability refers to that property of the drug which makes it available to tissues of the body. D. CHODOS & A. DiSANTO, *BASICS OF BIOAVAILABILITY* 16 (1973). "Bioavailability is a concept that is based on the assumption that the measurement of certain specific parameters (usually serially obtained blood or urine concentrations of drugs) following drug administration can be correlated with the clinical efficacy of that drug as evaluated in the therapy of specific disease." *Id.*

⁶⁴Coloring agents are excipients or ingredients other than the active ingredient. These agents may be incompatible, either physically or chemically, with the drug or they may cause undesirable variations in the release rate of the drug. Although excipients are not listed as the active ingredient, they are not necessarily inert. See REMINGTON'S, *supra* note 1, at 1309, 1355-67. For a further discussion of the role of excipients, see A. FISHBURN, *AN INTRODUCTION TO PHARMACEUTICAL FORMULATION* 3-10 (1965).

⁶⁵See, e.g., *SK&F, Co. v. Premo Pharmaceutical Laboratories, Inc.*, 625 F.2d 1055, 1060 (3d Cir. 1980); *Identification Guide for Solid Dosage Forms*, 182 J. A.M.A. 1145 (1962).

⁶⁶Davis, *Exert Your Power to Ensure that Oral Solids are Visually Identifiable*, 14 HOSP. PHARM. 180 (1979) (editorial).

⁶⁷The *PDR* is an annual publication compiling the manufacturers' package inserts for many drugs. It is not a complete compilation, however; many manufacturers choose not to pay the fee to have their drug monographs included. The *PDR* also includes a color pictorial section of a limited number of drugs that serves as a helpful identification guide. See *PHYSICIANS' DESK REFERENCE* (36th ed. 1982) [hereinafter cited as *PDR*]; Jackowitz, *Survey of the Monogramming of Solid Dosage Forms by the Pharmaceutical Industry*, 14 DRUG INFO. J. 113, 115 (1980).

⁶⁸Jackowitz, *supra* note 67, at 115.

⁶⁹There are several products, for example, which are currently marketed in maroon and white capsules, but which are totally unrelated therapeutically. For example, Duricef 500 mg. (Mead Johnson & Co.) (antibiotic); Extra-Strength Tylenol (MacNeil Laboratories) (analgesic); Serax 30 mg. (Wyeth Laboratories) (anti-anxiety). *PDR, supra* note 67, at 417, 440.

it is not necessarily bioequivalent. The tablet or capsule may contain the same chemical, but it may not be capable of producing the same pharmacological effect at the same rate in the same dosage.⁷⁰ Each manufacturer must develop its own process and formulation of active and inactive ingredients, any of which may alter the product's bioavailability.⁷¹ When an innovator company's patent expires, only the drug itself and not the company's product formulation passes into the public domain.⁷²

Although not all drugs have been demonstrated to show differences in bioavailability, there have been studies that show potential bioavailability problems with seventy-three commonly prescribed drugs.⁷³ Although the comparative bioavailability of the various drug formulations is always important,⁷⁴ there are three instances when bioequivalence becomes critical to effective therapy: (1) when the drug has a low therapeutic index,⁷⁵ for example, cardiac drugs, anti-neoplastic agents, oral anti-diabetic drugs, and anti-coagulants; (2) when the drug requires the maintenance of specific blood levels, for example, antibiotics and anti-hypertensives; and, (3) when the drug's effect must be measured by sensitive lab parameters, for example, thyroid hormones, electrolytes, and diagnostic steroids.⁷⁶ In each of these instances, the difference in a product's bioavailability may mean the difference between effective treatment and under- or over-dosage.⁷⁷

In many chronic drug regimens, such as anti-hypertensive, anti-diabetic, anti-convulsant, or cardiac therapies, the patient's actual drug dosage will be adjusted individually until the desired effect is

⁷⁰D. CHODOS & A. DiSANTO, *supra* note 63, at 16. For examples of bio-inequivalence in specific drugs, see Arnold, Gerber & Levy, *Absorption and Dissolution Studies on Sodium Diphenylhydantoin Capsules*, 5 CAN. J. PHARM. SCI. 89 (1970) (phenytoin, an anti-convulsant); Goldfinger, *supra* note 60 (digoxin, a heart medication); Griffith & Black, *A Comparison of Blood Levels After Oral Administration of Erythrocin and Erythromycin Estolate*, 12 ANTIBIOTICS & CHEMOTHERAPY 398 (1962) (erythromycin, an antibiotic).

⁷¹See note 64 *supra*.

⁷²See 21 U.S.C. § 331(j) (1976); *United States v. Generix Drug Corp.*, 654 F.2d 1114, 1117 (5th Cir. 1981); D. CHODOS & A. DiSANTO, *supra* note 63, at 6; *Generic Deceit*, *supra* note 17, at 64; *Unapproved Generics*, *supra* note 52, at 14-16.

⁷³D. CHODOS & A. DiSANTO, *supra* note 63, at 10.

⁷⁴*Id.* at 37.

⁷⁵A drug's therapeutic index is a quantitative ratio comparing a therapeutic and an untoward effect. A low therapeutic index indicates that there is a low ratio between the dosage which will give the desired therapeutic effect and the dosages which will cause serious unwanted effects. REMINGTON'S, *supra* note 1, at 674.

⁷⁶*The Clinical Relevancy of Bioavailability*, BULL. ONT. C. PHARM. 117-18 (1972).

⁷⁷M. WEINER, BIOLOGICAL AVAILABILITY AND THE PRACTICING PHARMACIST 4-5 (1974).

achieved.⁷⁸ Once this effect is reached and maintained, the patient is said to be "stabilized on his medication."⁷⁹ If the patient changes to a product formulation that does not have the same bioavailability, he could become "unstabilized" and therefore unable to achieve the desired effect at the same dosage. Hence, the physician has an interest in ensuring that a patient is receiving the same product every time the patient renews his prescription. The pharmacist has an interest in being able to exchange sufficient information with the patient in order to ascertain exactly which product the patient has been taking.

3. *Consumers.*—Each of the foregoing interests also has an impact on the patient or ultimate consumer. The consumer-patient has an economic interest in the availability of quality drug products at reasonable prices. The presence of generic products not only results in low cost drugs, but perhaps also keeps the brand-name companies from unnecessarily inflating their prices.⁸⁰ On the other hand, consumers have an interest in receiving quality drugs and in receiving benefits from future drug research.

In light of the encouragement which patients are given to "shop around" for each prescription, it becomes increasingly important for the *patient* to be able to distinguish between competing drug products.⁸¹ The pharmacist who originally filled a given prescription will typically continue to refill the prescription with the same manufacturer's product. However, prescriptions are usually not refillable for more than one year regardless of the number of refills indicated.⁸² Therefore, even in life-long or chronic therapy a patient will be periodically given a new prescription for the same medication—a prescription which is increasingly being written using generic drug names.⁸³ Even if the patient takes a new generically written prescription to the same pharmacist, there is a substantial chance that it will be filled with a different manufacturer's product. A patient benefits if he can assist the pharmacist in identifying exactly which product he has been taking.

In addition, the consumer-patient must be able to distinguish between the products in order to protect himself from an unscrupulous pharmacist who might substitute generics for brand-

⁷⁸A.G. GILMAN, L. GOODMAN & A. GILMAN, GOODMAN & GILMAN'S THE PHARMACOLOGICAL BASIS OF THERAPEUTICS 43-48 (6th ed. 1980).

⁷⁹See *id.*

⁸⁰But see Cocks, *supra* note 53, at 22.

⁸¹See Tyler, *supra* note 23.

⁸²*E.g.*, IND. CODE § 25-26-13-25(d) (Supp. 1981).

⁸³FTC REPORT, *supra* note 4, at 45; Hecht, *supra* note 4, at 20.

name drugs, but charges for the latter.⁸⁴ Consumers should not be deprived of a means to distinguish products simply because consumers must depend upon a physician to prescribe and a pharmacist to dispense drug products.

III. JUDICIAL TREATMENT OF PHARMACEUTICAL LOOK-ALIKE CASES

The courts have become increasingly involved in balancing the interests of the parties concerned and in determining what mechanisms are to be used in differentiating drug products. The following discussion will be divided chronologically into the judicial treatment of look-alikes during the period of anti-substitution laws and the treatment after the repeal of these laws. The differing treatments given look-alike drugs during these two periods have resulted from a shift in who is deemed responsible for ensuring that consumers receive the drug products ordered. During the anti-substitution period, the burden of supplying the appropriate product was on the pharmacist; however, the repeal of these statutes has shifted more of this burden to consumers and manufacturers. This shift has been conducive to the use of trademark theories. Despite the courts' reluctance to adopt trademark theories, there appear to be possible benefits in using such an approach. Existing case law already contains aspects of trademark theories or could easily be adopted to do so.

A. *Look-Alike Cases under Anti-Substitution Laws*

The court decisions during the period of anti-substitution laws reflected public policy by denouncing unauthorized substitution.⁸⁵ Because pharmacists were not allowed by law to substitute, the prevention of deception was understandably directed at these professionals. Although the imitator companies were not deceiving the pharmacists as to the product's source, the use of look-alike products made it possible for the pharmacist to deceive the ultimate consumer.⁸⁶ The actual use of look-alikes was not enjoined, however. The courts merely required that the imitator company place on the label a warning to pharmacists not to substitute the product for the

⁸⁴Swenson, *Property Rights and Look-Alike Pharmaceutical Products*, U.S. PHARM., Mar. 1978, at 20, 21.

⁸⁵See *William R. Warner & Co. v. Eli Lilly & Co.*, 265 U.S. 526 (1924); *Upjohn Co. v. Schwartz*, 246 F.2d 254 (2d Cir. 1957); *Smith, Kline & French Laboratories v. Clark & Clark*, 157 F.2d 725 (3d Cir.), *cert. denied*, 329 U.S. 796 (1946). For a review of the early look-alike cases, see Swenson, *Property Rights in the Color and Shape of Capsules*, 32 FOOD DRUG COSM. L.J. 361 (1977).

⁸⁶See, e.g., *William R. Warner & Co.*, 265 U.S. at 530-32.

innovator's product.⁸⁷ Before the innovator company could obtain even this token relief, however, it had to show either that its product's nonfunctional shape and color had acquired a secondary meaning and that the imitator's product was likely to cause confusion, or that the defendant had either actively or inferentially induced the palming off of its product.⁸⁸

In one of the earliest cases, *William R. Warner & Co. v. Eli Lilly & Co.*,⁸⁹ the plaintiff-innovator Lilly failed to establish that its use of chocolate in a liquid quinine preparation was nonfunctional. The Supreme Court held that because the chocolate flavoring masked the bitter taste of quinine, its use was functional and thus could not acquire a secondary meaning for protection purposes.⁹⁰

The plaintiff was required to show that the defendant had both induced fraudulent behavior and had provided the means to implement it.⁹¹ The Court found that because the imitator-defendant had used the similar appearance and flavor to actively encourage pharmacists to substitute its product for the plaintiff's, the plaintiff had proven his case and the defendant was guilty of unfair competition practices.⁹² The Court very clearly stated, however, that the wrong was only in the unfair purposes with which the defendant had used the similarity between the products, and not in the similarity itself.⁹³

The Court in *Warner* recognized nothing more than a common law action for fraud. The resulting injunction did little more than slap the greedy hand of the imitator. If the innovator company was to obtain more satisfactory relief, however, it would be necessary to circumvent the Court's finding that a product's color was functional. That step was taken in *Smith, Kline & French Laboratories v. Heart Pharmaceutical Corp.*⁹⁴

In *Heart*, the innovator-plaintiff carried its burden of proving nonfunctionality of both the product's heart shape and color by showing that the same product had previously been marketed as a round white tablet.⁹⁵ In addition, the plaintiff introduced evidence of a deliberate and arbitrary selection of its product's new shape and

⁸⁷*Id.* at 532-33; *Upjohn Co.*, 246 F.2d at 262; *Smith, Kline & French Laboratories*, 157 F.2d at 731.

⁸⁸See *William R. Warner & Co.*, 265 U.S. at 530; *Upjohn Co.*, 246 F.2d at 257-61; *Smith, Kline & French Laboratories*, 157 F.2d at 729-31.

⁸⁹265 U.S. 526 (1924).

⁹⁰*Id.* at 529. *But see* Cooper, *supra* note 37, at 9-11.

⁹¹265 U.S. at 530-31.

⁹²*Id.* at 529-30.

⁹³*Id.* at 532.

⁹⁴90 F. Supp. 976, 978 (S.D.N.Y. 1950). Compare *id.* with *Smith, Kline & French Laboratories*, 157 F.2d at 731.

⁹⁵90 F. Supp. at 977.

color, as well as evidence of the large amounts of money it had spent on promoting the product's new appearance.⁹⁶ Although the court recognized that this new appearance had acquired a secondary meaning for both the professional consumer and the ultimate consumer,⁹⁷ it nevertheless based its decision upon a common law action for palming off.⁹⁸

Although ostensibly applying the same test used in *Warner* to sustain an unfair competition action based on common law fraud, the court in *Heart* broadened the test's application.⁹⁹ Unlike in *Warner*, the plaintiff in *Heart* presented no evidence that the defendants had actually induced the pharmacists to substitute their products for the plaintiff's, although specific instances of pharmacists palming off were shown. Nonetheless, the court reasoned that "the practical effect of the defendants' advertisements and the use of the term 'Color Guaranteed' "¹⁰⁰ left no other conclusion than that the defendants had intended pharmacists to use their products as substitutes.¹⁰¹ The court therefore enjoined the defendants from continuing to market their drug products as look-alikes.¹⁰²

The test used in *Warner* was again expanded in *Upjohn Co. v. Schwartz*,¹⁰³ to grant relief in those cases where actual instances of palming off had not been shown. The court held that it was sufficient if the circumstances surrounding the defendant's use and promotion of its look-alike products had made it reasonable to anticipate that confusion with the plaintiff's products would result.¹⁰⁴ The court stated that a "suggestion . . . of the possibility of substitution . . . was itself unfair"¹⁰⁵ and that it was unnecessary for the plaintiff to show that pharmacists "did what defendant had made it possible for them to do."¹⁰⁶ Although the test in this form appears to be the same test utilized to discern liability in trademark infringement at common law,¹⁰⁷ the plaintiff did not prove that the colors and shapes of its various tablets had acquired the requisite secondary meaning necessary for protection as trademarks.¹⁰⁸ The court did find,

⁹⁶*Id.*

⁹⁷*Id.*

⁹⁸*Id.* at 978.

⁹⁹*Id.* (quoting 265 U.S. at 530-31).

¹⁰⁰90 F. Supp. at 978.

¹⁰¹*Id.*

¹⁰²*Id.*

¹⁰³246 F.2d 254 (2d Cir. 1957).

¹⁰⁴*Id.* at 258.

¹⁰⁵*Id.*

¹⁰⁶*Id.*

¹⁰⁷See Lanham Act § 2(f), 15 U.S.C. § 1052(f) (1976).

¹⁰⁸246 F.2d at 257.

however, that proof of the "likelihood of confusion" coupled with the defendant's affirmative activities,¹⁰⁹ supported an unfair competition action based on palming off.¹¹⁰ The defendant was enjoined from suggesting that its product be used as a substitute and was required to include a statement to that effect on its products' labels.¹¹¹ Schwartz, however, was not enjoined from actually marketing look-alike products.¹¹²

These decisions are representative of the limited relief that the innovator-plaintiffs could expect under anti-substitution laws. Generally, a warning not to substitute the imitator's product, coupled with the threat of serious administrative and statutory sanctions,¹¹³ were considered sufficient to deter unlawful substitution by pharmacists. Under the anti-substitution laws, it was the pharmacist, aided by the manufacturer's look-alikes, who deceived the public. Thus, it may have been logical, if not totally satisfactory, to limit the plaintiff's relief to a warning label directed at the pharmacist. If the plaintiff could prove that its product's appearance had acquired a secondary meaning, however, then the imitators were held more responsible for the actual deception of the public, and therefore, more likely to be enjoined from producing look-alikes.¹¹⁴ The consumer in that instance relied not only upon the pharmacist's ethics in dispensing the appropriate drug product, but also upon his own knowledge concerning the product's appearance to assure himself that he had received the correct product.

As long as the anti-substitution laws were in effect, the traditional equitable interests, which were considered in deciding whether the plaintiff was entitled to an injunction prohibiting look-alikes, generally balanced out against granting the relief.¹¹⁵ The public's health interests were considered adequately protected by the anti-substitution laws, and the public's interest in free competition appeared to outweigh the plaintiff's loss.

Once the repeal of anti-substitution laws began and the pharmacists were no longer faced with sanctions for merely substituting, the equitable balance began tipping in the plaintiff's favor.¹¹⁶ As the

¹⁰⁹*Id.* at 261. The defendant not only marketed look-alike drug products but provided pharmacists with color charts as substitution guides and actively suggested that pharmacists substitute the products. *Id.* at 259-61.

¹¹⁰*Id.* at 261-62.

¹¹¹*Id.* at 262.

¹¹²*Id.*

¹¹³*See, e.g., PMA, supra* note 9, at 6; *REMINGTON'S, supra* note 1, at 27.

¹¹⁴*See Smith, Kline & French Laboratories*, 90 F. Supp. at 977-78.

¹¹⁵*See William R. Warner & Co.*, 265 U.S. at 531-33; *Upjohn Co.*, 246 F.2d at 258-62; *Smith, Kline & French Laboratories*, 157 F.2d at 731.

¹¹⁶*See Ives Laboratories, Inc. v. Darby Drug Co.*, 638 F.2d 538 (2d Cir.), *rev'd*

courts' views toward look-alikes changed in keeping with the theories underlying substitution laws, the extent of judicial remedies also changed.

B. Look-Alike Cases under Substitution Laws

The recent court decisions affecting look-alike drug products continue to be concerned with assuring the public that illegal substitution or palming off does not occur. However, the distinction between the promotion of lawful substitution and the unfair practice of palming off is often muddled by the use of look-alikes.

The courts still require proof of actual instances of palming off that are either actively or implicitly induced by the defendant,¹¹⁷ or in the alternative, proof that the appearance of the innovator's product has attained common law trademark status before the defendant's product entered the market.¹¹⁸ The difficulty in proving the latter¹¹⁹ has resulted in the majority of injunctions being granted, as before, upon proof of palming off.¹²⁰ Recently, proof of palming off has generally been predicated upon an implied rather than an active inducement by the defendant. This trend can be attributed to the generic companies' increased reliance on catalogs rather than detail men. Additional changes can be seen in an apparent tipping of the equity interest balance in the plaintiff's favor which has resulted in the granting of more satisfactory injunctions. These changes are easily recognized in *Pennwalt Corp. v. Zenith Laboratories, Inc.*,¹²¹ a

and remanded sub nom. *Inwood Laboratories, Inc. v. Ives Laboratories, Inc.*, 50 U.S.L.W. 4592 (1982); *SK & F, Co. v. Premo Pharmaceutical Laboratories, Inc.*, 481 F. Supp. 1184 (D.N.J. 1979), *aff'd*, 625 F.2d 1055 (3d Cir. 1980); *Pennwalt Corp. v. Zenith Laboratories, Inc.*, 472 F. Supp. 413 (E.D. Mich. 1979), *appeal dismissed mem.*, 615 F.2d 1362 (6th Cir. 1980).

¹¹⁷*See* *Ives Laboratories, Inc. v. Darby Drug Co.*, 638 F.2d 538, 542-43 (2d Cir.), *rev'd and remanded sub nom.* *Inwood Laboratories, Inc. v. Ives Laboratories, Inc.*, 50 U.S.L.W. 4592 (1982); *SK & F, Co. v. Premo Pharmaceutical Laboratories, Inc.*, 481 F. Supp. 1184, 1187-88 (D.N.J. 1979), *aff'd*, 625 F.2d 1055, 1063-64 (3d Cir. 1980); *Pennwalt Corp. v. Zenith Laboratories, Inc.*, 472 F. Supp. 413, 418-20 (E.D. Mich. 1979), *appeal dismissed mem.*, 615 F.2d 1362 (6th Cir. 1980); *Marion Laboratories, Inc. v. Michigan Pharmacal Corp.*, 338 F. Supp. 762, 769-70 (E.D. Mich. 1972), *aff'd mem.*, 473 F.2d 910 (6th Cir. 1973).

¹¹⁸*SK&F, Co. v. Premo Pharmaceutical Laboratories, Inc.*, 481 F. Supp. 1184, 1188 (D.N.J. 1979), *aff'd*, 625 F.2d 1055, 1063-64 (3d Cir. 1980); *Marion Laboratories, Inc. v. Michigan Pharmacal Corp.*, 338 F. Supp. 762, 769 (E.D. Mich. 1972) *aff'd mem.*, 473 F.2d 910 (6th Cir. 1973).

¹¹⁹*See* notes 32-34 *supra* and accompanying text.

¹²⁰*See, e.g.*, *SK&F, Co. v. Premo Pharmaceutical Laboratories, Inc.*, 625 F.2d 1055, 1063 (3d Cir. 1980); *Pennwalt Corp. v. Zenith Laboratories, Inc.*, 472 F. Supp. 413, 418-20 (E.D. Mich. 1979), *appeal dismissed mem.*, 615 F.2d 1362 (6th Cir. 1980).

¹²¹472 F. Supp. 413 (E.D. Mich. 1979), *appeal dismissed mem.*, 615 F.2d 1362 (6th Cir. 1980).

case decided not long after the effective repeal of Michigan's anti-substitution law.¹²²

In *Pennwalt*, the trial court employed a subjective-objective test requiring the plaintiff to prove that the defendant knew or should have known from the circumstances that its product was likely to be used deceptively.¹²³ The court granted the plaintiff, Pennwalt, an injunction prohibiting Zenith from selling its look-alike product to pharmacists¹²⁴ even though there was no evidence that Zenith itself had palmed off its product.¹²⁵ The district court found that because Pennwalt's product was the resin form of the drug phentermine and Zenith's product was the generically inequivalent hydrochloride salt form, a substitution of one product for the other was a violation of the Michigan substitution law.¹²⁶ Despite this generic inequality, Zenith had distributed catalogs which included statements in the products' descriptions which indicated that its products were "[s]imilar [t]o" competing brand name products and implying that they were also generic equivalents.¹²⁷ The court reasoned that these circumstances coupled with the fact that Zenith deliberately chose the identical color scheme of Pennwalt's product, had created a situation which Zenith should have reasonably anticipated would, and did, lead to deception or confusion.¹²⁸

In applying the traditional equity tests involved in any injunctive request, the court stated that the public's interest in obtaining equivalent therapeutic effects from substituted drugs outweighed the public's interest in benefiting from the substitution of a less expensive product.¹²⁹ The court also indicated that the balance of equitable interests tipped heavily in favor of maintaining the integrity of the drug substitution guidelines and that these policies would be undermined if Zenith were allowed to continue marketing a look-alike product that was not generically equivalent.¹³⁰

In *SK&F, Co. v. Premo Pharmaceutical Laboratories, Inc.*,¹³¹ the actual inequality between the two drug products again played an im-

¹²²The Michigan statute prohibiting substitution, MICH. COMP. LAWS § 338.1117(l) (1970), was never actually repealed. Instead, additional code sections were added which re-defined "substitution," MICH. COMP. LAWS ANN. § 338.1101(u) (1980), and allowed substitution of generic products, *id.* § 338.1114(a). See Note, *Improving Michigan's Generic Drug Laws*, 9 U. MICH. J.L. REF. 394 (1975-76).

¹²³472 F. Supp. at 420.

¹²⁴*Id.* at 423.

¹²⁵*Id.* at 419.

¹²⁶*Id.* at 416-17, 419.

¹²⁷*Id.* at 416.

¹²⁸*Id.* at 420.

¹²⁹*Id.* at 423.

¹³⁰*Id.*

¹³¹481 F. Supp. 1184 (D.N.J. 1979), *aff'd*, 625 F.2d 1055 (3d Cir. 1980).

portant role in the ultimate balancing of the equitable interests. In *Premo*, the defendant Premo's product was shown to have a higher bioavailability than did the plaintiff SK&F's product, Dyazide.¹³² Although the two products might properly have been termed "generic equivalents" because they contained the same two active ingredients,¹³³ they were not bioequivalent.¹³⁴ Because Premo's product provided higher blood levels than a physician would have expected when prescribing Dyazide,¹³⁵ the two products were not safely interchangeable as required by the theories underlying substitution. It was therefore not in the public's best interests to facilitate their substitution.¹³⁶

The trial court granted SK&F an injunction prohibiting Premo from continuing to market its Dyazide look-alike. It based its decision both on findings that SK&F had sufficiently established that the maroon and white capsule arbitrarily chosen for Dyazide had acquired a secondary meaning¹³⁷ and that Premo's argument in defense of its deliberate imitation was "calculated to encourage fraud and deception."¹³⁸

By following the reasoning of the *Premo* court, the production of look-alike products could be enjoined even without a basic inequality between the products—as long as the product's appearance had acquired secondary meaning. But without either factor—a basic inequality of products or a showing of secondary meaning—the question whether to grant an injunction becomes much more difficult. The question in this form, stripped of the weighted inequality factors, is the essential issue presented by the look-alike controversy. The issue in this form has finally been addressed in *Ives Laboratories, Inc. v. Darby Drug Co.*¹³⁹ An examination of the district and appellate court decisions reveal the difficulty courts have in balancing the equities when presented with the "pure" form of this issue.

In *Ives*, the plaintiff Ives had marketed its patented cyclandelate product under the brand-name of Cyclospasmol in blue

¹³²481 F. Supp. at 1190; 625 F.2d at 1061.

¹³³Both products contained 50 mg. of triamterene and 25 mg. of hydrochlorthiazide. 481 F. Supp. at 1187.

¹³⁴*Id.* at 1190.

¹³⁵*Id.* The FDA recalled Premo's product on February 11, 1980. Studies showed that because Premo's product had a greater absolute bioavailability than did Dyazide, it could cause hyperkalemia, a toxic buildup of potassium. 625 F.2d at 1061 n.4.

¹³⁶481 F. Supp. at 1090-91.

¹³⁷*Id.* at 1188.

¹³⁸*Id.*

¹³⁹455 F. Supp. 939, 945 (E.D.N.Y. 1978), *aff'd and remanded*, 601 F.2d 631 (2d Cir. 1979); 488 F. Supp. 394 (E.D.N.Y. 1980), *rev'd and remanded*, 638 F.2d 538 (2d Cir.), *rev'd and remanded sub nom.* Inwood Laboratories, Inc. v. Ives Laboratories, Inc., 50 U.S.L.W. 4592, (1982).

or combination blue and red capsules¹⁴⁰ for some years. When Ives' patent on the drug cyclandelate expired in 1972, several manufacturers began marketing generic versions in variously colored capsules. The defendant manufacturers and wholesalers chose to market their generic products in capsules of the same size and color as the Ives product. Although Ives convinced the Second Circuit that an injunction was warranted which prohibited the defendant from marketing look-alike products,¹⁴¹ the plaintiff not only had a more difficult time establishing that the equities were balanced in its favor, but also that the defendants had contributed to the instances of actual palming off.

The district court refused to grant Ives an injunction because it found that the defendants' practice of listing or comparing their products with the trademark products¹⁴² was not designed to suggest that pharmacists illegally substitute.¹⁴³ The court instead held that any illegal substitution was caused by the pharmacists' misunderstanding of the New York substitution laws.¹⁴⁴ Those substitution laws required the pharmacist to place the manufacturer's name, in addition to the substituted drug's generic name, on the prescription label.¹⁴⁵ Because the defendants' products were equivalent, both generically and in terms of bioavailability,¹⁴⁶ the district court reasoned that the defendants' promotional catalogs could not be construed to suggest *illegal* substitutions.¹⁴⁷ In other words, the catalogs were not construed as suggesting that pharmacists mislabel the substituted drug product as "Cyclospasmol" rather than use the appropriate labeling "cyclandelate—X manufacturer." The court of appeals reversed the district court and in recommending that the requested injunction be granted, stated that the catalogs, coupled with the lower prices of the defendants' products and their identical appearance to Cyclospasmol, impliedly suggested that pharmacists illegally substitute the products.¹⁴⁸

¹⁴⁰Ives marketed Cyclospasmol 200 mg. in pale blue capsules and Cyclospasmol 400 mg. in red and blue capsules. 455 F. Supp. at 941.

¹⁴¹638 F.2d at 544. This injunction, however, has yet to be imposed pending resolution of an appeal to the Supreme Court.

¹⁴²488 F. Supp. at 396.

¹⁴³*Id.* at 397.

¹⁴⁴*Id.*

¹⁴⁵N.Y. EDUC. LAW § 6816-a(1)(c) (McKinney Supp. 1981-1982).

¹⁴⁶488 F. Supp. at 396.

¹⁴⁷*Id.* at 397.

¹⁴⁸638 F.2d at 543-44. The ruling of the court of appeals dealt strictly with the section 32 claim of contributory infringement. The court did not rule on either the section 43(a) claim nor on the issue of secondary meaning. *Id.* at 539-40. Therefore, even if the generic manufacturers are successful in their appeal to the Supreme Court, the trademark companies will have lost little if any ground. The court's contributory

Although not discussed by the court of appeals, there is another important aspect of the district court's opinion. The district court had also denied relief regarding Ives' claim that the defendants had infringed upon its common law trademark, on the grounds that there was insufficient evidence to show that Cyclospasmol's appearance had acquired a secondary meaning.¹⁴⁹ In fact, the district court pointed out that the very nature of a pharmaceutical product made it extremely difficult to prove secondary meaning, primarily because the promotional advertising is not aimed at the ultimate consumer.¹⁵⁰ This reasoning is unsatisfactory in light of the guidelines for recognizing secondary meaning in pharmaceutical products as set forth by Justice Learned Hand in *Bayer Co. v. United Drug Co.*,¹⁵¹ a case quoted by the district court in its discussion of secondary meaning.¹⁵²

In *Bayer*, the defendant company was enjoined from selling its product, labeled only as "aspirin," to manufacturing chemists, physicians, and pharmacists. However, the defendant was allowed to label its product merely as "aspirin" when selling it directly to the public.¹⁵³ The court reasoned that because the professional-level consumer had been educated to understand that "aspirin" was only a tradename identifying the particular source of the drug acetyl salicylic acid, the word "aspirin" deserved protection with reference to these consumers.¹⁵⁴ The public, however, had come to recognize the drug itself only by the word "aspirin," and made no connection between the word and the plaintiff. Therefore, the word did not deserve the same protection with reference to this group.¹⁵⁵

The *Ives* court failed to recognize that an analogy exists between the name factor in *Bayer* and the color situation in the look-alike cases. Physicians and pharmacists in the look-alike cases have additional information regarding source afforded by the manufacturers' various package dressings and advertisements, just as the professional level consumers in *Bayer* had been educated as to the true meaning of "aspirin." The consumers in the look-alike cases, however, know the tablet or capsule only by its color, much as the public in *Bayer* knew the drug only by the word "aspirin," and

infringement ruling is more reminiscent of cases decided during the anti-substitution era. Compare *id.* with the cases cited in notes 85 & 117-18 *supra*.

¹⁴⁹488 F. Supp. at 400-01. See note 148 *supra*.

¹⁵⁰488 F. Supp. at 401.

¹⁵¹272 F. 505 (S.D.N.Y. 1921).

¹⁵²488 F. Supp. at 400 (quoting 272 F. at 509-10).

¹⁵³272 F. at 514-15.

¹⁵⁴*Id.* at 513-14.

¹⁵⁵Compare the relief granted in *Bayer*, 272 F. at 514-15, with the limited injunction issued in *Pennwalt Corp.*, 472 F. Supp. at 422-24.

should therefore be treated in accordance with this relationship. It is important to realize that the various factors involved, such as advertising and color recognition, cannot be summarily lumped together, but rather must be carefully scrutinized and accorded their proper relationships within the interests of the two consumer groups. The district court in *Ives* failed to assign the proper relationships of colors and drug products as used by the ultimate consumer.

Although the district court did acknowledge that patients do identify their medications by color,¹⁵⁶ the court stopped short of fully applying the reasoning of *Bayer*. The court implied that patients only associate the color of their medication with the *class* of drug and not with the *source* of the drug.¹⁵⁷ Using the district court's reasoning, secondary meaning does not attach unless the patient first associates the red and blue capsules with the *brand-name* Cyclospasmol, and *then* associates that name with a single, although anonymous, source.¹⁵⁸

This interpretation incorporates a second association step in the traditional concept of secondary meaning. Regardless of whether the patient knows the name of his specific medication, or even who the actual manufacturer is, the medication's color has acquired a secondary meaning for him. Rather than the patient associating the capsule's color with a particular drug *class*, he probably associates the color with a particular drug *product* within the class. For example, if the patient knows that he has been taking a heart medication and that his *specific* medication is a red and blue capsule, he feels safe in assuming that he will always receive the same particular medication when he takes a red and blue capsule for his heart. Under the district court's reasoning, the patient would expect *all* heart medications to be in red and blue capsules, not just a particular one. That is clearly not how colors are associated with drug products in which the color is nonfunctional.

Using this rationale, it is easy to see how trademark theories can be utilized. The consumer must be afforded a means by which to distinguish goods. If he can only differentiate between products by the combination of their nonfunctional shape and color, that means should be made available to him.¹⁵⁹ Although the look-alike cases have not been specifically decided on trademark grounds, the various aspects of the theory have pervaded the decisions.

¹⁵⁶488 F. Supp. at 400.

¹⁵⁷*Id.*

¹⁵⁸*Id.*

¹⁵⁹See *Ex parte* Nuodex Prods. Co., 107 U.S.P.Q. (BNA) 300 (Dec. Comm'r Pat. 1955); *Ex parte* Oscar Mayer & Co., 47 U.S.P.Q. (BNA) 234 (Dec. Comm'r Pat. 1940). See also *In re* Swift & Co., 223 F.2d 950 (C.C.P.A. 1955).

IV. PROPOSAL

With the advent of pro-substitution laws, courts have been more willing to enjoin the production of look-alike products. However, the courts have not yet gone far enough. The district court in *Premo* recognized that "[p]rophylaxis is not only a medical term. It is also a legal term expressing methods for preventing intentional or accidental violations of the law."¹⁶⁰ Although an injunction is prophylactic in the sense that it prevents offensive conduct from continuing, it is merely remedial in the sense that the offensive conduct must first have occurred. In the case of drug products, this requirement of prior misconduct may prove very costly.¹⁶¹

The underlying goal governing the relationship between brand-name and generic drug products should be the same as with any other product, that is, to let the consumer know what he is receiving. The effectiveness of the three possible mechanisms for satisfying this goal, as discussed or utilized by the courts, can be easily compared in terms of the predictability of obtaining the desired result and the satisfaction of legitimate interests.

A. *Comparison of Mechanisms*

1. *Anti-Substitution Laws.*—The anti-substitution laws provided the consumer, as well as the professionals and manufacturers, with a high degree of predictability. Because it was illegal to substitute one product for another,¹⁶² the consumer was reasonably assured of

¹⁶⁰*SK&F, Co. v. Premo Pharmaceutical Laboratories, Inc.*, 481 F. Supp. 1184, 1189 (D.N.J. 1979), *aff'd*, 625 F.2d 1055 (3d Cir. 1980).

¹⁶¹*See, e.g., SK&F, Co. v. Premo Pharmaceutical Laboratories, Inc.*, 625 F.2d 1055, 1061 n.4 (3d Cir. 1980); *Pennwalt Corp. v. Zenith Laboratories, Inc.*, 472 F.Supp. 413, 416-17 (E.D. Mich. 1979), *appeal dismissed mem.*, 615 F.2d 1362 (6th Cir. 1980). *See also* Jordan, *CNS Stimulants Sold as Amphetamines*, 38 AM. J. HOSP. PHARM. 29 (1981) (letter); Passe, *Pill Pourri*, 4 STREET PHARMACOLOGIST 6 (1981); *Indianapolis Star*, Apr. 2, 1982, at 4, col. 1.

For example, amphetamine "look-alikes" are being legally sold on the street. However, these "look-alikes," unlike the type focused upon in this Note, are products dressed up to look like a brand-name amphetamine, but do not contain any amphetamines. Generally, they contain caffeine and either ephedrine or phenylpropanolamine which are commonly used as antihistamines and decongestants. These imposter drugs are available in nonprescription strengths and are advertised in various "underground" magazines and newspapers as "legal stimulants." Although these drugs do affect the central nervous system (CNS), they are extremely weak compared to the drugs they look like. However, the combined effect of the substituted ingredients is unpredictable and deaths have been attributed to their use. Therefore, this particular type of look-alike is very dangerous—for both the amphetamine user who unknowingly takes an imposter and for the regular user of the imposter who mistakenly takes the same number of real amphetamines.

¹⁶²*See* notes 13-15 *supra* and accompanying text.

receiving the precise drug which his physician prescribed. Both the physician and the pharmacist benefited from this predictability. The physician knew and controlled the exact medications his patients received; the pharmacist knew exactly which product to dispense and knew the consequences if he substituted.

Anti-substitution laws did not, however, adequately satisfy the interests of these parties. Although satisfying the consumer's need for reliable identification, the laws frustrated the consumer's interest in receiving less expensive health care. Anti-substitution laws protected the good will and property interests of the brand-name companies, but unnecessarily hindered the public's interest in free competition.¹⁶³ A more refined technique was needed to allow consumers the economic benefits offered by generic products, but also designed to protect consumers from unscrupulous pharmacists, and manufacturers.

2. *Pro-Substitution Laws.*—The pro-substitution laws resulted in lower priced generics for consumers. However, they also decreased the degree of conduct predictability previously enjoyed under the anti-substitution laws. Because pharmacists are now allowed to substitute,¹⁶⁴ the physician and consumer are no longer assured that the patient will receive the precise drug ordered. The consumer has been forced to take a more active role in identifying and monitoring the specific drug product received.¹⁶⁵

These laws, although making generic products more accessible, have created a system within pharmacy which is more conducive to problems of palming off whether inadvertent or intentional.¹⁶⁶ These laws and the FDA have encouraged pharmacists to substitute; however, substitution also makes the pharmacist more vulnerable to consumer lawsuits if adverse reactions occur.¹⁶⁷ In addition, if substitution occurs, the present difficulty in generating sufficient bioavailability data lessens the assurance that the patient will

¹⁶³See generally *William R. Warner & Co. v. Eli Lilly & Co.*, 265 U.S. 526, 529-32 (1924); *Upjohn Co. v. Schwartz*, 246 F.2d 254, 258, 261-62 (2d Cir. 1957); *Smith, Kline & French Laboratories v. Clark & Clark*, 157 F.2d 725, 731 (3d Cir.), *cert. denied*, 329 U.S. 796 (1946); *Smith, Kline & French Laboratories v. Heart Pharmaceutical Corp.*, 90 F. Supp. 976, 977-78 (S.D.N.Y. 1950).

¹⁶⁴See notes 17-27 *supra* and accompanying text.

¹⁶⁵See notes 80-84 *supra* and accompanying text.

¹⁶⁶See generally *Ives Laboratories, Inc. v. Darby Drug Co.*, 488 F. Supp. 394 (E.D.N.Y. 1980), *rev'd and remanded*, 638 F.2d 538 (2d Cir.), *rev'd and remanded sub nom.* *Inwood Laboratories, Inc. v. Ives Laboratories, Inc.* 50 U.S.L.W. 4592 (1982); PMA, *supra* note 9, at 5.

¹⁶⁷*Generic Deceit*, *supra* note 17, at 65.

receive a drug equivalent in quality to one prescribed by his physician.¹⁶⁸

The generic companies' interest in breaking into the drug market was well met. Pro-substitution laws typically require that if a substitution is made, a pharmacist must substitute a less expensive product.¹⁶⁹ However, this approach swings the pendulum too far, because the brand-name companies receive little support for their products in the pro-substitution laws. The presumption that a substitution was the result of palming off no longer operates in the brand-name companies' favor. The presumption has shifted to one which requires the brand-name companies to rebut the assertion that the substitution was lawful and in good faith.

3. *Trademark Theories.*—Although the courts have fallen short of adopting trademark theories in relation to the look-alike drug cases, these theories are particularly applicable. The look-alike drug issue includes four primary interests: (1) to provide consumers with an opportunity for less expensive drug products; (2) to provide the consumer with a reasonable means of identifying the actual product received; (3) to protect the generic drug companies' opportunity to engage in free competition; and, (4) to protect the good will and investments of the brand-name companies. Each of these interests is adequately satisfied by the use of trademarks.

Trademarks afford a means within a freely competitive market to distinguish among similar products. The marks also protect a company's good will and reputation for quality because courts will enjoin the unauthorized use of a recognized trademark.¹⁷⁰ There is also a high degree of conduct predictability associated with a mark's use because the mark is recognized as a symbol of the product's source and identity. The manufacturers can rely on judicial protection of their trademarks and consumers can rely on the marks as a means of product identification. If the mark is registered,¹⁷¹ then notice has effectively been given to potential infringers.¹⁷² Thus infringement and, in the case of look-alikes, deception can be curtailed before it begins and the harm is done.

¹⁶⁸See generally Davis, *Substitution Means Poor Therapy*, PRIVATE PRAC., May 1978, at 9; Tyler, *supra* note 23, at 454; *The Priceless Ingredient*, 70 J. IND. ST. MED. A. 455 (1980).

¹⁶⁹See Tyler, *supra* note 23, at 455-57; see also Goldberg & DeVito, *supra* note 11, at 75; *Drug Substitution: Where Does Your State Stand?*, NARD J., Oct. 1980, at 44; Note, *supra* note 11, at 395-406; *Overview*, *supra* note 11, at 15.

¹⁷⁰Lanham Act §§ 32, 43(a), 15 U.S.C. §§ 1114, 1125(a) (1976).

¹⁷¹See Lanham Act §§ 1-2, 15 U.S.C. §§ 1051-1052 (1976).

¹⁷²RESEARCH INSTITUTE OF AMERICA, *PREPARING FOR THE NEW TRADE-MARK LAW* 9 (1946). See Lane, *A Primer for the General Practitioner on Trademarks and Unfair Competition*, 34 J. MO. BAR 86 (1978).

B. Color as a Trademark

Color can not be relied upon *alone* to provide a means of satisfying the interests of both professionals and ultimate consumers; these interests, as well as those of the manufacturers, would be served by allowing the companies to trademark the *combination* of color, size, and shape. In this way, the manufacturers would not acquire a monopoly in the size or shape or color individually, but only in reference to a single drug entity which would be sufficient to protect its investment. Consumers would be able to readily distinguish among products containing the same drug, although color could not be solely relied upon to identify the drug entity. Physicians and pharmacists would be able to converse with the patient regarding his continued medication and, if an assigned product numbering system were required, would also be able to easily and accurately identify a tablet or capsule by looking up its number on a list. The use of trademarks would also provide judicial economy because infringement action could be decided more readily. In short, the satisfaction of all aspects of conduct predictability would be increased.

The Lanham Act of 1946 does not specifically prohibit the registration of color as a trademark, and indeed, can be easily construed to permit such practice in particular circumstances.¹⁷³ However, courts have been extremely reluctant to recognize color alone as a valid trademark.¹⁷⁴ The courts' reluctance is grounded in the depletion doctrine which holds that because there are only a finite number of colors available, it would be an unfair restraint on trade to allow manufacturers to trademark, and thus deplete the available colors.¹⁷⁵

The applicability of this doctrine to drug products, however, is questionable because there are approximately sixty-one coloring agents available for drugs,¹⁷⁶ and "[b]y selective combinations of the colorants one can create unique colors for special effects such as mint green, lemon, or lime, chocolate, raspberry, wine, and others."¹⁷⁷ Even further distinctions are possible because hard

¹⁷³Cooper, *supra* note 37, at 3-7.

¹⁷⁴See, e.g., *Plastilite Corp. v. Airlite Plastics Co.*, 390 F. Supp. 1141 (D. Neb.), *rev'd*, 526 F.2d 1078 (8th Cir. 1975), *cert. denied*, 425 U.S. 938 (1976); *Plastilite Corp. v. Kassnar Imports*, 508 F.2d 824 (C.C.P.A. 1975); *In re Shaw*, 184 U.S.P.Q. (BNA) 253 (P.O.T.M. App. Bd. 1974).

¹⁷⁵A. SEIDEL, *WHAT THE GENERAL PRACTITIONER SHOULD KNOW ABOUT TRADEMARKS AND COPYRIGHTS* 109 (4th ed. 1979).

¹⁷⁶Hefferren, *Description of the Identification Guide*, 182 J. A.M.A. 1146, 1150 (1962).

¹⁷⁷H. ANSEL, *INTRODUCTION TO PHARMACEUTICAL DOSAGE FORMS* 70 (1959), *quoted in* Cooper, *supra* note 37, at 25.

gelatin capsules are composed of two separate pieces, each capable of being colored differently or left transparent.¹⁷⁸

Although tablets may present a more limited range of color distinctions due to functional considerations,¹⁷⁹ they too may take advantage of colors and color combinations. For example, a tablet may be coated with various colored dyes or have different colored layers laminated together. A tablet may be embossed or imprinted with designs or made into various shapes, including any classic geometric form as well as flattened cylinders or football shapes. If a company were required to trademark its product's color in conjunction with shape and size, there would be even less danger of depletion.

Color, shape, and size combinations alone, however, although satisfactory for consumers' interests, would not satisfy the needs of professionals. Combination trademarking would enable both the pharmacist and physician to monitor whether the patient was receiving the same product each time, but would not promote easy identification of products in emergency situations. For example, although Dyazide is the only maroon and white diuretic, there are other nondiuretics which utilize the same color combination.¹⁸⁰ Yet, Dyazide is easily identified if one of three things is also known at the time a single capsule is presented: (1) the name of the manufacturer; (2) what the drug was prescribed for; or, (3) the presence of identifying marks.¹⁸¹ Without the identifying logos "SKF" or "Dyazide," an accurate identification of the capsule cannot be made if the patient is unable to explain why he was taking the medication.¹⁸²

Even the imprinted logos become meaningless without a means, such as the *PDR*, to explain them. Many companies neither mark nor numerically code their products, and even those that do, do not always list them in the *PDR*. An imprint or a numbered code on all single dosage forms, where feasible, would certainly promote identification. In order to be completely effective, these code numbers could then be compiled in a list made available to physicians and pharmacists. Although a National Drug Code (NDC) number identifying both the manufacturer and drug is presently assigned to each

¹⁷⁸*Id.* This has been perhaps best demonstrated by a color wheel used by Eli Lilly & Co., a leading producer of empty gelatin capsules. The wheel contains forty-two colors used for capsules which may be variously combined to create over twelve thousand color combinations. *Marion Laboratories, Inc. v. Michigan Pharmacal Corp.*, 338 F. Supp. 762, 766-67 (E.D. Mich. 1972), *aff'd mem.*, 473 F.2d 910 (6th Cir. 1973).

¹⁷⁹See note 64 *supra*.

¹⁸⁰See note 69 *supra*.

¹⁸¹See Davis, note 66 *supra*.

¹⁸²But see note 186 *infra* and accompanying text.

approved drug on the market,¹⁸³ not all manufacturers imprint these numbers on their capsules or tablets.¹⁸⁴ In addition, some unscrupulous companies print confusingly similar numbers on capsules identical to brand-name drugs but which contain nonprescription drugs which are neither generically equivalent nor equally potent to the brand-name drug.¹⁸⁵ These problems are compounded by the fact that the numerical code is sometimes printed too small to be easily read by consumers.¹⁸⁶

V. CONCLUSION

There is a genuine place for quality generic drug products in a system of free competition. There should be, however, no place for unknown or inferior drug products. Look-alike drug products make it too easy to substitute unknown products for those respected and ordered, and should therefore be abolished.

Recent judicial decisions enjoining the production of look-alikes have demonstrated a willingness to protect the trust and good will established by the brand-name companies, and to protect consumers from fraudulent and dangerous substitution. However, these steps have not gone far enough. Before an injunction can be granted, the harm must have already occurred, both to the brand-name company and to the ultimate consumer. Because of the inherent danger of drugs, this can prove to be a costly prerequisite.

Even though courts have referred to basic trademark principles throughout their opinions, these theories have not been the basis for the decisions granting relief. Trademark theories are easily applicable to the look-alike drug situation, however, and should be used.¹⁸⁷ Drug companies should be allowed to trademark the combination of color, size, and shape as it pertains to their particular drug product.

¹⁸³Cobb, *The National Drug Code System: Its Purpose and Potential*, 11 HOSP. FORMULARY 593 (1976); Jacknowitz, *supra* note 67, at 113.

¹⁸⁴Jacknowitz, *supra* note 67, at 114.

¹⁸⁵See note 161 *supra*.

¹⁸⁶SK&F, Co. v. Premo Pharmaceutical Laboratories, Inc., 625 F.2d 1055, 1061 (3d Cir. 1980); Pennwalt Corp. v. Zenith Laboratories, Inc., 472 F. Supp. 413, 420 (E.D. Mich. 1979), *appeal dismissed mem.*, 615 F.2d 1362 (6th Cir. 1980).

¹⁸⁷Although the theories themselves are easily applied, a legislature would have to be extremely careful in its wording of any statute incorporating the suggestions in this Note. The definition of a "similar product" would necessarily have to be drawn very narrowly and precisely in order to prevent the erosion of traditional trademark law.

For example, at present the word "Darvon" is an exclusive and arbitrary trademark owned by Eli Lilly & Co. which identifies Lilly's formulations containing the analgesic propoxyphene hydrochloride. If, however, the legislature loosely defined "similar product," "Darvon" antibiotics could spring up, as could "Darvon" antihistamines, or even "Darvon" scabicides. And these could all be protected as long as they were not marketed in the same color, shape and size combination as Lilly's analgesic Darvon.

The doctrine of depletion, traditionally used to block the trademarking of color, is not a valid obstacle in the drug industry. Any vestiges of its applicability to drug products is outweighed by the public's need to distinguish between drug products.

The use of a product's color, size, and shape, coupled with the product's NDC number, is a logical and convenient means of distinguishing among drug products. The public's interest in free competition is not adversely affected because the generic product may still be marketed and, state law permitting, substituted. The generic drug company is only prevented from copying the color, size, and shape of its product's brand-name counterpart, thus protecting the good will and investments of the brand-name company and decreasing the opportunity for deceptive substitutions. Most importantly, the ultimate consumer will have a means of monitoring the various drug products he is given.

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