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LANHAM ACT PROTECTION FROM THE COPYING OF TRADE DRESS BY GENERIC DRUG MANUFACTURERS

Manufacturers of generic drugs[1] often copy the appearance, or trade dress, of a generic drug's name brand counterpart.[2] The copying of trade dress has increased dramatically due to the recent proliferation of generic substitution laws.[3] Generic substitution laws decrease the cost of prescription drugs by allowing dispensing pharmacists to substitute a generic drug for the name brand drug.[4] To prevent improper substitution, manufacturers of name brand drugs[5] seek protection under the Lanham Act (Act)[6] from the copying of trade dress.[7] The Act protects manufacturers against misidentification of trademarks[8] by providing for

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[1] A generic drug has the same ingredients and dosage as a drug originally introduced by another manufacturer. Rogers & Kahan, *Recent Developments Regarding Look-Alike Drugs*, 35 FOOD DRUG COSM. L.J. 4, 4 n.1 (1980) [hereinafter cited as *Recent Developments*]. The manufacturer of the generic drugs may identify the drug to doctors, pharmacists, and consumers by its generic name which indicates the chemical class to which the drug belongs or may identify the drug by a trademark or a brand name. Note, *Consumer Protection and Prescription Drugs: The Generic Drug Substitution Laws*, 67 KY. L.J. 384, 388 (1978-79) [hereinafter cited as *Generic Substitution Laws*].

[2] *See* H. L. Swenson, *Property Rights in the Color and Shape of Capsules*, FOOD DRUG COSM. L.J. 361, 361 (1977) [hereinafter cited as *Property Rights*] (Manufacturers have copied competitors' products for centuries).

[3] Prior to 1977, manufacturers of name brand drugs sought protection against copying of trade dress only in a few instances. *See Property Rights*, *supra* note 2, at 362-66. Since 1977, however, manufacturers of name brand drugs have sought protection against the copying of trade dress in a number of instances. *E.g.*, Ives Laboratories, Inc. v. Darby Drug Co., 638 F.2d 538 (2d Cir. 1981); SK&F, Co. v. Premo Pharmaceutical Laboratories, Inc., 625 F.2d 1055 (3rd Cir. 1980); Hoffman La Roche, Inc. v. Premo Pharmaceutical Laboratories, Inc., 502 P.T.C.J. (BNA) A-4 (D.N.J. 1980); Boehringer Ingelheim G.m.b.H. v. Pharmadyne Laboratories, 502 P.T.C.J. (BNA) A-1 (D.N.J. 1980); A.H. Robins Co. v. Medicine Chest Corp., 206 U.S.P.Q. (BNA) 1015 (E.D. Mo. 1980).

Between 1972 and 1979 thirty-one states and the District of Columbia adopted generic substitution laws. *Generic Substitution Laws*, *supra* note 1, at 395.

[4] *Generic Substitution Laws*, *supra* note 1, at 388-89; *see, e.g.*, CAL. BUS. & PROF. CODE § 4047.6 (West Supp. 1981); N.J. STAT. ANN. § 24:6E-7 & -8 (West Supp. 1980); N.Y. EDUC. LAW § 6816-a (McKinney Supp. 1980). *See* note 1 *supra*.

[5] Name brand drug refers to a drug of a particular chemical class well known in the prescription drug market by the name under which the manufacturer markets the drug.

[6] 15 U.S.C. §§ 1051-1132 (1976).

[7] *See, e.g.*, SK&F, Co. v. Premo Pharmaceutical Laboratories, Inc., 625 F.2d 1055 (3rd Cir. 1980); Ives Laboratories, Inc. v. Darby Drug Co., 601 F.2d 631 (2d Cir. 1979); A. H. Robins Co. v. Medicine Chest Corp., 206 U.S.P.Q. (BNA) 1015 (E.D. Mo. 1980).

[8] A trademarket includes any combination of words, names, symbols or devices adopted and used by a manufacturer to identify his goods and distinguish them from those manufactured or sold by others. 15 U.S.C. § 1127 (1976). Ownership rights in a trademark accrue only through open use of the trademark to further the marketability of a product. The

registration and a federal cause of action for unfair competition.[9] Name brand drug manufacturers seeking protection under the Act argue that the courts should grant trademark protection for the trade dress of name brand prescription drugs due to the particular nature of the prescription drug market.[10] Manufacturers of generic drugs, however, argue that the public policy demand for low prescription drug prices which supports generic substitution laws also supports the copying of the trade dress of a generic drug's name brand counterpart. Generic drug manufacturers argue that consumers will refuse generic drugs and, therefore, lose the benefit of lower prices if generic drugs do not copy the appearance of name brand drugs.[11]

The peculiar misidentification problems of the prescription drug market result from the consumer's deference to the greater skill and knowledge of a physician.[12] Normally, a consumer chooses to purchase a product after examining the product and its packaging. A consumer of prescription drugs, however, receives a drug only after a physician

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manufacturer or merchant must adopt the trademark in good faith. Needle, *A Patent and Trademark Primer*, 15 GA. B.J. 58, 60 (1978) [hereinafter cited as *Trademark Primer*].

[9] Manufacturers or merchants of goods sold or shipped in interstate commerce or subject to federal regulation may register the goods' trademark in the U.S. Patent and Trademark Office under the provisions of the Act. 15 U.S.C. § 1127 (1976); *Trademark Primer, supra* note 8, at 60. Section 32 of the Act provides protection for registered trademarks. *See* 15 U.S.C. § 1114 (1976); text accompanying notes 20-21 *infra*. Section 43(a) of the Act provides some protection for unregistered trademarks. *See* 15 U.S.C. § 1125(a) (1976); text accompanying note 26 *infra*. The federal courts have jurisdiction in actions pursuant to the Act without regard to the amount in controversy or diversity of citizenship. 15 U.S.C. § 1121 (1976); *Trademark Primer, supra* note 8, at 60.

[10] *See* Ives Laboratories, Inc. v. Darby Drug Co., 638 F.2d 538, 541 (2d Cir. 1981); SK&F, Co. v. Premo Pharmaceutical Laboratories, Inc., 625 F.2d 1055, 1059 (3rd Cir. 1980); Hoffman La Roche, Inc. v. Premo, 502 P.T.C.J. (BNA) A-1, A-1, A-2 (D.N.J. 1980); Boehringer Ingelheim G.m.b.H. v. Pharmadyne Laboratories, 502 P.T.J.C. (BNA) A-1, A-1, A-2 (D.N.J. 1980).

[11] Cooper, *Trademark Aspects of Pharmaceutical Product Design*, 70 THE T.M. REP. 1, 28 (1980) [hereinafter cited as *Pharmaceutical Design*]; *see* SK&F, Co. v. Premo Pharmaceutical Laboratories, Inc., 481 F. Supp. 1184, 1188 (D.N.J. 1979), *aff'd*, 625 F.2d 1055 (3rd Cir. 1980) (court rejected argument that generic drug laws require copying of trade dress so patients will not reject cheaper generic drugs clearly differing in appearance); Hoffman La Roche, Inc. v. Premo, 502 P.T.C.J. (BNA) A-4, A-6 (D.N.J. 1980) (court found unpersuasive argument that copying of trade dress required to avoid upsetting patients who receive generic substitutes); Boehringer Ingelheim G.m.b.H. v. Pharmadyne Laboratories, 502 P.T.C.J. (BNA) A-1, A-2 (D.N.J. 1980) (court rejected defendants' assertion that copying of trade dress fills both purpose and spirit of generic substitution laws); A.H. Robins Co. v. Medicine Chest Corp., 206 U.S.P.Q. (BNA) 1015, 1020 (E.D. Mo. 1980) (public policy underlying generic substitution laws not offended by requiring generic drugs to differ in trade dress).

[12] Misidentification problems in the over the counter drug market differ from misidentification problems in the prescription drug market. The consumer of over the counter drugs may examine the drug's packaging before purchasing. The consumer of prescription drugs, however, only receives the drug and the packaging in which the dispensing pharmacist places the drug.

prescribes the drug[13] and a pharmacist dispenses, labels, and packages the drug. Misidentification problems may occur when a pharmacist substitutes a generic drug for a prescribed name brand drug. The pharmacist may inadvertently label the generic drug as the name brand drug or may fail to notify the consumer of the substitution,[14] as required by most generic substitution laws.[15] The pharmacist may also attempt to "pass off" the generic drug as the name brand drug. Passing off the generic drug entails knowing substitution of the generic drug at the name brand price without notifying the consumer.[16] The consumer, therefore, receives a generic drug thinking he has received a name brand drug. Misidentification violates the consumer's right to informed consent to generic substitution[17] and may subject the manufacturer of the name brand drug to liability if the bioavailability[18] of the generic and name brand drugs differ.[19]

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[13] *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, 244 (1980).

[14] *See* Ives Laboratories, Inc. v. Darby Drug Co. 601 F.2d 631, 636 (2d Cir. 1979). The *Ives* court labeled cases of inadvertent misidentification as "intermediate." *Id.*

[15] *See, e.g.*, CAL. BUS. & PROF. CODE § 4047.6 (West Supp. 1981); N.J. STAT. ANN. § 24:6E-7 & -8 (West Supp. 1980); N.Y. EDUC. LAW § 6816-a (McKinney Supp. 1980).

[16] *See* SK&F, Co. v. Premo Pharmaceutical Laboratories, Inc., 625 F.2d 1055, 1063 (3rd Cir. 1980) (unscrupulous pharmacists guilty of passing off when they substitute less expensive generic for name brand drug without informing consumer or passing along lower cost); Ives Laboratories, Inc. v. Darby Drug Co., 601 F.2d 631, 636 (2d Cir. 1979) (most serious case of actionable misidentification occurs when pharmacist fills prescription for name brand drug with generic drug and labels prescription as name brand drug).

The First Restatement of Torts defines passing off as fraudulently marketing one's goods or services as those of another. RESTATEMENT OF TORTS § 711(a) (1938); *see* SK&F, 625 F.2d at 1062.

[17] The informed consent doctrine requires that a physician disclose to the patient the reasonably foreseeable risk and benefits of a procedure and any potentially advantageous alternative procedures. *Pharmaceutical Design, supra* note 11, at 33.

One court suggested that informed consent is impossible if there is covert substitution of a look-alike drug. *See* SK&F, Co. v. Premo Pharmaceutical Laboratories, Inc., 481 F. Supp. 1184, 1190 (D.N.J. 1979), *aff'd*, 625 F.2d 1055 (3rd Cir. 1980); *Pharmaceutical Design, supra* note 11, at 33. The trial court in *SK&F* stated that manufacturers should not expose consumers to the unknown risk of having a prescription filled with an allegedly "generic equivalent." 481 F. Supp. at 1190. Many generic substitution laws reflect the requirement of informed consent by requiring notification of a substitution. *See* note 15 *supra*.

[18] The bioavailability of a drug is a measure of the rate a drug absorbs into the blood stream, an index of the drug's medical efficacy. 481 F. Supp. at 1190; STEDMAN'S MEDICAL DICTIONARY 173 (4th unabr. Lawyer's Ed.).

[19] The Third Circuit in *SK&F, Co. v. Premo Pharmaceutical Laboratories, Inc.* noted that a manufacturer of a name brand drug might be exposed to liability if a patient unknowingly received a generic substitute. The court suggested that a patient might react differently to the generic if the generic and name brand drug were not bioequivalents. SK&F would be unable to prove that the patient took a generic drug if the prescription required the name brand drug and the patient had taken all of the drug. SK&F, Co. v. Premo Pharmaceutical Laboratories, Inc., 625 F.2d 1055, 1066 (3rd Cir. 1980). For a discussion of equivalency problems resulting from varying bioavailability of name brand and generic drugs *see Generic Substitution Laws, supra* note 1, at 392-95.

The Act, in two separate sections, provides manufacturers of name brand drugs with protection from the copying of trade dress by generic drug manufacturers. Section 32 of the Act protects against unfair competition by prohibiting both infringement and contributory infringement of a registered trademark.[20] Trademark infringement occurs when a person manufactures or sells a colorable imitation of a registered trademark without the consent of the registrant.[21] To prove trademark infringement the plaintiff must show that consumers are likely to confuse the imitated and registered trademarks.[22] Contributory infringement occurs when a person intentionally aids another in infringing upon a registered trademark.[23] A manufacturer is liable for contributory infringement if the manufacturer knowingly produces a product so similar to a product produced by another that the similarities enable a retail dealer to pass the product off as the original. A manufacturer also is liable for contributory infringement if the manufacturer encourages passing off.[24]

Section 43(a) of the Act provides broader protection than section 32 against unfair competition.[25] Section 43(a) protects both registered and unregistered trademarks against unfair competition that occurs in the form of false designation of origin or false description or representation of the goods.[26] Proof of section 43(a) unfair competition requires a showing that the copied feature is nonfunctional and has acquired a secondary

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[20] 15 U.S.C. § 1114 (1976). Section 32 of the Act provides that:

> Any person who shall, without the consent of the registrant—(a) use in commerce any reproduction, counterfeit, copy, or colorable imitation of a registered mark in connection with the sale . . . of any goods . . . with which such use is likely to cause confusion, or to cause mistake, or to deceive . . . shall be liable in a civil action by the registrant. . .

Id. See also Ives Laboratories, Inc. v. Darby Drug Co., 601 F.2d 631, 636 (2d Cir. 1979) (discussing copyright infringement action pursuant to § 32 of the Act).

[21] *See* 15 U.S.C. § 1114 (1976); BLACK'S LAW DICTIONARY 702 (5th ed. 1979).

[22] *See* 2 J. MCCARTY, TRADEMARKS AND UNFAIR COMPETITION § 23.1 (1973) [hereinafter cited as MCCARTY].

[23] *See id.* at § 25.2; BLACK'S LAW DICTIONARY 702 (5th ed. 1979); text accompanying notes 54-55 *infra*.

[24] MCCARTY, *supra* note 22, § 25.2.

[25] Trademark infringement is part of the broader law of unfair competition. Facts supporting an action for infringement under section 32 of the Act also would support an action for unfair competition under section 43(a) of the Act. *See* James Burrough Ltd. v. Sign of the Beefeater, Inc., 540 F.2d 266, 274 (7th Cir. 1976); Heaton Distributing Co. v. Union Tank Car Co., 387 F.2d 477, 483 (8th Cir. 1967).

[26] 15 U.S.C. § 1125(a) (1976). Section 43(a) of the Act provides that:

> Any person who shall affix, apply, or annex, or use in connection with any goods . . . a false designation of origin, or any false description or representation . . . tending falsely to describe or represent the same . . . shall be liable to a civil action . . . by any person who believes that he is or is likely to be damages by the use of any such false description or representation.

Id. See also Trademark Primer, supra note 1, at 60 (section 43(a) provides some protection for unregistered trademarks).

meaning.[27] A nonfunctional feature serves no purpose other than identification.[28] A feature of goods has acquired secondary meaning if the feature causes the prospective purchaser to regard the goods as uniquely those of the initial distributor.[29] Courts, however, do not require showings of nonfunctionality and secondary meaning to enjoin the sale of imitations if the manufacturer of the imitation engaged in the predatory practice of encouraging passing off.[30]

In two recent cases, courts protected manufacturers of name brand drugs from the copying of trade dress by generic drug manufacturers under the Act. In *Ives Laboratories, Inc. v. Darby Drug Co.*,[31] the Second Circuit protected a name brand drug manufacturer under section 32 of the Act.[32] In *SK&F, Co. v. Premo Pharmaceutical Laboratories, Inc.*,[33] the Third Circuit protected a name brand drug manufacturer against unfair competition under section 43(a) of the Act.[34]

In *Ives*, the plaintiff, Ives Laboratories (Ives), manufactured and marketed a prescription drug under a registered trademark.[35] The defendants manufactured or marketed the generic drug in capsules of the same dosages and trade dress as the drugs produced by Ives.[36] Ives brought an action charging the defendants with contributory infringement in violation of section 32 of the Act and false designation of origin

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[27] *See Recent Developments, supra* note 1, at 5.

[28] SK&F, Co. v. Premo Pharmaceutical Laboratories, Inc., 625 F.2d at 1063; RESTATEMENT OF TORTS § 742 (1938).

[29] *See* SK&F, Co. v. Premo Pharmaceutical Laboratories, Inc., 625 F.2d at 1063; RESTATEMENT OF TORTS § 741(b)(c) (1938).

[30] *See Recent Developments, supra* note 1, at 6.

[31] 638 F.2d 538 (2d Cir. 1981), *rev'g*, 488 F. Supp. 394 (E.D.N.Y. 1980), *on remand from*, 601 F.2d 631 (2d Cir. 1979).

[32] 638 F.2d at 540, 543.

[33] 625 F.2d 1055 (3rd Cir. 1980), *aff'd*, 481 F. Supp. 1184 (D.N.J. 1979).

[34] *Id.* at 1057. Three district courts have addressed the issue of unfair competition under section 43(a) of the Act since *SK&F*. In each case, the court enjoined the defendant's copying of trade dress based on section 43(a) by relying upon a standard to infer passing off similar to the standard used by the Third Circuit in *SK&F*. *See* Boehringer Ingelheim G.m.b.H. v. Pharmadyne Laboratories, 502 P.T.C.J. (BNA) A-1, A-2 (D.N.J. Dec. 30, 1980); Hoffman La Roche, Inc. v. Premo Pharmaceutical Laboratories, Inc., 502 P.T.C.J. A-4, A-6 (D.N.J. Dec. 30, 1980); A.H. Robins Co. v. Medicine Chest Corp., 206 U.S.P.Q. (BNA) 1015, 1019-21 (E.D. Mo. 1980) (defendants created situation where they knew or should have anticipated passing off through copying trade dress). *See also* text accompanying note 69 *infra* (*SK&F*'s standard for showing of passing off under section 43(a) of Act).

[35] 601 F.2d at 634. Ives manufactured and marketed cyclandelate under the registered trademark "Cyclospamol." *Id.*

[36] Ives markets a 200 milligram dosage of "Cyclospasmol" in blue capsules and a 400 milligram dosage in red and blue capsules, both imprinted with the word "Ives." *Id.* The defendants manufactured or marketed generic cyclandelate in 200 and 400 milligram capsules in colors essentially identical to the capsules in which Ives markets "Cyclospasmol." *Id.* at 635. Defendant Premo began imprinting "Premo" on the generic cyclandelate it markets in June, 1978. Prior to that time, none of the defendants imprinted any mark on the generic cyclandate the defendants marketed. *See id.*

in violation of section 43(a) of the Act.[37] The United States District Court for the Eastern District of New York denied a preliminary injunction.[38]

In *Ives I*, the Second Circuit upheld the denial of a preliminary injunction.[39] The Second Circuit remanded, however, setting forth the standards applicable under sections 32[40] and 43(a)[41] of the Act to prevent manufacturers of generic drugs from copying the trade dress of name brand drugs. On remand, the district court applied the standards developed in *Ives I* and denied Ives permanent relief.[42]

On appeal after remand in *Ives II*,[43] the Second Circuit reversed. The *Ives II* court held that the defendants' manufacturing and marketing of the generic drug with a trade dress identical to the name brand drug constituted contributory infringement in violation of section 32 of the Act.[44] The *Ives II* court noted that the defendants could reasonably an-

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[37] *See id.* Ives also charged the defendants with unfair competition under New York's common and statutory law. *Id.* The *Ives I* court stated that the Second Circuit defined the requirements for a showing of unfair competition under New York Law in Flexitized, Inc. v. National Flexitized Corp., 335 F.2d 774, 781-82 (2d Cir. 1964), *cert. denied*, 380 U.S. 913 (1965). 601 F.2d at 644. In *Flexitized*, the Second Circuit noted that actionable unfair competition under New York law entails the misappropriation of the trademark of another even where the trademark has not acquired a secondary meaning. 335 F.2d at 781-82.

[38] *See* Ives Laboratories, Inc. v. Darby Drug Co., 455 F. Supp. 939, 952 (E.D.N.Y. 1978), *aff'd*, 601 F.2d 631 (2d Cir. 1979).

[39] Ives Laboratories, Inc. v. Darby Drug Co., 601 F.2d 631, 634 (2d Cir. 1979) (Ives I). The Second Circuit noted that the district court had not abused its discretion. *Id.*

[40] *See* text accompanying notes 53-54 *infra*.

[41] 601 F.2d at 642-43 (Ives I). The *Ives I* court indicated that section 43(a) requires a showing that the feature is nonfunctional and has acquired a secondary meaning. *Id.* The court indicated that it would assume nonfunctionality of trade dress unless the defendants demonstrated that the copying of the competitor's trade dress served a number of utilitarian purposes essential to effective competition. *Id.* at 643. The court also noted that the case for nonfunctionality depends on evidence offered by defendants that Ives' chosen trade dress serves several utilitarian purposes essential to effective competition. *Id.* The *Ives I* court should have established a standard implying liability under section 43(a) of the Act similar to the standard used by the *SK&F* court. *See* text accompanying notes 80-83 *infra*. Implication of passing off under section 43(a) of the Act is proper due to the peculiar nature of the prescription drug market. *See* text accompanying note 72 *infra*.

[42] Ives Laboratories, Inc. v. Darby Drug Co., 488 F. Supp. 394, 402 (E.D.N.Y. 1980). The *Ives I* court instructed the district court to apply the standards developed in *Ives I*. 601 F.2d at 644.

[43] Ives Laboratories, Inc. v. Darby Drug Co., 638 F.2d 538 (2d Cir. 1981).

[44] *Id.* at 540, 545. Ives produced fifteen instances of improper substitution at its first trial. 601 F.2d at 636. The fifteen instances were cases of primary infringement. *See* 638 F.2d at 543. Primary cases of infringement occur when the physician prescribed a name brand drug but the pharmacist fills the prescription with the generic drug and labels the prescription as the name brand drug. Primary cases of infringement are the most serious cases of infringement. *See* 601 F.2d at 636 (Ives I). The *Ives I* court noted that a trial court could reasonably conclude that fifteen instances of primary infringement did not justify a holding of contributory infringement under section 32. The court, therefore, affirmed the denial of a preliminary injunction. *Id.* at 634.

On remand from *Ives I*, Ives introduced additional evidence of intermediate cases of infringement discovered through two surveys. 638 F.2d at 543. The *Ives I* court defined "in-

ticipate that a substantial number of pharmacists would pass off the generic drug as the name brand drug.[45] The court noted that the production of generic drugs with trade dress identical to name brand drugs was a suggestion to pharmacists to pass off the generic as the name brand drug.[46] The court also noted that the defendants suggested passing off by distributing catalogues comparing the prices and the similarity in appearance of the generic and name brand drugs.[47] The *Ives II* court, granting an injunction based on section 32 of the Act, indicated that the court did not need to consider Ives' allegations that the defendants violated section 43(a) of the Act.[48]

The generic drug manufacturers in *Ives* argued that the public policy supporting generic substitution laws required that generic drug manufacturers copy the trade dress of a generic drug's name brand counterpart.[49] The *Ives II* defendants also argued that look-alike capsules reduce a patient's confusion and anxiety about taking a generic substitute and that look-alikes aid in identification of the drug in emergency situations.[50] The Second Circuit rejected the defendants' confusion and anxiety arguments. The court noted that a difference in trade dress would not increase a patient's anxiety if the dispensing pharmacist followed the laws and accepted professional practice relating to notification of the patient upon generic substitution.[51]

Prior to *Ives II*, no federal court had prohibited the copying of a prescription drug's trade dress based upon contributory infringement under section 32 of the Act. The Second Circuit's holding in *Ives II* establishes a new avenue for manufacturers of name brand drugs in sec-

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termediate cases" as those cases in which the prescription permits substitution and the pharmacist substitutes a generic for the name brand drug without notifying the consumer. 601 F.2d at 636. The *Ives II* court noted that the district court erred by failing to give any weight to the additional evidence introduced by Ives. The *Ives II* court held that the additional evidence introduced by Ives clearly was sufficient to establish contributory infringement under section 32 of the Act. 638 F.2d at 543 (Ives II).

In the first of Ives' two surveys, test shoppers presented prescriptions for "Cyclospasmol" that permitted substitution at forty-two drug stores selected from a list of drug stores believed to carry both "Cyclospasmol" and generic cyclandelate. Six of the eighteen pharmacists who dispensed the generic product mislabeled the generic product by including "Cyclospasmol" on the label. In the second Ives' survey, Ives' test shoppers submitted the same prescription to 41 pharmacists selected at random. Four of the seventeen pharmacists that dispensed the generic product in the second survey mislabeled the generic product by including "Cyclospasmol" on the label. 638 F.2d at 543; 488 F. Supp. at 397.

[45] 638 F.2d at 542-43.

[46] *Id.* at 543.

[47] *Id.*

[48] *Id.* at 539-40. The Second Circuit remanded from *Ives II* for consideration of other remedies. *Id.* at 540 n.3.

[49] *See* 638 F.2d at 544-45.

[50] *Id.* at 544.

[51] *Id.* at 544-45. The *Ives II* court rejected the defendant's argument that copying trade dress would help officials identify drugs in emergency situations. *See id.* at 544.

tion 32 to prevent manufacturers of generic drugs from copying trade dress.[52] The *Ives I* court set out a standard that indicates a manufacturer or wholesaler is liable for contributory infringement if he suggests or implies that a retailer fill a prescription with a generic drug and apply the corresponding name brand drug's trademark to the label.[53] The *Ives I* court also indicates that a manufacturer or wholesaler is liable under section 32 if the manufacturer or wholesaler sells generic drugs to a pharmacist that the manufacturer or wholesaler knows or has reason to know engages in passing off.[54] The Second Circuit, however, was unclear about what type and how much evidence would establish contributory infringement.[55]

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[52] *See Recent Developments, supra* note 1, at 7. (*Ives I* differs from previous look-alike cases holding that court can find imitator of name brand drug liable for contributory infringement under § 32 of the Act).

[53] 601 F.2d at 636 (*Ives I*).

[54] *Id.*

[55] In *Ives I*, the Second Circuit considered the fifteen instances of improper substitution which Ives introduced at trial and held that the trial court was justified in concluding that Ives failed to adduce the quantum of proof necessary to establish contributory infringement under § 32 of the Act. 601 F.2d at 636; *see* note 44 *supra*. On remand to the district court, Ives introduced "additional evidence of 'intermediate cases' of contributory infringement" derived from two marketing surveys. Although the district court found the additional evidence insufficient to establish a section 32 violation, the circuit court in *Ives II* held that the additional evidence clearly was sufficient to establish contributory infringement under section 32 of the Act. 638 F.2d at 543; *see* note 44 *supra*. The court noted that the pattern of illegal substitution and mislabeling is precisely the sort of showing which the court held in *Ives I* would be "probative of a plaintiff's § 32 claim." *Id.* at 538.

The *Ives II* holding, however, fails to clearly establish what minimum quantum and type of evidence will establish a § 32 violation in the future. The difficulty in discerning a standard for the future stems from the *Ives II* court's failure to indicate whether the court relied on the additional evidence introduced on remand as merely adding to the quantum of proof of contributory infringement and thereby establishing a section 32 violation in conjunction with the fifteen instances of improper substitution introduced in the first trial, or whether the court viewed the additional evidence as a different type of evidence and relied on it as independently establishing a section 32 violation.

If the court viewed the additional evidence as establishing a section 32 violation only in conjunction with the previously introduced fifteen instances of improper substitution, it is unclear why the court required the additional evidence of "intermediate" cases of contributory infringement at all. Ives introduced only ten instances of contributory infringement. Courts consider cases of intermediate contributory infringement less severe violations than the violations represented by the original fifteen instances of improper substitution. *See* 638 F.2d at 543; note 44 *supra*. Therefore, the additional evidence of intermediate cases of contributory infringement added little of substance to the original fifteen cases of improper substitution. *See* 638 F.2d at 546 (Mulligan, J., dissenting). Additionally, because courts consider cases of contributory infringement less severe than the primary cases of contributory infringement demonstrated by the fifteen instances of improper substitution, and because the fifteen instances of improper substitution were insufficient to sustain a section 32 violation, the intermediate cases cannot independently support a section 32 violation. The *Ives II* court's emphasis on the additional evidence of intermediate cases of contributory infringement is confusing for future plaintiffs seeking section 32 relief.

Ultimately, the emphasis accorded by the *Ives II* court to the intermediate cases of contributory infringement may be due to the source, rather than the nature, of the informa-

Manufacturers of products other than generic drugs are liable for contributory infringement under section 32 of the Act if they encourage passing off or produce a product so similar to a product produced by another that the similarities enable a retailer to pass off the product.[56] The Second Circuit's standard in *Ives* for contributory infringement under section 32[57] is consistent with decisions holding manufacturers liable for contributory infringement if they encourage passing off. The Second Circuit correctly indicated that encouraging passing off includes both a suggestion by a manufacturer of generic drugs that a pharmacist pass off the generic as well as the sale of the drug to a pharmacist known to be guilty of passing off. The court, however, may have limited improperly the application of contributory infringement by requiring a showing of actual instances of passing off. Under the Act, the manufacturer of a generic drug that copies the trade dress of a corresponding name brand drug should be guilty of contributory infringement per se due to the peculiar nature of the prescription drug market.[58] Per se contributory infringement liability for generic drug manufacturers is consistent with decisions holding manufacturers liable for contributory infringement if they produce a product so similar to a product produced by another that the similarities enable a retailer to pass off the product. Since a consumer only receives the drug and the pharmacist's label, an unscrupulous pharmacist easily could substitute the generic for the name brand drug if the drugs are identical in appearance.[59]

SK&F, Co. v. Premo Pharmaceutical Laboratories, Inc. establishes an action for unfair competition under section 43(a) of the Act as another avenue for manufacturers of name brand drugs to prevent manufacturers of generic drugs from copying trade dress.[60] SK&F Co. (SK&F) manufactured and marketed a prescription oral diuretic.[61] Premo Pharmaceutical Laboratories, Inc. (Premo) marketed a generic diuretic in capsules extremely similar to the capsules in which SK&F marketed the name brand drug.[62] SK&F brought suit against Premo alleging patent in-

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tion. The *Ives II* court specifically noted that the intermediate cases derived from the marketing surveys that Ives conducted in a "rigorous, impartial manner." *Id.* at 543. Future plaintiffs seeking to establish section 32 violations in the Second Circuit, therefore, should seek to conduct their own Ives type marketing surveys. *See generally* note 44 *supra.*

[56] MCCARTY, *supra* note 22, § 25.2. *See* Corning Glass Works v. Jeannette Glass Co., 308 F. Supp. 1321, 1326 (S.D.N.Y.), *aff'd per cur.*, 432 F.2d 784 (2d Cir. 1970).

[57] *See* text accompanying notes 54-55 *supra.*

[58] *See* text accompanying notes 12-13 *supra.*

[59] The consumer of a prescription drug has no way of knowing if the pharmacist made a substitution unless the pharmacist so notifies the consumer because the consumer would receive only the identical generic.

[60] *See Recent Developments, supra* note 1, at 7 (*Ives I* differs from previous look-alike cases in holding that courts can find imitator of name brand drug liable for unfair competition under section 43(a) of Act); text accompanying note 65 *infra* (*SK&F* holding).

[61] 625 F.2d at 1057.

[62] *See id.* at 1057-58. SK&F markets "Dyazide" in half maroon and half white No. 3 hard gelatin capsules with the logos "Dyazide" and SK&F stamped on each half of the cap-

fringement and unfair competition under section 43(a) of the Act.[63] The United States District Court for the District of New Jersey granted a preliminary injunction against Premo.[64] The Third Circuit upheld the grant of a preliminary injunction under section 43(a) of the Act.[65]

The Third Circuit held that passing off one's goods as those of another as well as unprivileged imitation are actionable torts of unfair competition under section 43(a) of the Act.[66] The *SK&F* court indicated that actionable passing off occurs when manufacturers should reasonably anticipate that pharmacists will pass off generic drugs as their name brand counterpart because of the similarity between the two products. Actionable passing off occurs even if the generic manufacturer does nothing else to encourage passing off.[67] The Third Circuit's application of the standard for a showing of actionable passing off to the facts of *SK&F* indicates that the court will presume actionable passing off when a generic drug manufacturer copies the trade dress of a name brand drug unless the manufacturer can establish that he was unaware of passing off by pharmacists.[68]

The *SK&F* court noted that the second section 43(a) tort, unprivileged imitation, requires the name brand manufacturer to show secondary meaning and nonfunctionality.[69] Apparently, the court would imply secondary meaning from an assertion by a generic manufacturer that it copied that trade dress of the name brand drug so patients and doctors would associate the generic drug with the name brand drug.[70] The Third

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sules. *Id.* at 1057. Premo markets generic "Dyazide" in half maroon and half white No. 3 hard gelatin capsules with the logo "Premo" stamped on the capsules. *Id.* at 1058.

[63] *See id.* at 1057; 481 F. Supp. at 1186.

[64] *See* 625 F.2d at 1057; 481 F. Supp. at 1187. The *SK&F* court reserved decision on SK&F's allegation of patent infringement. 625 F.2d at 1057; 481 F. Supp. at 1187.

[65] 625 F.2d at 1057, 1068. SK&F presented evidence of a survey showing a 4% rate of unlawful substitution and a 23% rate of illegal mislabeling. *Id.* at 1059.

[66] *See* 625 F.2d at 1065 (discussing torts of passing off and unprivileged imitation); note 26 *supra* (language of § 43(a)). The *SK&F* court noted that § 43(a) has been construed broadly to proscribe other competitive torts. 625 F.2d at 1065.

[67] The *SK&F* court relied upon the wording of § 43(a) of the Act which states that a person is liable for introducing into commerce any words or symbols tending falsely to describe ones product as that of another. *Id.*; *see* note 26 *supra*. In analyzing § 43(a), the *SK&F* court found that § 43(a) proscribes passing off as does New Jersey law. 625 F.2d at 1065. The court stated that New Jersey law requires a finding of passing off when a generic drug manufacturer places a product in the hands of a pharmacist in a form which enables the manufacturer reasonably to anticipate that the pharmacist may pass off the generic product as the name brand product. Actionable passing off occurs under New Jersey law even if the generic drug manufacturer does nothing else to encourage passing off. 625 F.2d at 1062.

[68] *See* 625 F.2d at 1063 (no suggestion that defendant was unaware of passing off of defendant's generic look-alike by some unscrupulous pharmacist).

[69] *See id.* at 1063, 1065. In analyzing § 43(a) of the Act, the *SK&F* court found no essential difference between the tort of unprivileged imitation under New Jersey law and § 43(a) except the Act's required element of interstate commerce. *Id.* at 1065.

[70] *See* 625 F.2d at 1063-64; text accompanying note 29 *supra*. The *SK&F* court indicated that the defendant's admission that they copied the trade dress of the name brand

Circuit also indicated that a drug's trade dress is nonfunctional if other manufacturers successfully market equivalent drugs in a different trade dress.[71]

The *SK&F* court's prevention of trade dress copying by generic drug manufacturers was sound. In *SK&F*, the facts supported a finding of unprivileged imitation under section 43(a) of the Act because the trade dress of the name brand drug was nonfunctional and had acquired a secondary meaning.[72] The successful marketing of equivalent drugs of different trade dress indicated that trade dress was nonfunctional.[73] Further, the defendant admitted copying trade dress in order to associate the generic drug with the name brand drug in the mind of the patient and physician.[74] Such an admission was sufficient to indicate that the trade dress had acquired a secondary meaning in cases like *SK&F*, where trade dress is nonfunctional.[75]

The court in *SK&F* also properly found the defendants guilty of passing off.[76] The implication of passing off allowed by the Third Circuit under section 43(a) of the Act is consistent with the exception to the general rule that requires a showing of nonfunctionality and secondary meaning for the court to grant protection against unfair competition.[77]

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drug to facilitate association of generic drug with name brand drug by patients and doctors strongly supports a showing of secondary meaning. *See id.*

[71] *See id.* at 1064. The *SK&F* court noted that another manufacturer successfully markets equivalent drugs to SK&F's in orange tablet form. The court then found trade dress of name brand product nonfunctional. *Id.*

[72] *See* text accompanying notes 69-71 *supra.*

[73] *See* text accompanying note 71 *supra.* A nonfunctional feature serves no purpose other than identification. *See* text accompanying note 28 *supra.* If a competitor successfully markets an equivalent drug of differing trade dress, the trade dress of the name brand drug is not the only functional trade dress in which a manufacturer can market the drug. A competitor's successful marketing of an equivalent drug of differing trade dress, therefore, is an indication that the trade dress of the name brand drug is nonfunctional.

The *SK&F* court noted that of the 25 leading diuretics sold in the United States, the trade dress of SK&F's product was unique. 625 F.2d at 1059. Further, SK&F successfully markets the drug in Europe in an orange tablet. *Id.* at 1057. The court also listed a number of different drugs manufactured in capsules similar to the capsules in which SK&F markets "Dyazide." *Id.* at 1060.

[74] *See* 625 F.2d at 1060.

[75] *See* text accompanying note 70 *supra.* A nonfunctional feature serves no purpose other than identification. *See* text accompanying note 28 *supra.* If a feature is functional, a manufacturer intentionally can copy that feature to obtain the commercial advantage that feature provides. *See* text accompanying note 37 *supra.* If a feature is nonfunctional and has acquired a secondary meaning, however, a manufacturer cannot copy that feature. *See* text accompanying note 27 *supra.* A feature of goods has acquired secondary meaning if the feature causes the prospective purchaser to regard the goods as those of another. *See* text accompanying note 29 *supra.* Since the defendant in both cases admitted copying the trade dress of the name brand drug in order to associate the generic drug with the name brand drug in the mind of the patient and physician, the defendant effectively admitted secondary meaning.

[76] *See* text accompanying notes 66-68 *supra.*

[77] *See* text accompanying note 26 *supra.*

The exception allows courts to prevent unfair competition without a showing of nonfunctionality or secondary meaning when the defendant is guilty of the predatory practice of encouraging passing off.[78] The nature of the prescription drug market makes the copying of the trade dress a predatory act. A consumer of prescription drugs receives a bottle filled and labeled by his pharmacist. If a generic look-alike is available, an unscrupulous pharmacist easily could pass off illegally the identical generic as the name brand drug.[79] The *SK&F* court, therefore, properly considered the production of a generic drug of identical trade dress of the name brand drug an encouragement of passing off.

In *Ives II* and *SK&F*, the Second and Third Circuits properly granted manufacturers of name brand drugs protection under the Lanham Act against the copying of trade dress by manufacturers of generic drugs.[80] In *Ives II*, the Second Circuit, however, may have limited section 32 actions too severely by requiring evidence of actual passing off.[81] By manufacturing a generic drug that looks like a name brand drug counterpart, generic drug manufacturers enable and encourage pharmacists to pass off the generic as the name brand drug.[82] In future actions under the Lanham Act, therefore, federal courts should consider the copying of trade dress by generic drug manufacturers as a per se violation of the Lanham Act in order to prevent passing off.[83]

JAMES B. MCLAREN, JR.

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[78] *See* text accompanying note 30 *supra*.

[79] The consumer of a prescription has no way of knowing if the pharmacist made a substitution unless the pharmacist so notifies the consumer because the consumer would receive only the identical generic.

[80] *See* text accompanying notes 56-59 *supra*.

[81] *See* text accompanying notes 58-59 *supra*.

[82] *See* text accompanying notes 57-58 *supra*.

[83] *See* text accompanying notes 58-59 *supra*.