
Darrel C. Karl

Follow this and additional works at: http://scholarship.law.edu/lawreview

Recommended Citation


Available at: http://scholarship.law.edu/lawreview/vol32/iss2/11

This Notes is brought to you for free and open access by CUA Law Scholarship Repository. It has been accepted for inclusion in Catholic University Law Review by an authorized administrator of CUA Law Scholarship Repository. For more information, please contact edinger@law.edu.
"LOOK-ALIKE" CAPSULES, GENERIC DRUG SUBSTITUTION, AND THE LANHAM ACT: THE ELUSIVE CONTRIBUTORY INFRINGEMENT STANDARD OF INWOOD LABORATORIES, INC. V. IVES LABORATORIES, INC.

Since the early 1970's, over thirty states have enacted some form of legislation to allow pharmacists to substitute generic versions of name brand prescription drug products under appropriate circumstances. This flurry of legislative activity has resulted from growing consumer dissatisfaction with the high cost of prescription drugs, the increased availability of generic alternatives and the lobbying efforts of the generic drug manufacturers.

Although generic drug substitution laws reflect a public policy favoring competitive pricing, they have paradoxically increased the likelihood of

2. New York's generic substitution laws are typical of those found in most states. Statutes require that a physician's prescription form contain two signature lines: one labeled "dispense as written" and the other bearing the words "substitution permissible." N.Y. EDUC. LAW § 6810(6) (McKinney Supp. 1981-1982). A prescription signed "dispense as written" must be followed without deviation. If a prescription is instead signed "substitution permissible," substitution is mandatory if a generic equivalent appears on an approved state list. N.Y. EDUC. LAW § 6816-a(1) (McKinney Supp. 1981-1982); N.Y. PUB. HEALTH LAW § 206(1)(o) (McKinney Supp. 1981-1982). If a generic drug does not appear on such a list, then the decision to substitute is left to the discretion of the pharmacist in the individual case. Unless the physician requests otherwise, a prescription filled with a generic drug must bear a label containing the generic drug name and the name of the generic drug manufacturer. N.Y. EDUC. LAW § 6816-a(1)(c) (McKinney Supp. 1981-1982). New York's generic drug substitution law was recently found to be constitutional in Pharmaceutical Mfrs. Ass'n v. Whalen, 54 N.Y.2d 486, 446 N.Y.S.2d 217 (1981).
3. See Pharmaceutical Soc'y of New York, Inc. v. Lefkowitz, 454 F. Supp. 1175, 1177-78 (S.D.N.Y.); aff'd, 586 F.2d 953 (2d Cir. 1978); Note, supra note 1, at 387.
5. Over 12% of the more than eight billion dollar prescription drug market is generic. This percentage is expected to increase as more states pass generic drug substitution laws. See Rogers & Kahan, Recent Developments Regarding Look-Alike Drugs, 35 FOOD DRUG COSM. L.J. 4 (1980).
illegal drug substitution at the expense of the consumer. Many generic
drug manufacturers seek to capitalize on the public's familiarity with the
shape and color combinations of name brand drugs by adopting identical
shape and color schemes for their own products once the particular
branded drug's patent has expired. These "look-alike" drugs make it rel-
atively easy for a druggist to illegally substitute a generic drug for a name
brand product and charge the customer the branded drug's typically
higher price with little fear that the consumer will detect the fraud.

Traditionally, courts have resisted the efforts of commercial drug com-
panies to monopolize specific color schemes for particular drug products.
A color, by itself, is not protectable under the principles of trademark
law. Protection is possible only if a color is but one of numerous ele-
ments comprising, as a whole, a distinctive shape or design that is protect-
able. In addition, the color element must be nonfunctional and it must

7. Patent laws provide protection against the copying of an invention for a period of
seventeen years, and the patent cannot be renewed. 35 U.S.C. § 154 (Supp. IV 1980). A
trademark registration is valid for a twenty-year period but the registration may be repeated-
between patents and trademarks, see generally J. McCarthy, Trademarks and Unfair
Competition, § 6 (1973).
8. Many of the major drug patents expired in the late 1960's, allowing the generic drug
companies to enter the market in direct competition with the original patent holders. See
Hooke, Generic Drug Laws and Unfair Competition Claims Under the Lanham Act—An Un-
easy Alliance: Ives Laboratories, Inc. v. Darby Drug Co., 33 Rutgers L. Rev. 227, 246 n.158
(1980).
10. See Campbell Soup Co. v. Armour & Co., 175 F.2d 795 (3d Cir.), cert. denied, 338
U.S. 847 (1949). In Campbell Soup, the court noted that there are only seven primary colors
and that competition would be stifled by a depletion of this limited supply: "If they may
thus monopolize red in all its shades the next manufacturer may monopolize orange in all its
shades and the next yellow in the same way. Obviously, the list of colors will soon run out."
Id. at 798. See also Leschen Rope Co. v. Broderick, 201 U.S. 166, 170-71 (1906) (trademark
for a distinctively-colored streak woven into a wire rope held invalid for overbreadth when
it would be infringed by a rope containing a streak of any color, however applied).
11. See Quabaug Rubber Co. v. Fabiano Shoe Co., 567 F.2d 105 (1st Cir. 1977); In re
Data Packaging Corp., 453 F.2d 1300 (C.C.P.A. 1972); American Waltham Watch Co. v.
12. A feature of a trademark is functional only if it provides a product with greater
utility or contributes to its economy of manufacture, serving some purpose other than identi-
fication of the product. J. McCarthy, supra note 7, at § 7:26(A). Trademarks with func-
tional features are not registerable and may be freely copied by the general public. Id. at
§ 7:26.
have acquired a secondary meaning\textsuperscript{13} in the marketplace.\textsuperscript{14}

If a pharmacist dispenses a generic drug with a label containing the registered mark of another, the name brand drug manufacturer may bring suit for trademark infringement under the federal trademark laws.\textsuperscript{15} Section 32(1) of the Federal Trademark (Lanham) Act of 1946\textsuperscript{16} provides a civil cause of action for the misuse of another's registered trademark in connection with the sale or advertisement of goods where such use is likely to cause confusion or deception. In addition, a body of judicially-created law has arisen under section 32 to predicate liability upon manufacturers and distributors who, by aiding or encouraging others to infringe a trademark, contribute to the confusion and deception of the consumer.\textsuperscript{17}

Although the marketing of imitative drug products may not per se infringe a registered trademark, the colors of such drugs may nonetheless facilitate illegal substitution by pharmacists. Recently, in \textit{Inwood Laboratories, Inc. v. Ives Laboratories, Inc.},\textsuperscript{18} the Supreme Court addressed the circumstances in which a manufacturer of "look-alike" generic drugs may be held liable for contributory infringement under the Lanham Act. On purely procedural grounds, the Court reversed a Second Circuit ruling that generic drug companies that manufactured drug capsules identical to a

\begin{footnotesize}
\begin{enumerate}
\item[$\text{13.}$] Secondary meaning arises as a result of a mental association in the consuming public's mind between the trademark of a good and the source or origin of that product. \textit{Id.} at § 15:2.
\item[$\text{14.}$] \textit{See} Dallas Cowboys Cheerleaders, Inc. v. Pussycat Cinema, Ltd., 604 F.2d 200 (2d Cir. 1979) (colors and design of cheerleader uniform held nonfunctional and use of a strikingly similar costume in a sexually explicit film found to cause consumers to erroneously associate Texas professional football team with the film's producers and characters).
\item[$\text{16.}$] Section 32(1) of the Lanham Act provides in part:

\begin{quote}
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, offering for sale, distribution, or advertising of any goods or services on or in connection with which such use is likely to cause confusion, or to cause mistake, or to deceive; or (b) reproduce, counterfeit, copy, or colorably imitate a registered mark and apply such reproduction . . . to labels . . . intended to be used in commerce upon or in connection with the sale . . . of goods or services on or in connection 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 for the remedies hereinafter provided.
\end{quote}

\item[$\text{18.}$] 102 S. Ct. 2182 (1982).
\end{enumerate}
\end{footnotesize}
name brand product were liable for contributory infringement under section 32 of the Act.

Ives Laboratories was the manufacturer of cyclandelate, a prescription drug sold under the registered trademark "Cyclospasmol." The arbitrary color-dosage scheme developed by Ives for "Cyclospasmol" was copied by many of the generic drug companies after Ives' patent had expired. Responding to instances of mislabeling and illegal substitution by pharmacists, Ives brought suit under section 32 of the Lanham Act to enjoin the manufacturers and wholesalers of the generic version of "Cyclospasmol" from marketing their drug products in identically colored capsules. Ives contended that the imitative capsule colors and suggestive comparison catalogs induced pharmacists to infringe the "Cyclospasmol" mark. Additional claims for relief were based on section 43(a) of the Lanham Act.

19. "Cyclospasmol" is a peripheral and cerebral vasodilator used to increase blood flow in patients with vascular diseases. Id. at 2184.

20. Ives markets "Cyclospasmol" in pale blue 200 milligram capsules imprinted with "Ives 4124" and in blue and red 400 milligram capsules imprinted with "Ives 4148." Id. at 2184. Only after litigation began did some of the defendants imprint identifying marks on their capsules. Id. at 2184 n.3.

21. Ives Labs., Inc. v. Darby Drug Co., 455 F. Supp. 939, 944 (E.D.N.Y. 1978). One of the original defendants in the case was Lowitt Labs., Inc., a retail pharmacist. Lowitt consented to a court decree enjoining it from further acts of substitution and mislabeling. Id. at 942.

22. Manufacturers Premo Pharmaceutical Laboratories, Inc., Inwood Laboratories, Inc., and MD Pharmaceutical Co., Inc. each purchased cyclandelate powder and empty capsules and assembled the final generic product. Wholesalers Darby Drug Co., Inc., Rugby Laboratories, Inc., and Sherry Pharmaceutical Co., Inc. purchased the cyclandelate capsules and resold them to retail pharmacies. Id. at 941-42.

23. These catalogs, aimed at the retail pharmacist, described the color of the cyclandelate capsules, emphasized their equivalence to "Cyclospasmol," and included a price comparison chart highlighting the lower cost of the generic cyclandelate capsules. 102 S. Ct. at 2185.

24. Ives claimed that the generic drug manufacturers' imitation of the capsule colors of "Cyclospasmol," nonfunctional features of the drug, constituted a false designation of the drug's true origin. Section 43(a) of the Lanham Act provides:

Any person who shall affix, apply, or annex, or use in connection with any goods or services, or any container or containers for goods, a false designation of origin, or any false description or representation, including words or other symbols tending falsely to describe or represent the same, and shall cause such goods or services to enter into commerce, and any person who shall with knowledge of the falsity of such designation of origin or description or representation cause or procure the same to be transported or used in commerce or deliver the same to any carrier to be transported or used, shall be liable to a civil action by any person doing business in the locality falsely indicated as that of origin or the region in which said locality is situated, or by any person who believes that he is or is likely to be damaged by the use of any such false description or representation.

and the New York unfair competition laws.\textsuperscript{25}

The district court denied Ives' request for a preliminary injunction. It held that Ives had not shown that the generic drug manufacturers knowingly and deliberately conspired with pharmacists or suggested that they disregard prescription orders for "Cyclospasmol."\textsuperscript{26} The United States Court of Appeals for the Second Circuit concluded that the lower court had applied an overly narrow standard for contributory infringement. It held that "a manufacturer or wholesaler would be liable under section 32 if he suggested, even if only by implication, that a retailer fill a bottle with the generic capsules" and apply another's mark to the label or if it continued to supply the generic drug capsules to a pharmacist who the manufacturer "knew or had reason to know was engaging" in such practices.\textsuperscript{27} Nonetheless, the court of appeals held that Ives' evidentiary showing was insufficient to grant a preliminary injunction.\textsuperscript{28}

On remand, the district court dismissed the suit. It concluded that the evidence of mislabeling presented at trial did not demonstrate that the generic drug companies "suggested by implication" that pharmacists could infringe upon Ives' mark.\textsuperscript{29} The court also rejected Ives' other claims, finding that the capsule colors were functional\textsuperscript{30} and that secondary meaning had not been established.\textsuperscript{31} In a two-to-one decision, the Second Circuit reversed and held that the evidence demonstrated that the generic drug manufacturers could anticipate that a substantial number of druggists

\begin{itemize}
\item 26. \textit{Ives}, 455 F. Supp. at 945.
\item 27. \textit{Ives Labs., Inc. v. Darby Drug Co.}, 601 F.2d 631, 636 (2d Cir. 1979).
\item 28. \textit{Id.}
\item 29. \textit{Ives Labs., Inc. v. Darby Drug Co.}, 488 F. Supp. 394, 397 (E.D.N.Y. 1980). The court also suggested that the instances of mislabeling were due to pharmacists who misunderstood the requirements of the New York generic drug substitution laws. \textit{Id.} at 397-98.
\item 30. The district court accepted the generic drug manufacturers' evidence that: (1) color has a therapeutic effect and elderly patients accustomed to the colors of "Cyclospasmol" would refuse to take or would be upset by a generic drug of a different capsule color; (2) patients often mix multiple prescription drugs in a single container and remember which drug to take by its color; and (3) color serves to identify the drug in an emergency overdose situation. \textit{Id.} at 398-99.
\item 31. \textit{Id.} at 401. The district court found that patients do not associate the name "Cyclospasmol" with a particular manufacturer but only with its healing effect or with a particular ailment. The court gave little credence to an undocumented study of thirty-six "Cyclospasmol" patients. Only one-third of the patients correctly identified the pale blue or blue and red capsules as "Cyclospasmol" without prompting, another one-third were able to make the association after being provided with a list of ten drug names, and the remaining third were unaware that the drug they had been taking was called "Cyclospasmol." \textit{Id.} at 399-400.
\end{itemize}
would use "look-alike" capsules to either illegally substitute the generic product or mislabel it as "Cyclospasmol." The appellate court remanded the case and ordered the district court to enjoin the sale of cyclandelate in "look-alike" capsules.

The Supreme Court reversed on procedural grounds. Writing for the majority, Justice O'Connor stated that the court of appeals was bound by the "clearly erroneous" standard of the Federal Rules of Civil Procedure. Therefore, the Second Circuit could not overturn the district court's finding merely because it would have given different weight to or drawn different conclusions from the evidence. Because the court of appeals never reached Ives' remaining claims, the Court remanded the case for further proceedings. In a concurring opinion, Justice White, joined by Justice Marshall, maintained that the court of appeals had impermissibly weakened the standard for a section 32 violation and criticized the ma-

32. Ives Labs., Inc. v. Darby Drug Co., 638 F.2d 538, 545 (2d Cir. 1981). Cyclandelate is not on the New York list of approved generic drug substitutes. See supra note 2 and accompanying text. If a prescription is to be filled with "Cyclospasmol" but is actually filled with generic cyclandelate, an illegal substitution has occurred. If substitution is permissible and a generic form is indeed dispensed but labeled as "Cyclospasmol," an "intermediate" case of trademark infringement has occurred. Id. at 543.

Ives conducted two studies to demonstrate the frequency of illegal substitution. Forty-one pharmacies were randomly selected from the Hayes Directory of New York drug stores, while an additional forty-two were personally selected by Ives. In each case, a pharmacist was provided with a prescription for "Cyclospasmol" signed "substitution permissible." In the control (Hayes) survey, 17 pharmacists dispensed generic cyclandelate and 4 labeled it as 'Cyclospasmol.' In the Ives survey, 18 dispensed cyclandelate and 6 mislabeled it as "Cyclospasmol." In one case, the higher brand name price was passed on to the consumer. Id. at 542.

Premo Pharmaceutical Laboratories, Inc. also conducted its own survey of 50 pharmacies, half with prescriptions for "Cyclospasmol" to be dispensed as written, the other for "cyclandelate" to be dispensed as written. Nonetheless, two of the cyclandelate prescriptions were labeled "Cyclospasmol." Id. at 543 n.7.

33. Id. at 545. Dissenting, Judge Mulligan took issue with the majority's finding that the generic drug companies had failed to offer any "persuasive" evidence for using the same capsule color scheme without characterizing the lower court's finding of functionality as "clearly erroneous." Id. at 547. He also disputed the reliability and significance of the mislabeling surveys. Id. at 546. As the majority correctly noted in a footnote to its discussion of the surveys, Mulligan's finding that the percentage of cases involving mislabeling was 12%, as opposed to the majority's figure of 29%, was based fallaciously on the total sample size. Such a base figure was overinclusive because there was no opportunity for mislabeling when a prescription for "Cyclospasmol" was filled with "Cyclospasmol." Id. at 543 n.7.

34. Inwood, 102 S. Ct. at 2188; see FED. R. CIV. P. 52(a).
35. 102 S. Ct. at 2189.
36. Having found a violation of § 32, the Second Circuit did not address the § 43(a) or state unfair competition claims. Ives, 638 F.2d at 540.
37. 102 S. Ct. at 2191.
Contributory Infringement Standard

iority for silently acquiescing to such a change. In addition, Justice White declared that a showing of functionality should provide a complete affirmative defense to a contributory infringement claim. In a brief concurrence, Justice Rehnquist disagreed with the majority's determination that the district court's findings were not clearly erroneous, arguing that the court of appeals was better equipped to decide such a question.

Ives raises significant questions concerning the standards and defenses involved in a section 32 violation. This Note will examine the development of common law and statutory principles in the areas of contributory infringement and trademark protection for colored drug products. It will analyze and evaluate the Ives Court's conclusions in light of prior case decisions and the evidence presented at trial. The Ives decision will be criticized for both its failure to clarify the contributory infringement standard and its failure to address the overriding issue of capsule color protection. Finally, the potential impact of Ives upon consumers and brand name manufacturers will be discussed.

I. COMMON LAW CONTRIBUTORY INFRINGEMENT AND UNFAIR COMPETITION STANDARDS

The earliest and most frequently cited Supreme Court opinion on contributory trademark infringement prior to the passage of the Lanham Act is William R. Warner & Co. v. Eli Lilly & Co. Lilly manufactured a chocolate-flavored quinine preparation under the trademark "Coco-Quinine." It sought to enjoin Warner from manufacturing a similar product under the mark "Quin-Coco." The Court found that Warner was attempting to profit from the commercial reputation of "Coco-Quinine" by suggesting that it would be in a druggist's interest to fill orders for "Coco-Quinine" with the lower-cost "Quin-Coco," and that substitution could be made without danger of detection. The Court concluded that Warner's salesmen induced the substitution "in direct terms or by suggestion or insinuation," and that such wrongful actions enabled dealers to pass off Warner's preparation as that of Lilly. The Court found that one "who induces another to commit a fraud and furnishes the means of consum-

38. Id. at 2192.
39. Id.
40. Id. at 2193.
41. 265 U.S. 526 (1924).
42. Id. at 527-28.
43. Id. at 529-30.
44. Id. at 530.
mating it is equally guilty and liable for the injury." Although the Court granted an injunction against further fraudulent activity, it refused to enjoin the use of chocolate because the evidence demonstrated that it was a functional ingredient. Instead, the Court required Warner's packages to bear labels clearly distinguishing the two products with a warning that "Quin-Coco" was not to be used in filling prescription orders for "Coco-Quinine."

In Kellogg Co. v. National Biscuit Co., the Supreme Court addressed the relevance of functionality and secondary meaning in a situation where a manufacturer attempts to protect its product after the patent has expired. National Biscuit held the patent rights to the process for making the cereal product known as "Shredded Wheat." When the patent expired, Kellogg began to market its own version of the cereal. National Biscuit brought suit under a state unfair competition statute, alleging that Kellogg's use of the name "Shredded Wheat" and the cereal's corresponding "pillow shape" enabled Kellogg and others to pass off the product as one produced by National Biscuit. The Court refused to protect National Biscuit's use of the words "Shredded Wheat," noting that the term was generic and that it accurately described the product as it was generally known by the public. Because the term became generic before the expiration of the patent, both the right to make the product and the right to apply the name associated with it passed into the public domain.

---

45. Id. at 530-31 (citing Hostetter Co. v. Brueggeman-Reinert Distilling Co., 46 F. 188, 189 (C.C.E.D. Mo. 1891)).
46. 265 U.S. at 532.
47. Id. at 532. While chocolate served no therapeutic purpose, it imparted a distinctive color and "masking" flavor to the preparation and served as a suspension medium for the quinine. Id.
48. Id. at 532-33. Commentators have criticized this type of remedy as ineffective, because it calls attention to the product's lower cost and ignores the existence of other distinctive flavors. See, e.g., Swenson, Property Rights in the Color and Shape of Capsules, 32 Food Drug Cosm. L.J. 361, 363 (1977); Cooper, supra note 9, at 10.
49. 305 U.S. 111 (1938).
50. Id. at 116.
51. The word "generic" as applied in trademark law is a term of art. It denotes the name of the product and not the name of its source. Since a generic term does not indicate source or origin, it may never be protected by a trademark. If a producer of a new good fails to impress upon the public that the mark identifies the manufacturer or retailer rather than the type of good, a court may declare a mark to be generic and the mark will pass into the public domain. J. McCarthy, supra note 7, at § 12:1-9. See, e.g., King-Seeley Thermos Co. v. Aladdin Indus., Inc., 321 F.2d 577 (2d Cir. 1963) ("thermos"); Du Pont Cellophane Co. v. Waxed Prods. Co., 85 F.2d 75 (2d Cir. 1936) ("cellophane"); Charles R. De Bevoise Co. v. H. & W. Co., 69 N.J. Eq. 114, 60 A. 407 (1905) ("brassiere").
52. 305 U.S. at 116.
Contributory Infringement Standard

The Court also found that National Biscuit failed to demonstrate that the name “Shredded Wheat” had acquired a secondary meaning. The Court concluded that the term’s primary significance in the consumer’s mind was the cereal itself and not its source.54 Similarly, the cereal’s unique “pillow shape” could not be protected because the patented machines that produced the shredded wheat were designed to produce it only in this shape. In addition, the public had become accustomed to associating the pillow shape with the product,55 and the Court found this pillow shape design to be functional.56 Unlike Warner, there was no evidence that Kellogg intended to deceive consumers.57 Kellogg’s different packaging and distinctive labels58 demonstrated that it had taken reasonable precautions to prevent confusion or deception in the sale of its product.59 In dismissing the case, the Court declared that a company’s desire to share in the goodwill of a product not protected by a patent or a trademark is a right which can be freely exercised by the public at large.60

The last major pronouncement on the contributory infringement standard prior to the enactment of the Lanham Act was made in Coca-Cola Co. v. Snow Crest Beverages, Inc.61 Coca-Cola brought an action for trademark infringement and unfair competition under federal and Massachusetts law, alleging that retail dealers were passing off Snow Crest’s “Polar Cola” for a similar soft drink produced by Coca-Cola.62 Coca-Cola’s primary claim concerned the aural similarity between the two cola names.63 The court found that the sounds were not strikingly similar or confusing when understood in the context of color, spelling, script, and general background.64 The standard for contributory infringement, the court said, was whether the wrongful actions of another “might well have

54. 305 U.S. at 118.
55. Id. at 119-20.
56. The evidence suggested that the use of any other shape in the manufacture of shredded wheat would result in an increased cost or an overall lower quality product. Id. at 122.
57. Id.
58. Id. at 120-21.
59. Id. at 122.
60. Id.
62. 64 F. Supp. at 982, 987.
63. Id. at 987. Like marks with imitative design features, protection may be denied to names likely to be confused with other trademarked goods when spoken aloud. J. Mccarthy, supra note 7, at § 23:5. See, e.g., Communications Satellite Corp. v. Comcet, Inc., 429 F.2d 1245 (4th Cir. 1970) (Comsat and Comcet); La Touraine Coffee Co. v. Lorraine Coffee Co., 157 F.2d 115 (2d Cir. 1946) (La Touraine and Lorraine); Esso, Inc. v. Standard Oil Co., 98 F.2d 1 (8th Cir. 1938) (Esso and S.O.).
64. 64 F. Supp. at 990-91.
been anticipated" by the manufacturer. Although it recognized that one is not per se responsible for the actions of another, the court said accountability should turn on whether a reasonable person in a similar position would realize that he had created an opportunity or a temptation for another to commit a wrong or that he was dealing with one known or believed to be engaging in unethical business practices. The court dismissed the suit, finding no evidence that Snow Crest had suggested in its sales talks, advertising, or packaging that retailers should substitute "Polar Cola" on specific orders for "Coca-Cola."

Although a doctrine of contributory trademark infringement was formulated before the passage of the Lanham Act, the federal trademark statutes existing at the time were generally considered to be inadequate to protect fully the trademark registrant. The legislative history of the Lanham Act indicates that the statute was intended to create uniform trademark rights throughout the United States by codifying, clarifying, and modernizing common law trademark concepts that had been diluted by state courts and legislatures. The Act also liberalized trademark registration procedures and the remedies for trademark infringement.

The Lanham Act contains two significant sections providing relief for trademark infringement. Section 32 creates a civil cause of action for the registrant of a valid federal trademark if an infringer uses a confusingly similar trademark in commerce. The plaintiff must show that the use of the similar trademark is likely to cause consumer confusion. In evaluating

65. Id. at 989.
66. Id.
67. Id. at 987. The evidence also indicated that other brands were frequently substituted for "Coca-Cola." Only 24 specific orders for "Coca-Cola" were actually filled out of 201 such orders in 35 taverns. The remaining orders were filled by at least five other cola brands. Id. at 986-87.
68. The 1905 Trademark Act made it difficult for United States citizens to register trademarks in foreign countries, federal registration was only prima facie evidence of ownership which could be rebutted, and the statutory language was too narrow to encompass the realities of twentieth century commerce. J. McCarthy, supra note 7, at § 5:3-4.
70. Id.
73. See supra note 16 and accompanying text.
the mark, courts look to the strength\textsuperscript{74} of the mark, the similarity between the marks, the type of goods protected, and any evidence of actual consumer confusion.\textsuperscript{75} No one factor is dispositive and the protection afforded any given mark will depend upon the facts and circumstances in the particular case.

Section 43(a) of the Act provides a trademark owner who does not possess a federally registered mark a cause of action for unfair competition under federal common law.\textsuperscript{76} To prevail, a plaintiff must establish that goods or services are involved, that interstate commerce is affected, and that the infringer has falsely designated the source or origin of the product.\textsuperscript{77} Section 43(a) broadened the earlier prohibition against a false designation of geographic origin to include any false description or representation.\textsuperscript{78} The test for a section 43(a) violation is similar to that for a section 32 claim: whether the infringer's mark is likely to cause confusion as to the source of the good or service.\textsuperscript{79} In addition, section 43(a) provides a civil action for false advertising.\textsuperscript{80}

II. THE DRUG COLOR CASES: FUNCTIONAL OR FRAUDULENT USE OF COLOR?

In the early common law decisions, courts often looked to the corresponding packaging of the goods in determining questions of trademark infringement. Even today, courts may conclude that bottles of over-the-counter liquid medicines, cardboard boxes of cereal, and cartons of soda sufficiently distinguish essentially identical products so as to prevent consumer confusion or deception. Prescription drug products, however, inherently lack such distinctive packaging. Customers never see the manufacturers' cartons in which the drugs are shipped. They must rely solely upon the pharmacist-typed label and the features of the individual tablet or capsule to identify the source of the drug. Thus, drug companies

\textsuperscript{74} Whether a mark is "strong" or "weak" is a reflection of its likelihood to confuse consumers of that good. Arbitrary, fanciful, and suggestive marks are entitled to trademark protection. Marks which are descriptive are protectable only if they have acquired a secondary meaning. Thus, a strong mark would be highly fanciful and arbitrary, while a weak mark would be primarily descriptive. See J. McCarthy, supra note 7, at § 23:15(F).


\textsuperscript{76} See supra note 24 and accompanying text.


\textsuperscript{78} Trade-Marks: Hearings on H.R. 13486 Before the House Comm. on Patents, 69th Cong., 2d Sess. 87 (1927).


\textsuperscript{80} See supra note 24 and accompanying text.
have attempted to establish consumer identification with the shapes and colors of their particular drug products and have fought vigorously to enforce their rights against "copycat" competitors.\footnotemark[81]

Smith, Kline & French Laboratories v. Clark & Clark\footnotemark[82] is one of the earliest cases involving generic drug substitution. Smith, Kline & French (SKF) sought an injunction against the manufacture and sale of Clark & Clark's patent-infringing amphetamine tablets under New Jersey unfair competition laws.\footnotemark[83] The court found that the infringing tablets closely resembled those produced by SKF in shape, color, and scoring and that the two tablets were distinguishable only upon close examination.\footnotemark[84] The court, however, refused to grant an injunction beyond the life of SKF's patent, recognizing that SKF would not have an exclusive right to manufacture the tablets after the patent expired\footnotemark[85] and finding that the various features of the amphetamine tablets were functional.\footnotemark[86] Instead, the court upheld the district court's findings of unfair trade practices. The evidence showed that Clark & Clark's salesman suggested that its tablets could be used to fill prescriptions for SKF's tablets with little risk of detection and that he emphasized the enhanced profit to be made by such conduct.\footnotemark[87] The court enjoined any further palming off\footnotemark[88] and required Clark & Clark's tablets to be stamped with a distinguishing mark such as "C&C."\footnotemark[89]
The evidentiary proof necessary to prevail in an intentional palming off action was considerably reduced by the United States Court of Appeals for the Second Circuit in Upjohn Co. v. Schwartz. Schwartz manufactured and sold seven drug preparations that were virtually identical in size, shape, and color to Upjohn's products. Upjohn brought an action for both trademark infringement and unfair competition. The district court considered many of the shapes, sizes, and colors of Upjohn's products to be nonfunctional, but it dismissed the trademark infringement count because Upjohn failed to demonstrate proof of secondary meaning. Because Upjohn was unable to produce any evidence that pharmacists were actually substituting Schwartz's products for those of Upjohn, the court also dismissed the unfair competition claim. Holding the lower court's requirement of actual substitution to be in error, the court of appeals reversed. It noted that the marketing strategy of the company consisted of the use of printed cards that listed Schwartz's products. Each drug listing was accompanied by a corresponding blank line, upon which Schwartz's salesmen would write in the name of Upjohn's equivalent product. The court considered these cards "suggestive." Although there was no evidence of any actual palming off, the court concluded that the use of the comparison cards, when considered with Schwartz's marketing of the prescription at one-half the price of Upjohn's products demonstrated Schwartz's intent to compete unfairly and to deceive the public.

90. 246 F.2d 254 (2d Cir. 1957).
91. Id. at 256.
93. Id. at 653.
94. Id. at 655.
96. Id. at 257-58. See also Smith Kline & French Labs. v. Broder, 125 U.S.P.Q. 299 (S.D. Tex. 1959), in which the defendant's advertising in circulars emphasized the similarities in appearance and dosage between SKF's trademarked capsules and tablets and those it produced. In some instances, samples of the imitative heart-shaped tablets were mailed without any identification or description as to composition or source other than the attached below-market price. The court found that such advertisements were suggestive and that pharmacists were thereby induced to substitute imitative products. 125 U.S.P.Q. at 301-02.
Schwartz was enjoined from "either directly or indirectly, representing or suggesting" that its products be substituted for those of Upjohn. In addition, the court ordered that Schwartz's containers bear a notice stating that the contents were not to be sold or dispensed as Upjohn's product.97

Although the liberal ruling in Upjohn should have increased the brand name manufacturers' ability to protect colored drug products, another Second Circuit case decided just two years later, Norwich Pharmacal Co. v. Sterling Drug, Inc.,98 made it more difficult to establish that a drug's color is to be considered nonfunctional and that it can acquire a secondary meaning. Norwich marketed a pink over-the-counter stomach remedy known as "Pepto-Bismol" and claimed that the marketing of Sterling's product constituted unfair competition.99 Like other courts, the Second Circuit refused to consider whether color could be monopolized in association with a specific product.100 The court found that the color of the stomach remedy was functional, not because it possessed any inherent therapeutic value, but because it was intended to create a "pleasing appearance" to the sufferer.101 The court also found no conclusive evidence to suggest that the color had acquired a secondary meaning. Norwich's public opinion survey, introduced at trial, indicated only the popularity of "Pepto-Bismol," not the existence of secondary meaning. The court concluded that the presence of over thirty other pink upset stomach remedies would prevent the public from associating the pink color exclusively with "Pepto-Bismol."102 In the absence of any evidence of palming off, actual deception, or appropriation of property rights,103 the court held that an injunction was not justified.

Twelve years passed before a court again addressed the issues involved in a drug color case.104 Marion Laboratories, Inc. v. Michigan Pharmacal

---

97. 246 F.2d at 262.
98. 271 F.2d 569 (2d Cir. 1959).
99. Id. at 570.
100. Id. at 572 (citing Campbell Soup Co. v. Armour & Co., 175 F.2d 795 (3d Cir.), cert. denied, 338 U.S. 847 (1949); Doeskin Prods., Inc. v. Levinson, 132 F. Supp. 180 (S.D.N.Y. 1955); and Radio Corp. of America v. Decca Records, Inc., 51 F. Supp. 493 (S.D.N.Y. 1943)).
101. 271 F.2d at 572. "Psychosomatic functionality" has been widely criticized. See, e.g., Cooper, supra note 9, at 13-14.
102. 271 F.2d at 572.
103. Id. at 571.
104. In addition to the decision in Norwich, at least two additional factors may account for the dearth of trademark prosecution during this time. First, the lack of legally substitutable generic drugs undoubtedly precluded the need to contest the marketing of "look-alike" capsules in most cases. The repeal of the antisubstitution drug laws in the late sixties and early seventies changed this. See supra note 1 and accompanying text.

Second, and perhaps more important, the Supreme Court held, in a pair of decisions, that
Corp. involved two claims of unfair competition under Michigan law. Marion packaged its trademark drug "Pavabid" in brown and clear capsules. Michigan Pharmacal marketed the generic form in an identically colored capsule. The court agreed that the color of Marion's capsules should be given protection as an element of the product's trade dress. It found the features to be nonfunctional and concluded that purchasers could be induced to buy the product because of the color's assumed indication of origin. Nonetheless, Marion was denied relief due to its inability to demonstrate that the features had acquired secondary meaning prior to Michigan Pharmacal's entrance into the marketplace.

The court also concluded that Marion had failed to document any in-state laws of unfair competition could not prevent the copying of an unpatented product. Sears, Roebuck & Co. v. Stiffel Co., 376 U.S. 225 (1964); Compco Corp. v. Day-Brite Lighting, Inc., 376 U.S. 234 (1964). For an in-depth analysis of the significance of these decisions, see Dannay, The Sears-Compco Doctrine Today: Trademarks and Unfair Competition, 67 TRADE-MARK REP. 132 (1977). See also Cooper, supra note 9, at 15-22; Hooke, supra note 8, at 240-44, 248-54. For over a decade, the practical effect of the Sears-Compco doctrine was to cast doubt upon the applicability of the Lanham Act when functional features were copied. The Ives court held that the Sears-Compco doctrine did not bar federal unfair competition claims under § 43(a). Ives, 601 F.2d at 642. Other circuits have reached a similar conclusion. See, e.g., SK&F, Co. v. Premo Pharmaceutical Labs., Inc., 625 F.2d 1055 (3d Cir. 1980); Truck Equip. Serv. Co. v. Fruehauf Corp., 536 F.2d 1210 (8th Cir. 1976).


106. The court found that the law of Michigan was consistent with the general law of unfair competition and noted that both state and federal courts freely borrow decisions from each other, as well as from the entire body of law on unfair competition. 338 F. Supp. at 767.

107. Id. at 763.

108. A similar argument was advanced in E. R. Squibb & Sons, Inc. v. Premo Pharmaceutical Labs., Inc., 195 U.S.P.Q. 545 (S.D.N.Y. 1977). Squibb contended that Premo's use of a gold foil wrapper on its generic nystatin was confusingly similar to Squibb's intravaginal tablets marketed as "Mycostatin." Although the court had jurisdiction of Squibb's § 43(a) Lanham Act claim, it granted a permanent injunction under New York unfair competition law because a likelihood of consumer confusion had been established. Id. at 550-51.

109. 338 F. Supp. at 766-68. The capsule color was found to be nonfunctional because the gelatin could take on any shade or degree of transparency irrespective of the color of the drug itself. Marion also introduced at trial a color wheel provided by Eli Lilly & Co. which illustrated that as many as 12,000 color combinations are available. Id. at 768. Counsel for Ives attempted to make a similar argument. On the motion for preliminary injunction, the district court refused to consider capsules and their corresponding colors as "trade dress," holding that because the capsules were ingested by the patient, they were themselves "goods." Ives, 455 F. Supp. at 948. The court of appeals took a more liberal view, remarking that it saw "no basis in principle for saying that simply because the colored capsule is ingested, the color cannot constitute 'trade dress.'" Ives, 601 F.2d at 644.

110. Although Marion was able to show that secondary meaning was established by 1970, Michigan had been doing business as early as 1967. 338 F. Supp. at 769.
stances of actual palming off. Like other jurisdictions, Michigan did not require proof of actual deception to establish a claim of unfair competition if deception would be the natural and probable consequence of a defendant's actions. Although Michigan Pharmacal's catalogs listed Marion's "Pavabid" as comparable to its own product, the catalogs specifically stated that the comparison was made for the pharmacist's "reference and reminder." Unlike other drug company advertisements, the catalogs made no reference to the product's color or price. In addition, there was no evidence that Michigan Pharmacal's salesmen suggested or encouraged any substitution. As a result, the court dismissed the suit, finding that Marion had failed to meet its burden of proof on either of its claims.

Unlike the result in *Marion Laboratories*, the burden of proof for a claim of intentional palming off was met in *Merrell-National Laboratories, Inc. v. Zenith Laboratories, Inc.* Merrell manufactured DEP, a prescription appetite suppressant sold under two trademarks. Zenith's product simulated the color, shape, and appearance of Merrell's tablets, and Zenith's literature described the two drugs as comparable. Merrell brought suit for unfair competition and false representation, accusing Zenith of placing an instrumentality of fraud into the hands of retail pharmacists. Merrell was able to document at least nine instances where pharmacists had passed off Zenith's product as DEP, as well as one instance in which the wrong product was shipped on a specific order for Merrell's tablets.

The court found this evidence to illustrate passing off in its "most blatant form." In determining whether or not the manufacturers could be held contributorily liable for the actions of the pharmacists, the court stated that "if the passing off is foreseeable or reasonably may be anticipated, liability rests with the manufacturer even in the absence of any intent to pass off by the manufacturer." Therefore, the court granted a preliminary injunction prohibiting the manufacture of DEP products in a form similar to Merrell's tablets and enjoined any attempt to pass Zenith's

---

111. *Id.*
112. *Id.* at 767 (citing Weisman v. Kuschewski, 243 Mich. 223, 219 N.W. 937 (1928)).
113. 338 F. Supp. at 770.
114. *Id.*
116. 194 U.S.P.Q. at 158.
117. *Id.*
118. *Id.*
119. *Id.* at 159.
120. *Id.* at 160 (citing Stix Prods., Inc. v. United Merchants & Mfrs., 295 F. Supp. 479, 496 (S.D.N.Y. 1968)).
III. The Ives Analysis

_Inwood Laboratories, Inc. v. Ives Laboratories, Inc._122 is the first drug color case to have been considered by the Supreme Court.123 Unlike earlier generic drug cases, the issue on appeal was based upon section 32 of the Lanham Act, rather than on section 43(a).124 Justice O'Connor began the _Ives_ opinion by framing the overriding issue, namely, the circumstances in which a generic drug manufacturer, who designedly duplicates the appearance of a competitor's equivalent product, can be held vicariously liable for the actions of pharmacists who improperly dispense the generic drug.125 After Justice O'Connor reviewed the proceedings below, she briefly analyzed the contributory infringement standard. She acknowledged, as did the lower courts, that under certain circumstances a manufacturer can be held responsible for trademark infringement at the distribution level, even if the manufacturer does not directly control others involved in the distribution process:

> [I]f a manufacturer or distributor intentionally induces another to infringe a trademark, or if it continues to supply its product to one whom it knows or has reason to know is engaging in trade-

---

122. 102 S. Ct. 2182 (1982).
123. Since the time Ives first filed suit in federal court, at least five other cases involving generic drugs have been reported. In each of these suits, the plaintiffs pressed claims under state unfair competition laws and § 43(a) of the Lanham Act. In each case, the plaintiff was granted injunctive relief after successfully demonstrating consumer confusion as to source, secondary meaning, nonfunctional features, or predatory practices. See SK&F, Co. v. Premo Pharmaceutical Labs., Inc., 625 F.2d 1055 (3d Cir. 1980); Boehringer Ingelheim G.m.b.H. v. Pharmadyne Labs., Inc., 211 U.S.P.Q. 1163 (D.N.J. 1981); Hoffman La Roche, Inc. v. Premo Pharmaceutical Labs., Inc., 210 U.S.P.Q. 374 (D.N.J. 1980); A.H. Robins Co. v. Medicine Chest Corp., 206 U.S.P.Q. 1015 (E.D. Mo. 1980); Pennwalt Corp. v. Zenith Labs., Inc., 472 F. Supp. 413 (E.D. Mich. 1979), appeal dismissed, 615 F.2d 1362 (6th Cir. 1980). While the _Ives_ courts were, of course, bound by the precedent that existed when the suit commenced, the Supreme Court, had it reached the merits of _Ives_, would have been free to take judicial notice of these recent developments. The SK&F decision is especially noteworthy since the identical color functionality claims present in _Ives_ were argued and rejected as invalid. SK&F, Co. v. Premo Pharmaceutical Labs., 625 F.2d at 1061-62.
124. While Ives' major claim was a § 43(a) violation, the § 32 violation was the only substantive issue fully discussed on appeal to both the Second Circuit and to the Supreme Court. 102 S. Ct. at 2193. This is not unexpected given the difficulty in documenting illegal substitution and the lack of prior law under § 32 in a drug color context. The court of appeals remarked that it was "surprising" that Ives was able to produce as many cases of illegal pharmacist activity as it did. _Ives_, 638 F.2d at 543. Much of the case law discussed throughout the procedural history of _Ives_ relies on § 43(a), pre-Lanham Act common law principles, and New York state unfair competition laws.
125. 102 S. Ct. at 2184.
mark infringement, the manufacturer or distributor is contribu-
torially [sic] responsible for any harm done as a result of the
deceit.\textsuperscript{126}

In a footnote, the Court acknowledged that language in the court of ap-
peals opinion suggesting that the generic manufacturers "could reasonably
anticipate" illegal substitution would in itself be an incorrect standard but
the Court interpreted that statement as mere support for the court of ap-
peals conclusion that the criteria had been met.\textsuperscript{127}

Having explicated the correct contributory infringement standard to be
applied, the Court devoted the remainder of the opinion to procedural er-
rors committed by the court of appeals. Justice O'Connor found that the
court of appeals improperly overturned the district court holding that the
generic drug companies did not intentionally induce substitution or supply
pharmacists likely to mislabel, without first ruling that such conclusions
were "clearly erroneous."\textsuperscript{128} Recognizing that a trial judge has a unique
opportunity to weigh evidence and to evaluate the credibility of wit-
tesses,\textsuperscript{129} the Court held that an appellate court must accept a trial court's
findings unless it possesses a "definite and firm conviction that a mistake
has been committed."\textsuperscript{130} According to Justice O'Connor, the court of ap-
peals erred when it rejected the district court's findings simply because it
would have given more weight to the evidence of mislabeling than the trial
court did.\textsuperscript{131}

The Court also held that the court of appeals erred in substituting its
own interpretation of the evidence for that of the trial court when it con-
cluded that the generic drug companies could have reasonably anticipated
misconduct. In addition, the court of appeals also erred when it ignored
findings suggesting that any confusion was due to a misunderstanding as to
the requirements of New York law, when it maintained that illegal substi-
tution was not the \textit{de minimus} in New York, and when it declared that
there were no legitimate reasons for marketing an imitative product.\textsuperscript{132}
The Court mentioned, without elaboration, that a finding of functionality,

\textsuperscript{126} \textit{Id.} at 2188 (citing William R. Warner & Co. v. Eli Lilly & Co., 265 U.S. 526 (1924)
and Coca-Cola Co. v. Snow Crest Beverages, Inc., 64 F. Supp. 980 (D. Mass. 1946), aff'd,
162 F.2d 280 (1st Cir.), \textit{cert. denied}, 332 U.S. 809 (1947)).

\textsuperscript{127} 102 S. Ct. at 2188 n.13.

\textsuperscript{128} \textit{Id.} at 2188 (citing \textit{FED. R. CIV. P.} 52(a) and Pullman-Standard v. Swint, 102 S. Ct.
1781 (1982)).

\textsuperscript{129} 102 S. Ct. at 2188-89 (citing Zenith Radio Corp. v. Hazeltine Research, Inc., 395
U.S. 100 (1969)).

\textsuperscript{130} 102 S. Ct. at 2189 (citing United States v. United States Gypsum Co., 333 U.S. 364,
395 (1948)).

\textsuperscript{131} 102 S. Ct. at 2189.

\textsuperscript{132} \textit{Id.} at 2189-90.
normally an issue in cases alleging a section 43(a) Lanham Act violation, may have some relevance in a section 32 action. Since the court of appeals never reached the section 43(a) or state unfair competition claims, the majority remanded the case for further review.

In a concurring opinion, Justice White, joined by Justice Marshall, challenged the majority for deciding the case on procedural grounds. Justice White noted that the issue of whether the court of appeals had misapplied the clearly erroneous standard was not included in the generic drug manufacturers' petitions for certiorari. The majority suggested no reason for ignoring their own procedural rules for certiorari, and Justice White himself expressed doubt as to whether he would have granted certiorari on the purely fact-bound questions which the majority addressed. Nonetheless, he concurred with the result because of his belief that the court of appeals "watered down to an impermissible extent" the standard for a section 32 contributory infringement violation.

Justice White contended that the court of appeals abandoned the test it set out on the earlier preliminary injunction motion. He felt that the court of appeals, in reviewing the case on the merits, was satisfied merely by the ability of the generic drug companies to "reasonably anticipate" that illegal substitution was likely, rather than a showing of intentional illegal substitution. He noted that both courts and commentators have suggested that the mere possibility that a dealer might pass off goods or that some illegal substitution could occur is insufficient to predicate liability upon the manufacturers of generic drugs. He then accused the majority of implicitly endorsing the standard employed by the court of appeals and thereby silently acquiescing to a significant change in the traditional test for contributory infringement. He agreed that the court of appeals erred when it set aside the district court's finding that the capsule colors were functional without first declaring that such a finding was clearly erroneous. Although the court of appeals found no persuasive evidence to justify the use of imitative colors, such a conclusion was inapposite to the finding that

133. Id. at 2190 n.20. No authority was supplied to support this proposition.
134. Id. at 2190-91. This was conceded at oral argument by the petitioners. See Excerpts from Oral Argument, The Ires Case, 72 Trade-Mark Rep. 78, 103 (1982).
136. 102 S. Ct. at 2191.
137. Id.
139. 102 S. Ct. at 2191.
they eased patient anxiety or aided in identification. Justice White went further than the majority in explicating the proper role of functionality in a section 32 claim. According to Justice White, a finding of functionality should act as a complete affirmative defense to a section 32 contributory infringement action based solely upon the reproduction of a product's functional features.

IV. THE CONTRIBUTORY INFRINGEMENT STANDARD IN Ives: Form Over Functionality?

Ives provides Supreme Court authority for maintaining a suit for contributory trademark infringement under section 32 of the Lanham Act. It also sets out the appropriate test for imposing vicarious liability on manufacturers who induce trademark infringement. It is clear that the second prong of the test predicates liability on a generic drug manufacturer who supplies pharmacists known or believed to be engaged in illegal trademark infringement. The majority and Justice White are also in agreement as to the wording of the first prong, that a manufacturer may be liable for intentionally inducing another to infringe a trademark. They disagree, however, over exactly what will constitute intentional inducement.

Disagreement over the interpretation of the first prong centers on the court of appeals' use of the words "reasonably anticipate" in making out a finding of suggestive behavior on the part of the generic drug manufacturers. While neither the majority opinion nor the concurrence expressly states that a showing of "suggestion by implication" is sufficient to constitute intentional inducement of another to infringe a trademark, both approve of the standard set out earlier in the review of the preliminary injunction motion and the Warner decision which embodies such language. Yet, Justice White believes that the court of appeals abandoned this standard in favor of a showing that the generic drug manufacturers "reasonably anticipated" substitution and mislabeling. As the majority correctly notes, the court of appeals prefaced its decision with a statement that it was applying the legal principles set forth in its earlier

140. Id. White also notes that color and shape can be "psychologically reassuring." Id. at 2192 n.3 (citing 3 R. Callman, The Law of Unfair Competition, Trademarks, and Monopolies, § 82.1(m) (3d ed. Supp. 1981)).
141. 102 S. Ct. at 2191. No authority or precedent was cited in support of this theory.
142. Id. at 2188, 2191.
143. Id.
144. Id. at 2188, 2191-92.
145. Id. at 2191.
146. Id. at 2188 n.13.
Contributory Infringement Standard

A careful reading of the opinion of the court of appeals reveals that it did not assess liability merely because some unspecified amount of illegal substitution might possibly have occurred. Rather, the court held that the generic manufacturers could reasonably anticipate that a substantial number of druggists would illegally substitute or mislabel "look alike" cyclandelate capsules. It was the manufacturers' use of capsules identical in size, shape, and color to "Cyclospasmol," together with catalogs comparing the appearances and prices of the two drugs, that amounted to "suggestion by implication." The court of appeals did not merely conclude that a manufacturer might reasonably anticipate substitution, but that the generic manufacturers of cyclandelate adopted the same color capsules in actual anticipation that they would "successfully capitalize upon public acceptance of 'Cyclospasmol.'" While the Supreme Court interpreted this language as merely representing support for the basic finding of intent, it did not express an opinion as to the amount of weight, if any, that such a finding should be given in determining if "suggestion by implication" has been demonstrated. In any event, the court of appeals did not develop this "watered down" standard on its own. Language in the Coca-Cola decision and the drug color cases since Marion Laboratories support this view.

Assuming that the court of appeals did err in failing to employ the "clearly erroneous" standard, the Supreme Court opinion is still disappointing. While the Supreme Court set out a contributory infringement "standard," it provided neither the type of behavior nor the amount of evidence sufficient to constitute "suggestion by implication." To avoid reviewing the record and applying the standard to the facts of the case, the Court conveniently hid behind the truism that a trial court is in the best position to evaluate evidence and the character of witnesses. Yet, numerous decisions have held that an appellate court is as competent as a lower court to evaluate documentary evidence. Most of the proof on the con-
tributory infringement issue in *Ives* was squarely before the court of appeals: the “look-alike” capsules, the allegedly “suggestive” catalogs, and the evidence of mislabeling and illegal substitution. The court of appeals relied primarily on these factors to infer intent and assess liability. Even if one concedes that the results of the surveys were inconclusive, liability has been predicated on less evidence of suggestive or actual intent in past decisions. One must agree with Justice White that the majority was unjustified in deciding the case on an issue that was not raised in the petitions for certiorari. Merely to provide a standard without measuring the facts of the case against it creates an opinion of dubious utility.

Because the court of appeals failed to apply the “clearly erroneous” standard, it is now bound by the lower court’s ruling that the colors of the capsules are functional. Yet, the court of appeals found that there were other successful generic manufacturers of cyclandelate who did not adopt the same color scheme as *Ives*. It is difficult to conclude that color can be a functional attribute of a drug capsule or tablet in the absence of a universal color identification standard. Unless all cyclandelate capsules are blue and red, a given consumer may not be accustomed to identifying cyclandelate by such colors. The generic prescription that the consumer has been taking could be orange and black or any other color combination. The practical ability of a capsule’s color to allow identification of the type of drug and to relieve patient anxiety is inherently weakened by the presence of competitive, nonimitative generics.

Indeed, the very role of functionality in a section 32 claim is overempha-
sized by both the majority opinion and Justice White's concurrence. Since Warner was decided, courts and commentators have indicated that where actions involving intentional passing off have been established, relief should be granted despite a finding of functionality. While this position has generally been advanced in only state unfair competition cases, Justice White noted that a purpose of the Lanham Act was to codify the common law of state unfair competition, and he found no indication that Congress had intended to depart from Warner and its contemporaries. Adoption of Justice White's far-reaching and unsupported claim that functionality should act as a complete affirmative defense to a section 32 claim would provide tacit approval to infringement in such a situation and would ignore the very purpose of the Act. Functionality should not act as a shield to protect those who intentionally pass off their goods for those of another.

Although the majority posits that a finding of functionality may be somewhat relevant in a section 32 claim, it fails to elaborate upon this point. A critical analysis of the drug color cases reveals that a finding of functionality has traditionally affected only the remedy provided by a court once intentional passing off or infringement has been demonstrated. Thus, the cases fall into three discernible categories: (1) producers of nonfunctionally shaped or colored drugs who are enjoined from any further imitative copying; (2) producers of drugs with functional features who are required to employ precautionary labeling or packaging; and (3) producers of drugs possessing a psychosomatic effect who are en-
joined only after a court balances the hardships to the parties and the public policy issues involved.\textsuperscript{162}

The court of appeals in \textit{Ives} emphasized that physicians and pharmacists have the option of informing their patients that the different colored generics are identical in utility to the brand name variety, thus allowing the patient to decide whether to pay the typically higher price for a familiar capsule color.\textsuperscript{163} In the event that a patient might have an adverse reaction to a different color capsule due to a placebo effect, the doctor may then specifically order that the prescription be dispensed with only the trademarked drug.

Whether or not one agrees with the \textit{Ives} decision, one must still question why, in a case raising significant and competing issues of public policy in the prescription drug industry, the Court refused to address such issues.

\textsuperscript{162} Arguing in both the court of appeals and in the Supreme Court, the Justice Department, in an amicus curiae brief, sided with the generic drug manufacturers in favor of "fair and open competition in the prescription drug industry." \textit{See PAT. TRADEMARK & COPYRIGHT J. (BNA) No. 557, at A-7 (Dec. 3, 1981).} The Government argued that a § 32 analysis "requires a balancing of the procompetitive effect of trademarks in identifying products for consumers and the anticompetitive effect of raising barriers to market entry by forbidding imitation." \textit{Id.}

Perhaps the best response to this admittedly valid concern is found in SK&F, Co. v. Premo Pharmaceutical Labs., Inc., 625 F.2d 1055 (3d Cir. 1980):

\begin{quote}
[C]ertain kinds of business activity, while promoting competition in the short run, are in the long run apt to be destructive of competition. . . . Permitting a business climate in which substitutions of products over which the first manufacturer has no quality control in the long run can only discourage the effort to compete on the basis of reputation for quality. But even if the Lanham Act and the New Jersey law of unfair competition were not in the long range interests of competition, preventing deception of the public is itself in the public interest. . . . Neither offends the federal antitrust laws, for those laws have never been held to require toleration of acts or practices presently or potentially deceptive. \textit{Id.} at 1067.
\end{quote}

Since the Supreme Court decided \textit{Ives}, two district courts have concluded that the public interest would be best served by enjoining the sale of generic "look-alike" drugs. A preliminary injunction was imposed in each case once the district court found section 43(a) of the Lanham Act to have been violated. In Ciba-Geigy Corp. v. Bolar Pharmaceutical Co., Inc., 547 F. Supp. 1095 (D.N.J. 1982), the court declared that "the public will be harmed by the existence of defendant's product because it permits, if not encourages, illegal substitution." \textit{Id.} at 1117. In American Home Prods. v. Chelsea Labs., (D.N.J. 1982), the court emphasized that the public interest in preventing consumer deception was especially strong when prescription drugs are involved. \textit{See 24 PAT. TRADEMARK & COPYRIGHT J. (BNA), 415 (Aug. 26, 1982).}

\textsuperscript{163} \textit{Ives,} 638 F.2d at 544-45. A similar conclusion was reached in Ciba-Geigy Corp. v. Bolar Pharmaceutical Co., Inc., 547 F. Supp. 1095 (D.N.J. 1982), where the court concluded that the defendant's conduct endangered the public interest by "jeopardizing the consumer's admitted right to sufficient information so that he can give informed consent to such substitution." \textit{Id.} at 1117. \textit{See also Cooper, supra} note 9, at 33 (discussing the informed consent doctrine).
As Justice White suggested, the procedural issue dominating the majority opinion was not the likely basis for originally granting certiorari. One can only surmise that the Court, upon closer examination, realized that *Ives* should not be the test case for granting color capsule protection under the Lanham Act. In the past, all attempts to protect drug colors have been advanced under section 43(a) of the Act, which encompasses a broader claim for relief than those allowed under section 32. Thus, the anomaly of a claim for relief against the imitation of capsule colors under section 32 would be a major reason for any court to avoid deciding questions that are sufficiently controversial in their own right. In doing so, the Court leaves open the possibility that it may again face the color capsule problem and resolve it under more favorable circumstances.

V. Conclusion

*Inwood Laboratories, Inc. v. Ives Laboratories, Inc.* provides Supreme Court acknowledgement that liability may be imposed on a manufacturer who intentionally induces illegal substitution or who continues to supply goods to one it knows or has reason to know is committing trademark infringement under section 32 of the Lanham Act. Generic drug companies are not the only ones who will be affected by the Court's ruling. This decision may potentially have an impact upon all manufacturers of commercial goods and represents yet another judicial attempt to hold industry accountable for its direct or indirect actions.

Because the majority never applied the standard it promulgated to the facts of the case, the metes and bounds of the type of action that constitutes "suggestion by implication" in a generic drug context, remain shrouded in speculation. Until color capsule imitation and comparison catalogs are finally declared to be either legitimate or impermissibly suggestive, it is

---

164. See supra note 8.

165. Although the Court may not have realized it, the procedural ruling in *Ives* foreclosed further action by the court of appeals in its attempt to review the case. While § 43(a) admittedly encompasses a broad claim for relief, functionality is still a defense to the action. 102 S. Ct. at 2193 n.4 (citing International Order of Job's Daughters v. Lindeburg Co., 633 F.2d 912 (9th Cir. 1980), cert. denied, 452 U.S. 941 (1981)). On remand, the Second Circuit, bound by the district court's holding that cyclandelate capsule colors are functional, was unable to declare that a finding of functionality under § 43(a) was "clearly erroneous" if it was not found to be clearly erroneous under § 32(1). Accordingly, it affirmed the district court's ruling and dismissed both the § 43(a) and the state unfair competition claims. See Epilog, *The Ives Case*, 72 TRADE-MARK REP. 117 (1982).

166. At least one post-*Ives* court has interpreted the Supreme Court's purported rejection of the "reasonable anticipation" standard to be limited to § 32 claims, concluding that the *Ives* opinion had no affect on a "reasonable anticipation" standard under § 43(a). See Ciba-Geigy Corp. v. Bolar Pharmaceutical Co., Inc., 547 F. Supp. 1095, 1115-16.
unlikely that the generic drug companies will change their current marketing strategies. With the expiration of the patents on Valium over the next three years, it is foreseeable that imitation by generic drug manufacturers will only continue, increasing the likelihood of illegal substitution by unscrupulous pharmacists. Ultimately, it is the consumer's pocket, protected from the evils of a "color monopoly," that will be most injured by the Supreme Court's decision in *Inwood Laboratories, Inc. v. Ives Laboratories, Inc.*

*Darrel C. Karl*

---

167. The generic drug manufacturers may not have to change their marketing strategies. On July 22, 1982, Rep. Barney Frank (D-Mass.) introduced legislation that would amend § 43(a) of the Lanham Act to exempt generic "look-alike" drugs under certain circumstances. The bill, H.R. 6840, 97th Cong., 2d Sess. (1982), would not consider the use of bioequivalent FDA-approved drugs to constitute a false designation of origin or a false description or representation. In addition, the imprint of the manufacturer or distributor would be required when technologically feasible. *See* 24 PAT. TRADEMARK & COPYRIGHT J. (BNA), 412 (Aug. 26, 1982).