

INWOOD LABORATORIES, INC., ET AL. *v.* IVES  
LABORATORIES, INC.CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR  
THE SECOND CIRCUIT

No. 80-2182. Argued February 22, 1982—Decided June 1, 1982\*

Respondent manufactured and marketed the patented prescription drug cyclandelate to wholesalers, retail pharmacists, and hospitals in colored capsules under the registered trademark CYCLOSPASMOL. After respondent's patent expired, several generic drug manufacturers, including petitioner manufacturers, began marketing the drug, intentionally copying the appearance of the CYCLOSPASMOL capsules. Respondent then brought an action against petitioner manufacturers and wholesalers in Federal District Court under, *inter alia*, § 32 of the Trademark Act of 1946, alleging that some pharmacists had dispensed generic drugs mislabeled as CYCLOSPASMOL and that petitioners' use of look-alike capsules and catalog entries comparing prices and revealing the colors of generic capsules contributed to the pharmacists' mislabeling. Respondent sought injunctive relief and damages. The District Court entered judgment for petitioners, finding that although the pharmacists had violated § 32, respondent had not made the necessary factual showing that petitioners had intentionally induced the pharmacists to mislabel generic drugs or continued to supply cyclandelate to pharmacists who the petitioners knew or should have known were mislabeling generic drugs. The Court of Appeals reversed, rejecting the District Court's findings and holding that the District Court failed to give sufficient weight to the evidence respondent offered to show a pattern of illegal substitution and mislabeling. After completing its own review of the evidence, the Court of Appeals further held that the evidence was "clearly sufficient to establish a § 32 violation."

*Held:* The Court of Appeals erred in setting aside the District Court's findings of fact. Pp. 853-858.

(a) In reviewing such findings, the Court of Appeals was bound by the "clearly erroneous" standard of Federal Rule of Civil Procedure 52(a). P. 855.

(b) By rejecting the findings simply because it would have given more weight to evidence of mislabeling than did the trial court, the Court of

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\*Together with No. 81-11, *Darby Drug Co., Inc., et al. v. Ives Laboratories, Inc.*, also on certiorari to the same court.

Appeals clearly erred. Determining the weight and credibility of the evidence is the special province of the trier of fact. Because the District Court's findings concerning the significance of the instances of mislabeling were not clearly erroneous, they should not have been disturbed. Pp. 855-856.

(c) Moreover, each of the conclusions that the Court of Appeals made in holding that the evidence established a § 32 violation was contrary to the District Court's findings. An appellate court cannot substitute its interpretation of the evidence for that of the trial court simply because the reviewing court "might give the facts another construction, resolve the ambiguities differently, and find a more sinister cast to actions which the District Court apparently deemed innocent." *United States v. Real Estate Boards*, 339 U. S. 485, 495. Pp. 856-858.

638 F. 2d 538, reversed and remanded.

O'CONNOR, J., delivered the opinion of the Court, in which BURGER, C. J., and BRENNAN, BLACKMUN, POWELL, and STEVENS, JJ., joined. WHITE, J., filed an opinion concurring in the result, in which MARSHALL, J., joined, *post*, p. 859. REHNQUIST, J., filed an opinion concurring in the result, *post*, p. 864.

*Milton A. Bass* argued the cause for petitioners. With him on the briefs for petitioner Inwood Laboratories, Inc., in No. 80-2182 were *Jacob Laufer* and *Steven R. Trost*. *Peter T. Cobrin* filed briefs for petitioner Premo Pharmaceutical Laboratories, Inc., in No. 80-2182. *Robert V. Marrow* filed briefs for petitioners in No. 81-11.

*Marie V. Driscoll* argued the cause for respondent. With her on the brief were *Gerald W. Griffin*, *Egon E. Berg*, and *Steven J. Baron*.

*Jerrold J. Ganzfried* argued the cause for the United States as *amicus curiae* urging reversal. With him on the brief were *Solicitor General Lee*, *Assistant Attorney General Baxter*, *Deputy Solicitor General Shapiro*, *Barry Grossman*, and *Robert J. Wiggers*.†

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†Briefs of *amici curiae* urging reversal were filed by *Robert Abrams*, Attorney General, *Shirley Adelson Siegel*, Solicitor General, and *Peter G. Cray*, Assistant Attorney General, for the State of New York; by *Alfred*

JUSTICE O'CONNOR delivered the opinion of the Court.

This action requires us to consider the circumstances under which a manufacturer of a generic drug, designed to duplicate the appearance of a similar drug marketed by a competitor under a registered trademark, can be held vicariously liable for infringement of that trademark by pharmacists who dispense the generic drug.

## I

In 1955, respondent Ives Laboratories, Inc. (Ives), received a patent on the drug cyclandelate, a vasodilator used in long-term therapy for peripheral and cerebral vascular diseases. Until its patent expired in 1972, Ives retained the exclusive right to make and sell the drug, which it did under the registered trademark CYCLOSPASMOL.<sup>1</sup> Ives marketed the drug, a white powder, to wholesalers, retail pharmacists, and hospitals in colored gelatin capsules. Ives arbitrarily se-

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*Miller* for the American Association of Retired Persons et al.; and by *Milton A. Bass, Jacob Laufer, I. Scott Bass, and Steven R. Trost* for the National Association of Pharmaceutical Manufacturers, Inc.

Briefs of *amici curiae* urging affirmance were filed by *Gerald W. Gorman* for the American Academy of Family Physicians; by *Michael R. Sonnenreich, Michael X. Morrell, and William H. Kenety* for Medicine in the Public Interest; and by *Joel E. Hoffman, Jerry D. Anker, Daniel L. Koffsky, and Louis G. Santucci* for the Pharmaceutical Manufacturers Association.

*Alfred B. Engelberg* filed a brief for the Generic Pharmaceutical Industry Association as *amicus curiae*.

<sup>1</sup>Under the Trademark Act of 1946 (Lanham Act), 60 Stat. 427, as amended, 15 U. S. C. § 1051 *et seq.*, the term "trade-mark" includes "any word, name, symbol, or device or any combination thereof adopted and used by a manufacturer or merchant to identify his goods and distinguish them from those manufactured or sold by others." 15 U. S. C. § 1127. A "registered mark" is one registered in the United States Patent and Trademark Office under the terms of the Lanham Act "or under the Act of March 3, 1881, or the Act of February 20, 1905, or the Act of March 19, 1920." *Ibid.*

lected a blue capsule, imprinted with "Ives 4124," for its 200 mg dosage and a combination blue-red capsule, imprinted with "Ives 4148," for its 400 mg dosage.

After Ives' patent expired, several generic drug manufacturers, including petitioners Premo Pharmaceutical Laboratories, Inc., Inwood Laboratories, Inc., and MD Pharmaceutical Co., Inc. (collectively the generic manufacturers), began marketing cyclandelate.<sup>2</sup> They intentionally copied the appearance of the CYCLOSPASMOL capsules, selling cyclandelate in 200 mg and 400 mg capsules in colors identical to those selected by Ives.<sup>3</sup>

The marketing methods used by Ives reflect normal industry practice. Because cyclandelate can be obtained only by prescription, Ives does not direct its advertising to the ultimate consumer. Instead, Ives' representatives pay personal visits to physicians, to whom they distribute product literature and "starter samples." Ives initially directed these efforts toward convincing physicians that CYCLOSPASMOL is superior to other vasodilators. Now that its patent has expired and generic manufacturers have entered the market, Ives concentrates on convincing physicians to indicate on prescriptions that a generic drug cannot be substituted for CYCLOSPASMOL.<sup>4</sup>

The generic manufacturers also follow a normal industry practice by promoting their products primarily by distribu-

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<sup>2</sup> The generic manufacturers purchase cyclandelate and empty capsules and assemble the product for sale to wholesalers and hospitals. The petitioner wholesalers, Darby Drug Co., Inc., Rugby Laboratories, Inc., and Sherry Pharmaceutical Co., Inc., in turn, sell to other wholesalers, physicians, and pharmacies.

<sup>3</sup> Initially, the generic manufacturers did not place any identifying mark on their capsules. After Ives initiated this action, Premo imprinted "Premo" on its capsules and Inwood imprinted "Inwood 258."

<sup>4</sup> Since the early 1970's, most States have enacted laws allowing pharmacists to substitute generic drugs for brand name drugs under certain conditions. See generally Note, Consumer Protection and Prescription

tion of catalogs to wholesalers, hospitals, and retail pharmacies, rather than by contacting physicians directly. The catalogs truthfully describe generic cyclandelate as "equivalent" or "comparable" to CYCLOSPASMOL.<sup>5</sup> In addition, some of the catalogs include price comparisons of the generic drug and CYCLOSPASMOL and some refer to the color of the generic capsules. The generic products reach wholesalers, hospitals, and pharmacists in bulk containers which correctly indicate the manufacturer of the product contained therein.

A pharmacist, regardless of whether he is dispensing CYCLOSPASMOL or a generic drug, removes the capsules from the container in which he receives them and dispenses them to the consumer in the pharmacist's own bottle with his

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Drugs: The Generic Drug Substitution Laws, 67 Ky. L. J. 384 (1978-1979). The New York statutes involved in this action are typical of these generic substitution laws. New York law requires that prescription forms contain two lines, one of which a prescribing physician must sign. N. Y. Educ. Law § 6810 (McKinney Supp. 1981-1982). If the physician signs over the words "substitution permissible," substitution is mandatory if a substitute generic drug is on an approved list, N. Y. Educ. Law § 6816-a (McKinney Supp. 1981-1982); N. Y. Pub. Health Law § 206.1(o) (McKinney Supp. 1981-1982), and permissible if another generic drug is available. Unless the physician directs otherwise, the pharmacist must indicate the name of the generic manufacturer and the strength of the drug dispensed on the label. N. Y. Educ. Law § 6816-a(1)(c). In addition, the prescription form must specifically state that, unless the physician signs above the line "dispense as written," the prescription will be filled generically. § 6810(6)(a).

If a pharmacist mislabels a drug or improperly substitutes, he is guilty of a misdemeanor and subject to a fine, §§ 6811, 6815, 6816, and to revocation of his license. § 6808.

<sup>5</sup> Ives conceded that CYCLOSPASMOL and the petitioners' generic equivalents are bioequivalent and have the same bioavailability. See 455 F. Supp. 939, 942 (EDNY 1978), and 488 F. Supp. 394, 396 (EDNY 1980). Bioavailability is an absolute term which measures both the rate and the amount of a drug which reaches the general circulation from a defined dosage. Drugs are "bioequivalent" if, when administered in equal amounts to the same individual, they reach general circulation at the same relative rate and to the same relative extent. Remington's Pharmaceutical Sciences 1368 (15th ed. 1975).

own label attached. Hence, the final consumer sees no identifying marks other than those on the capsules themselves.

## II

## A

Ives instituted this action in the United States District Court for the Eastern District of New York under §§ 32 and 43(a) of the Trademark Act of 1946 (Lanham Act), 60 Stat. 427, as amended, 15 U. S. C. § 1051 *et seq.*, and under New York's unfair competition law, N. Y. Gen. Bus. Law § 368-d (McKinney 1968).<sup>6</sup>

Ives' claim under § 32, 60 Stat. 437, as amended, 15 U. S. C. § 1114,<sup>7</sup> derived from its allegation that some pharmacists had dispensed generic drugs mislabeled as CYCLOSPASMOL.<sup>8</sup>

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<sup>6</sup>The state law claim was not discussed in the decision under review, and no further reference will be made to it here.

<sup>7</sup>Section 32 of the Lanham Act, 60 Stat. 437, as amended, 15 U. S. C. § 1114, provides in part:

"(1) 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, counterfeit, copy, or colorable imitation to labels, signs, prints, packages, wrappers, receptacles or advertisements intended to be used in commerce upon or in connection with the sale, offering for sale, distribution, or advertising 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. Under subsection (b) of this section, the registrant shall not be entitled to recover profits or damages unless the acts have been committed with knowledge that such imitation is intended to be used to cause confusion, or to cause mistake or to deceive."

<sup>8</sup>The claim involved two types of infringements. The first was "direct" infringement, in which druggists allegedly filled CYCLOSPASMOL pre-

Ives contended that the generic manufacturers' use of look-alike capsules and of catalog entries comparing prices and revealing the colors of the generic capsules induced pharmacists illegally to substitute a generic drug for CYCLOSPASMOL and to mislabel the substitute drug CYCLOSPASMOL. Although Ives did not allege that the petitioners themselves applied the Ives trademark to the drug products they produced and distributed, it did allege that the petitioners contributed to the infringing activities of pharmacists who mislabeled generic cyclandelate.

Ives' claim under § 43(a), 60 Stat. 441, 15 U. S. C. § 1125(a),<sup>9</sup> alleged that the petitioners falsely designated the origin of their products by copying the capsule colors used by Ives and by promoting the generic products as equivalent to CYCLOSPASMOL. In support of its claim, Ives argued that the colors of its capsules were not functional<sup>10</sup> and that

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scriptions marked "dispense as written" with a generic drug and mislabeled the product as CYCLOSPASMOL. The second, "intermediate" infringement, occurred when pharmacists, although authorized by the prescriptions to substitute, allegedly mislabeled a generic drug as CYCLOSPASMOL. The one retail pharmacy originally named as a defendant consented to entry of a decree enjoining it from repeating such actions. 455 F. Supp., at 942.

<sup>9</sup>Section 43(a) of the Lanham Act, 60 Stat. 441, 15 U. S. C. § 1125(a), provides:

"(a) 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 in 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."

<sup>10</sup>In general terms, a product feature is functional if it is essential to the use or purpose of the article or if it affects the cost or quality of the article.

they had developed a secondary meaning for the consumers.<sup>11</sup>

Contending that pharmacists would continue to mislabel generic drugs as CYCLOSPASMOL so long as imitative products were available, Ives asked that the court enjoin the petitioners from marketing cyclandelate capsules in the same colors and form as Ives uses for CYCLOSPASMOL. In addition, Ives sought damages pursuant to § 35 of the Lanham Act, 60 Stat. 439, as amended, 15 U. S. C. § 1117.

### B

The District Court denied Ives' request for an order preliminarily enjoining the petitioners from selling generic drugs identical in appearance to those produced by Ives. 455 F. Supp. 939 (1978). Referring to the claim based upon § 32, the District Court stated that, while the "knowing and deliberate instigation" by the petitioners of mislabeling by pharmacists would justify holding the petitioners as well as the pharmacists liable for trademark infringement, Ives had made no showing sufficiently to justify preliminary relief. *Id.*, at 945. Ives had not established that the petitioners conspired with the pharmacists or suggested that they disregard physicians' prescriptions.

The Court of Appeals for the Second Circuit affirmed. 601 F. 2d 631 (1979). To assist the District Court in the upcoming trial on the merits, the appellate court defined the elements of a claim based upon § 32 in some detail. Relying primarily upon *Coca-Cola Co. v. Snow Crest Beverages, Inc.*, 64 F. Supp. 980 (Mass. 1946), *aff'd*, 162 F. 2d 280 (CA1), *cert. denied*, 332 U. S. 809 (1947), the court stated that the petitioners would be liable under § 32 either if they suggested, even by implication, that retailers fill bottles with generic cyclandelate and label the bottle with Ives' trademark or if

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See *Sears, Roebuck & Co. v. Stiffel Co.*, 376 U. S. 225, 232 (1964); *Kellogg Co. v. National Biscuit Co.*, 305 U. S. 111, 122 (1938).

<sup>11</sup>To establish secondary meaning, a manufacturer must show that, in the minds of the public, the primary significance of a product feature or term is to identify the source of the product rather than the product itself. See *Kellogg Co. v. National Biscuit Co.*, *supra*, at 118.

the petitioners continued to sell cyclandelate to retailers whom they knew or had reason to know were engaging in infringing practices. 601 F. 2d, at 636.

### C

After a bench trial on remand, the District Court entered judgment for the petitioners. 488 F. Supp. 394 (1980). Applying the test approved by the Court of Appeals to the claim based upon § 32, the District Court found that the petitioners had not suggested, even by implication, that pharmacists should dispense generic drugs incorrectly identified as CYCLOSPASMOL.<sup>12</sup>

In reaching that conclusion, the court first looked for direct evidence that the petitioners intentionally induced trademark infringement. Since the petitioners' representatives do not make personal visits to physicians and pharmacists, the petitioners were not in a position directly to suggest improper drug substitutions. Cf. *William R. Warner & Co. v. Eli Lilly & Co.*, 265 U. S. 526, 530-531 (1924); *Smith, Kline & French Laboratories v. Clark & Clark*, 157 F. 2d 725, 731 (CA3), cert. denied, 329 U. S. 796 (1946). Therefore, the court concluded, improper suggestions, if any, must have come from catalogs and promotional materials. The court determined, however, that those materials could not "fairly be read" to suggest trademark infringement. 488 F. Supp., at 397.

The trial court next considered evidence of actual instances of mislabeling by pharmacists, since frequent improper substitutions of a generic drug for CYCLOSPASMOL could provide circumstantial evidence that the petitioners, merely by making available imitative drugs in conjunction with comparative price advertising, implicitly had suggested that pharmacists substitute improperly. After reviewing the evi-

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<sup>12</sup>The District Court also found that the petitioners did not continue to provide drugs to retailers whom they knew or should have known were engaging in trademark infringement. 488 F. Supp., at 397. The Court of Appeals did not discuss that finding, and we do not address it.

dence of incidents of mislabeling, the District Court concluded that such incidents occurred too infrequently to justify the inference that the petitioners' catalogs and use of imitative colors had "impliedly invited" druggists to mislabel. *Ibid.* Moreover, to the extent mislabeling had occurred, the court found it resulted from pharmacists' misunderstanding of the requirements of the New York Drug Substitution Law, rather than from deliberate attempts to pass off generic cyclandelate as CYCLOSPASMOL. *Ibid.*

The District Court also found that Ives failed to establish its claim based upon § 43(a). In reaching its conclusion, the court found that the blue and blue-red colors were functional to patients as well as to doctors and hospitals: many elderly patients associate color with therapeutic effect; some patients commingle medications in a container and rely on color to differentiate one from another; colors are of some, if limited, help in identifying drugs in emergency situations; and use of the same color for brand name drugs and their generic equivalents helps avoid confusion on the part of those responsible for dispensing drugs. *Id.*, at 398-399. In addition, because Ives had failed to show that the colors indicated the drug's origin, the court found that the colors had not acquired a secondary meaning. *Id.*, at 399.

Without expressly stating that the District Court's findings were clearly erroneous, and for reasons which we discuss below, the Court of Appeals concluded that the petitioners violated § 32. 638 F. 2d 538 (1981). The Court of Appeals did not reach Ives' other claims. We granted certiorari, 454 U. S. 891 (1981), and now reverse the judgment of the Court of Appeals.

### III

#### A

As the lower courts correctly discerned, liability for trademark infringement can extend beyond those who actually mislabel goods with the mark of another. Even if a manufacturer does not directly control others in the chain of distribu-

tion, it can be held responsible for their infringing activities under certain circumstances. Thus, if 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 trademark infringement, the manufacturer or distributor is contributorily responsible for any harm done as a result of the deceit.<sup>13</sup> See *William R. Warner & Co. v. Eli Lilly & Co.*, *supra*; *Coca-Cola Co. v. Snow Crest Beverages, Inc.*, *supra*.

It is undisputed that those pharmacists who mislabeled generic drugs with Ives' registered trademark violated §32.<sup>14</sup>

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<sup>13</sup> JUSTICE WHITE, in his opinion concurring in the result, voices his concern that we may have "silently acquiesce[d] in a significant change in the test for contributory infringement." *Post*, at 861. His concern derives from his perception that the Court of Appeals abandoned the standard enunciated by Judge Friendly in its first opinion, a standard which both we and JUSTICE WHITE approve, *post*, at 859-860. The Court of Appeals, however, expressly premised its second opinion on "the governing legal principles . . . set forth in Judge Friendly's opinion upon the earlier appeal, 601 F. 2d 631 (2d Cir. 1979)," and explicitly claimed to have rendered its second decision by "[a]pplying those principles . . ." 638 F. 2d 538, 542 (1981).

JUSTICE WHITE's concern is based on a comment by the Court of Appeals that the generic manufacturers "could reasonably anticipate" illegal substitution of their drugs. *Id.*, at 543. If the Court of Appeals had relied upon that statement to define the controlling legal standard, the court indeed would have applied a "watered down" and incorrect standard. As we read the Court of Appeals' opinion, however, that statement was intended merely to buttress the court's conclusion that the legal test for contributory infringement, as earlier defined, had been met. See *infra*, at 856-857.

<sup>14</sup> Such blatant trademark infringement inhibits competition and subverts both goals of the Lanham Act. By applying a trademark to goods produced by one other than the trademark's owner, the infringer deprives the owner of the goodwill which he spent energy, time, and money to obtain. See S. Rep. No. 1333, 79th Cong., 2d Sess., 3 (1946). At the same time, the infringer deprives consumers of their ability to distinguish among the goods of competing manufacturers. See H. R. Rep. No. 944, 76th Cong., 1st Sess., 3 (1939).

However, whether these petitioners were liable for the pharmacists' infringing acts depended upon whether, in fact, the petitioners intentionally induced the pharmacists to mislabel generic drugs or, in fact, continued to supply cyclandelate to pharmacists whom the petitioners knew were mislabeling generic drugs. The District Court concluded that Ives made neither of those factual showings.

## B

In reviewing the factual findings of the District Court, the Court of Appeals was bound by the "clearly erroneous" standard of Rule 52(a), Federal Rules of Civil Procedure. *Pullman-Standard v. Swint*, ante, p. 273. That Rule recognizes and rests upon the unique opportunity afforded the trial court judge to evaluate the credibility of witnesses and to weigh the evidence. *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U. S. 100, 123 (1969). Because of the deference due the trial judge, unless an appellate court is left with the "definite and firm conviction that a mistake has been committed," *United States v. United States Gypsum Co.*, 333 U. S. 364, 395 (1948), it must accept the trial court's findings.<sup>15</sup>

## IV

In reversing the District Court's judgment, the Court of Appeals initially held that the trial court failed to give sufficient weight to the evidence Ives offered to show a "pattern of illegal substitution and mislabeling in New York. . . ."<sup>16</sup>

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<sup>15</sup> Of course, if the trial court bases its findings upon a mistaken impression of applicable legal principles, the reviewing court is not bound by the clearly erroneous standard. *United States v. Singer Manufacturing Co.*, 374 U. S. 174, 194, n. 9 (1963). However, in this instance the District Court applied correct legal principles when it adopted the precise test developed by the Court of Appeals. Compare 601 F. 2d 631, 636 (1979), with 488 F. Supp., at 397.

<sup>16</sup> As the opinions from the lower courts reveal, more than one inference can be drawn from the evidence presented. Prior to trial, test shoppers

638 F. 2d, at 543. By rejecting the District Court's findings simply because it would have given more weight to evidence of mislabeling than did the trial court, the Court of Appeals clearly erred. Determining the weight and credibility of the evidence is the special province of the trier of fact. Because the trial court's findings concerning the significance of the instances of mislabeling were not clearly erroneous, they should not have been disturbed.

Next, after completing its own review of the evidence, the Court of Appeals concluded that the evidence was "clearly sufficient to establish a § 32 violation." *Ibid.* In reaching its conclusion, the Court of Appeals was influenced by several factors. First, it thought the petitioners reasonably could have anticipated misconduct by a substantial number of the pharmacists who were provided imitative, lower priced products which, if substituted for the higher priced brand name without passing on savings to consumers, could provide an economic advantage to the pharmacists. *Ibid.*<sup>17</sup> Second, it

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hired by Ives gave CYCLOSPASMOL prescriptions on which the "substitution permissible" line was signed to 83 New York pharmacists. Forty-eight of the pharmacists dispensed CYCLOSPASMOL; the rest dispensed a generic drug. Ten of the thirty-five pharmacists who dispensed a generic drug included the word CYCLOSPASMOL on the label, although 5 of those 10 also included some form of the word "generic." Nine of the ten told the consumer of the substitution. Only 1 of the 10 charged the brand name price for the generic drug. 488 F. Supp., at 397.

The District Court concluded that that evidence did not justify the inference that the petitioners' catalogs invite pharmacists to mislabel. *Ibid.* The Court of Appeals, emphasizing that 10 of the 35 druggists who dispensed a generic drug mislabeled it as CYCLOSPASMOL, found a pattern of substitution and mislabeling. 638 F. 2d, at 543. The dissenting judge on the appellate panel, emphasizing that only 1 of 83 pharmacists attempted an illegal substitution and reaped a profit made possible by the color imitation, concluded the facts supported the District Court's finding that mislabeling resulted from confusion about the substitution laws rather than from profit considerations. *Id.*, at 546.

On the basis of the record before us, the inferences drawn by the District Court are not, as a matter of law, unreasonable.

<sup>17</sup> The Court of Appeals cited no evidence to support its conclusion, which apparently rests upon the assumption that a pharmacist who has been pro-

disagreed with the trial court's finding that the mislabeling which did occur reflected confusion about state law requirements. *Id.*, at 544.<sup>18</sup> Third, it concluded that illegal substitution and mislabeling in New York are neither *de minimis* nor inadvertent. *Ibid.*<sup>19</sup> Finally, the Court of Appeals indicated it was further influenced by the fact that the petitioners did not offer "any persuasive evidence of a legitimate reason unrelated to CYCLOSPASMOL" for producing an imitative product. *Ibid.*<sup>20</sup>

Each of those conclusions is contrary to the findings of the District Court. An appellate court cannot substitute its interpretation of the evidence for that of the trial court simply because the reviewing court "might give the facts another construction, resolve the ambiguities differently, and find a

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vided an imitative generic drug will be unable to resist the temptation to profit from illegal activity. We find no support in the record for such a far-reaching conclusion. Moreover, the assumption is inconsistent with the District Court's finding that only a "few instances," rather than a substantial number, of mislabelings occurred. 488 F. Supp., at 397.

<sup>18</sup> The Court of Appeals characterized the District Court's finding as resting on "a short and casual exchange with a witness . . ." 638 F. 2d, at 544. The District Court, however, stated that its conclusion that pharmacists did not understand the drug substitution law rested upon the fact that, in numerous instances, a pharmacist told a consumer that state law prohibited filling prescriptions with generic products, even though the consumer had presented a prescription allowing generic substitution. 488 F. Supp., at 397-398.

<sup>19</sup> In reaching that conclusion, the Court of Appeals took judicial notice of the fact that, in May 1980, six indictments were handed down in New York City charging pharmacists with substituting cyclandelate for CYCLOSPASMOL. We note that the evidence of which the Court of Appeals took judicial notice not only involved no convictions but also reflected knowledge that was not available when the District Court rendered its decision. Moreover, even if the District Court failed to consider relevant evidence, which would have been an error of law, the Court of Appeals, rather than make its own factual determination, should have remanded for further proceedings to allow the trial court to consider the evidence. See *Pullman-Standard v. Swint*, *ante*, at 291-292.

<sup>20</sup> The Court of Appeals reached that conclusion despite the District Court's express finding that, for purposes of § 43(a), the capsule colors

more sinister cast to actions which the District Court apparently deemed innocent." *United States v. Real Estate Boards*, 339 U. S. 485, 495 (1950).

## V

The Court of Appeals erred in setting aside findings of fact that were not clearly erroneous. Accordingly, the judgment of the Court of Appeals that the petitioners violated § 32 of the Lanham Act is reversed.

Although the District Court also dismissed Ives' claims alleging that the petitioners violated § 43(a) of the Lanham Act and the state unfair competition law, the Court of Appeals did not address those claims. Because § 43(a) prohibits a broader range of practices than does § 32, as may the state unfair competition law, the District Court's decision dismissing Ives' claims based upon those statutes must be independ-

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were functional. See *supra*, at 853. As the dissent below noted, the Court of Appeals' majority either disregarded the District Court's finding of functionality, see 638 F. 2d, at 545, n. 1 (Mulligan, J., dissenting), or implicitly rejected that finding as not "persuasive." See *id.*, at 547.

While the precise basis for the Court of Appeals' ruling on this issue is unclear, it is clear that the Court of Appeals erred. The appellate court was not entitled simply to disregard the District Court's finding of functionality. While the doctrine of functionality is most directly related to the question of whether a defendant has violated § 43(a) of the Lanham Act, see generally Note, The Problem of Functional Features: Trade Dress Infringement Under Section 43(a) of the Lanham Act, 82 Colum. L. Rev. 77 (1982), a finding of functionality may also be relevant to an action involving § 32. By establishing to the District Court's satisfaction that uniform capsule colors served a functional purpose, the petitioners offered a legitimate reason for producing an imitative product.

Nor was the Court of Appeals entitled simply to dismiss the District Court's finding of functionality as not "persuasive." If the District Court erred as a matter of law, the Court of Appeals should have identified the District Court's legal error. If the Court of Appeals disagreed with the District Court's factual findings, it should not have dismissed them without finding them clearly erroneous.

ently reviewed. Therefore, we remand to the Court of Appeals for further proceedings consistent with this opinion.

*Reversed and remanded.*

JUSTICE WHITE, with whom JUSTICE MARSHALL joins, concurring in the result.

We granted certiorari in these cases in order to review the legal standard employed by the Second Circuit in finding that a generic drug manufacturer is vicariously liable for trademark infringement committed by pharmacists who dispense the generic drug. The Court implicitly endorses the legal standard purportedly employed by the Court of Appeals, *ante*, at 853-854, but finds that the court erred in setting aside factual findings that were not clearly erroneous. The question whether the Court of Appeals had misapplied the clearly-erroneous rule, however, was not presented in the petitions for certiorari. This was conceded at oral argument.<sup>1</sup> Tr. of Oral Arg. 69. Our Rule 21.1(a) states that "[o]nly the questions set forth in the petition or fairly included therein will be considered by the Court." The majority suggests no reason for ignoring our own Rule. Furthermore, if the issue presented in the petitions for certiorari had been whether the clearly-erroneous standard, although properly invoked, was erroneously applied, it is doubtful in my mind that this fact-bound issue would have warranted certiorari. I nevertheless concur in reversal because I believe that the Court of Appeals has watered down to an impermissible extent the standard for finding a violation of § 32 of the Lanham Act, 15 U. S. C. § 1114.

In its first opinion in this litigation, the Court of Appeals indicated that a "manufacturer or wholesaler would be liable

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<sup>1</sup>The third question in petitioner Darby Drug Co.'s petition embraced the claim that the Court of Appeals had failed to observe Rule 52(a) in overturning the District Judge's finding of functionality. As discussed below, I agree with the Court's invocation of Rule 52 with respect to this aspect of the decision below.

under § 32 if he suggested, even if only by implication, that a retailer fill a bottle with the generic capsules and apply Ives' mark to the label, or continued to sell capsules containing the generic drug which facilitated this to a druggist whom he knew or had reason to know was engaging in the practices just described." 601 F. 2d 631, 636 (1979) (*Ives II*). The District Court applied this test but concluded that no violation of § 32 had been shown. On appeal after trial, a majority of the Second Circuit found defendants liable for contributory infringement by revising and expanding the doctrine of contributory trademark infringement. 638 F. 2d 538 (1981) (*Ives IV*):

"By using capsules of identical color, size, and shape, together with a catalog describing their appearance and listing comparable prices of CYCLOSPASMOL and generic cyclandelate, appellees *could reasonably anticipate* that their generic drug product would by a substantial number of druggists be substituted illegally . . . . This amounted to a suggestion, at least by implication, that the druggists take advantage of the opportunity to engage in such misconduct." *Id.*, at 543 (emphasis added).

*Ives II* required a showing that petitioners intended illegal substitution or knowingly continued to supply pharmacists palming off generic cyclandelate as CYCLOSPASMOL; *Ives IV* was satisfied merely by the failure to "reasonably anticipate" that illegal substitution by some pharmacists was likely. In my view, this is an erroneous construction of the statutory law governing trademark protection.

*William R. Warner & Co. v. Eli Lilly & Co.*, 265 U. S. 526 (1924), made clear that a finding of contributory infringement requires proof of either an intent to induce illegal substitution or continued sales to particular customers whom the manufacturer knows or should know are engaged in improper palming off. In that case, it was shown that the manufacturer's salesmen actively induced, either in direct terms or by insinuation, the filling of requests for Coco-Quinine with

Quin-Coco. "The wrong was in designedly enabling the dealers to palm off the preparation as that of the respondent."<sup>2</sup> *Id.*, at 530. *Coca-Cola Co. v. Snow Crest Beverages, Inc.*, 64 F. Supp. 980, 989 (Mass. 1946), *aff'd*, 162 F. 2d 280 (CA1), *cert. denied*, 332 U. S. 809 (1947), the case upon which the Court of Appeals relied in *Ives II*, stands for this very proposition. There was no contributory infringement in Snow Crest's manufacture of a product identical in appearance to that of Coca-Cola. Judge Wyzanski observed that

"any man of common sense knows that in any line of business . . . there are some unscrupulous persons, who, when it is to their financial advantage to do so, will palm off on customers a different product from that ordered by the customer." 64 F. Supp., at 988-989.

These cases reflect the general consensus. 2 J. McCarthy, *Trademarks and Unfair Competition* § 25:2 (1973) ("[T]he supplier's duty does not go so far as to require him to refuse to sell to dealers who merely *might* pass off its goods"). The mere fact that a generic drug company can anticipate that some illegal substitution will occur to some unspecified extent, and by some unknown pharmacists, should not by itself be a predicate for contributory liability. I thus am inclined to believe that the Court silently acquiesces in a significant change in the test for contributory infringement.

Diluting the requirement for establishing a *prima facie* case of contributory trademark infringement is particularly unjustified in the generic drugs field. Preventing the use of generic drugs of the same color to which customers had become accustomed in their prior use of the brand name product interferes with the important state policy, expressed in New York and 47 other States, of promoting the substitution of

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<sup>2</sup> Although *Warner* and other cases were decided before § 32 was enacted, the purpose of the Lanham Act was to codify and unify the common law of unfair competition and trademark protection. S. Rep. No. 1333, 79th Cong., 2d Sess. (1946). There is no suggestion that Congress intended to depart from *Warner* and other contemporary precedents.

generic formulations. See Warner, *Consumer Protection and Prescription Drugs: The Generic Drug Substitution Laws*, 67 Ky. L. J. 384 (1978-1979).

The Court of Appeals concluded that there was no "persuasive evidence of a legitimate reason" for petitioners to use imitative colors. The District Court, however, had expressly found that for purposes of §43(a), the capsule colors were functional. With respect to functionality, I fully agree with the Court that the Court of Appeals erred in setting aside factual findings without finding that they were clearly erroneous. The District Court found that capsule color was functional in several respects: patient anxiety and confusion were likely if accustomed medicine were dispensed in a different color; capsule colors assist patients in identifying the correct pill to take; standard colors help physicians identify the drug involved in case of overdose.<sup>3</sup> Clearly, the Court of Appeals could not reject these findings merely because it viewed the evidence as less persuasive than did the District Court. Rule 52(a) imposes a stricter standard.

Finally, although the Court states that a "finding of functionality may also be relevant to an action involving § 32," it does not explicate the relationship of functionality in a § 32 case. It is my view that a finding of functionality offers a complete affirmative defense to a contributory in-

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<sup>3</sup>"The reality is that for every link in the distributive chain (from producer to ultimate consumer) the color and shape of drugs dispensed by prescription do perform a function. For each of them, color or shape may be a convenient shorthand code by which to identify the drug and its milligram dosage so that mistakes can be avoided in the interests of pharmaceutical precaution and patient safety. For the patient-user, of course, the constancy of color and shape may be as psychologically reassuring and therefore as medically beneficial as the drug itself; in addition, they also serve to identify the drug for his ingestion . . . ."

"[I]f the generic producer is constrained by § 43(a), trademark law, or the law of unfair competition to adopt a substantially different color . . . the therapeutic value of his generic drug might be seriously impaired and confusion at the pharmacist level could be compounded beyond redemption." 3 R. Callmann, *Unfair Competition, Trademarks and Monopolies* § 82.1(m), pp. 217, 213 (Supp. 1981).

fringement claim predicated solely on the reproduction of a functional attribute of the product. A functional characteristic is "an important ingredient in the commercial success of the product," 601 F. 2d, at 643, and, after expiration of a patent, it is no more the property of the originator than the product itself. It makes no more sense to base contributory infringement upon the copying of functional colors than on the petitioners' decision to use the same formulation of the drug, or even to market the generic substitute in the first place. To be sure, the very existence of generic drugs "facilitates" illegal substitution. But Ives no longer has a patent for cyclandelate, "and the defendants have a right to reproduce it as nearly as they can." *Saxlehner v. Wagner*, 216 U. S. 375, 380 (1910) (Holmes, J.). Reproduction of a functional attribute is legitimate competitive activity.

I am also mindful that functionality is a defense to a suit under § 43(a) of the Lanham Act alleging damages from a competitor's "false designation of origin" on a good.<sup>4</sup> The use of a product or package design that is so similar to that of another producer that it is likely to confuse purchasers as to the product's source may constitute "false designation of origin" within the meaning of the Act.<sup>5</sup> As the Court of Appeals noted in *Ives II*, § 43(a) "goes beyond § 32 in making certain types of unfair competition federal statutory torts," 601 F. 2d, at 641. Section 43(a) offers the direct protection of Ives' interest in this case, and it is not surprising that the alleged

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<sup>4</sup> See, e. g., *International Order of Job's Daughters v. Lindeburg & Co.*, 633 F. 2d 912, 917 (CA9 1980), cert. denied, 452 U. S. 941 (1981); *Keebler Co. v. Rovira Biscuit Corp.*, 624 F. 2d 366, 378 (CA1 1980). See generally Note, The Problem of Functional Features: Trade Dress Infringement Under Section 43(a) of the Lanham Act, 82 Colum. L. Rev. 77, 81 (1982) ("Over the past three years the rule that functionality of a copied feature bars relief in section 43(a) claims for trade dress infringement or product imitation has become the plurality view").

<sup>5</sup> See, e. g., *Truck Equip. Serv. Co. v. Fruehauf Corp.*, 536 F. 2d 1210 (CA8), cert. denied, 429 U. S. 861 (1976); *Warner Bros., Inc. v. Gay Toys, Inc.*, 658 F. 2d 76 (CA2 1981). See also Note, 82 Colum. L. Rev., *supra*, at 78-80.

§ 43(a) violation was the primary claim in this litigation, as it has been in other cases of this genre. It would be anomalous for the imitation of a functional feature to constitute contributory infringement for purposes of § 32, while the same activity is not a "false designation of origin" under § 43(a).<sup>6</sup>

I would reverse the decision of the Court of Appeals and remand for review of the District Court's findings consistent with the principles stated above.

JUSTICE REHNQUIST, concurring in the result.

I agree that the judgment of the Court of Appeals should be reversed. That court set aside factual findings of the District Court without having found them to be clearly erroneous as required by Rule 52(a) of the Federal Rules of Civil Procedure. I disagree, however, with the Court's determining for itself that the findings of the District Court were not clearly erroneous. I think in the usual case this is a question best decided by the courts of appeals, who have a good deal more experience with the application of this principle than we do, and I see no reason to make an exception in this case.

I also assume, correctly I hope, that the Court's discussion of appellate review of trial court findings in bench trials, *ante*, at 855, is limited to cases in which the appellate court has not found the trial court findings to be "clearly erroneous." *United States v. United States Gypsum Co.*, 333 U. S. 364 (1948), upon which the Court relies, establishes the authority of a reviewing court to make its own findings, contrary to those of the trial court, where it has determined the latter to be "clearly erroneous."

I agree with the Court that these cases should be remanded to the Court of Appeals to review the District Court's dismissal of respondent's claims under § 43(a) of the Lanham Act and its state-law claims.

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<sup>6</sup> This is not to suggest that the copying of a functional feature protects a defendant from § 32 liability predicated on active inducement of trademark infringement or protects a defendant who has also reproduced nonfunctional features.