



10-1981

Inwood Laboratories, Inc. v. Ives Laboratories, Inc.

Lewis F. Powell Jr.

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Grant

Interesting trade mark case (see Mary's note below), but there is no conflict. And CA2 may have decided case on facts that indicated an intent to ~~profit~~ profit from another good will.

PRELIMINARY MEMORANDUM

SEP 28 1981

~~Summer List 15, Sheet 3~~

No. 80-2182

INWOOD LABORATORIES, INC., ET AL. (Drug mfrs.) *oll*

Cert to CA2 (Lumbard, Mansfield; Mulligan, dissenting)

v.

IVES LABORATORIES, INC. ✓

Federal/Civil Timely (w/ ext)

No. 81-11

DARBY DRUG CO., ET AL. *oll*
(Drug Wholesalers)

Cert to CA2 (Lumbard, Mansfield; Mulligan, dissenting)

v.

IVES LABORATORIES, INC. ✓

Federal/Civil Timely (w/ ext)

Reply brief in. re. distinguishing cases cited by resp (on a very detailed level). I would continue to be inclined to deny because there is no split yet. Mary

SUMMARY: The issue is whether the manufacturer of a brand-name prescription drug is entitled, under the Lanham Act, to an injunction prohibiting manufacturers of bioequivalent generic

Is it ~~also~~ trade-mark infringement for one drug manufacturer to market pills that look like brand-name pills? CA2 said yes. I agree with memo that this may be wrong. Consumers seem to like what pill looks like to what it is not to what it is. But no split. Deny? Mary

drugs from packaging the drug in capsules of the same color as those used for the brand name product.

FACTS: Plaintiff Ives Laboratories manufactures and sells the drug "cyclandelate" under the registered trademark "Cyclospasmol"; until 1972 Ives held a patent on the drug. Since 1962 Ives has marketed 200mg. dosages of Cyclospasmol in pale blue capsules imprinted "Ives 4124". Since 1975 it has sold 400mg. dosages in a blue and red capsule imprinted "Ives 4148".

Cyclandelate is a "peripheral vasodilator" used primarily by elderly patients on a regular basis to inhibit progression of certain vascular diseases. It is sold only by prescription, and the dispensing pharmacist places the capsules in containers bearing his own label. Thus, Ives directs its advertising to prescribing physicians and pharmacists rather than to the ultimate consumer.

Petr's Inwood and Premo "manufacture" generic cyclandelate by purchasing empty capsules and filling them with cyclandelate powder. They use blue and blue and red capsules identical to those used by Ives, and promote their product as "comparable" or "equivalent" to Cyclospasmol. Until recently, the capsules were not marked with the name of the manufacturer; in June 1978 (apparently after this suit had been filed) Premo began stamping its name on the capsules. Petr's Darby, Rugby, and Sherry are wholesalers who sell generic cyclandelate.

Under N.Y. law, a prescription is to be filled generically unless the prescribing physician indicates otherwise. Pharmacists are required to label prescriptions with the name of the drug and the manufacturer.

Ives sued petrs in the DC (J. Nickerson, E.D.N.Y.), contending that the sale of the generic drug in capsules identical in appearance to Cyclospasmol violated §§32 (trademark infringement) and 43 (a) (false designation of origin) of the Lanham Act (15 U.S.C. §§ 1114 & 1125 (a)), as well as N.Y. unfair competition law. Ives maintained that the use of blue capsules served no functional purpose and encouraged pharmacists to pass off the generic drug as Cyclospasmol. The DC denied a request for a preliminary injunction, and the CA (Friendly, Mulligan, Gagliardi [D.J.]) affirmed. Noting that it found the case more difficult than had the DC, the CA held that Ives would be entitled to relief: 1) under Lanham Act §32, for "contributory infringement", if it could show that petrs "suggested, even if only by implication, that a retailer fill a bottle with generic capsules and apply Ives' mark to the label", or that they continued to sell to retailers they knew were engaging in such deceptive practices; and 2) under Lanham Act §43 (a), if it could show that consumers associated the blue capsules with Cyclospasmol and that the capsule color was "nonfunctional".

After trial, the DC dismissed the complaint (with a minor exception not relevant here), finding that Ives had failed to make out a violation under the Lanham Act. With reference to the §32 claim, the court found that there were relatively few instances of intentional mislabelling by pharmacists, and that petrs (who, unlike other manufacturers, do not promote their products through personal visits to pharmacists) were not responsible for the illegal mislabelling that did occur. As for the §43 (a) claim, there was insufficient evidence that consumers associated the blue capsules with the source of the product,

Ives. To the contrary, consumers associated the blue capsules with the therapeutic effect of cyclandelate itself, and were confused by, and resisted using, cyclandelate when packaged in different color capsules. Thus, the blue capsules served a functional purpose. Moreover, uniform color coding of cyclandelate products was useful to patients who took several different medications, and to doctors in emergency situations. There was no justification for giving Ives a "monopoly" on the use of blue capsules as packaging for the drug.

HOLDING BELOW: The CA2 reversed, holding that Ives had proved "contributory infringement" in violation of §32. At trial, Ives introduced evidence of test "shoppings" at 83 drug stores. Out of the 35 instances where the druggist (as permitted by N.Y. law) substituted the generic drug for Cyclospasmol, in 10 instances the generic drug was mislabelled Cyclospasmol. (However, in 5 cases the label was "generic Cyclospasmol", which petrs contend is not misleading, and in only 1 case was the "brand name" price charged.) By providing pharmacists with capsules that look identical to Cyclospasmol, petrs were facilitating this deception and could reasonably anticipate it would occur. Indeed, petrs' catalogues explicitly compare their product with Cyclospasmol, in terms of appearance and price, and thus invite such conduct. The "functional" reasons for using blue capsules, enumerated by the DC, were "unconvincing"; and petrs have "scores of other colors, color combinations, and sizes" available to them. (The CA remanded to the DC, which enjoined petrs from selling capsules that are "confusingly similar in color, shape and size to those now used by plaintiff").

J. Mulligan, dissenting, maintained that the evidence of intentional mislabelling was minimal, that it failed to implicate petrs, and that the majority erred in refusing to credit the DC's finding, based on extensive testimony, that there were legitimate reasons for petrs to use blue colored capsules.

CONTENTIONS: 1) The CA penalized petrs for comparative advertising, which is protected not only under trademark law, Saxlehner v. Wagner, 216 U.S. 375 (1910), but also by the 1st Amendment, Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc., 425 U.S. 748 (1976). Petrs are being held accountable for the putative trademark infringement of pharmacists simply because they have emphasized comparisons between their products and Ives'.

2) The CA erred in holding that §32 grants trademark holders monopoly rights in the "trade dress" (i.e., size and color) of their product. While the color of a product may, in certain instances (where it is nonfunctional and has acquired "secondary meaning") be given some protection under §43 (a), it has little to do with the protection accorded trademarks under §32. Moreover, here the DC found that the color of the capsules had a functional aspect and had not acquired secondary meaning-- findings the CA ignored.

3) The CA decision is inconsistent with Sears, Roebuck & Co. v. Stiffel Co., 376 U.S. 225 (1964) and Compco Corp. v. Day-Brite Lighting, Inc., 376 U.S. 234 (1964), in which this court held that an article not protected by a patent and not covered by a trademark may be copied exactly. See also Kellogg Co. v. National Biscuit Co., 305 U.S. 111, 120 (1938).

4) The CA decision undercuts the state policy behind the N.Y. generic drug law. New York encourages substitution of generic drugs for brand name drugs; while a minority of pharmacists may be guilty of mislabelling, that is insufficient reason to impose a competitive handicap on generic drug manufacturers.

Resp primarily relies on the CA opinion. Sears and Compro are inapposite since they dealt with preemption of state law, and here the CA found commission of a "federal tort". There is no 1st Amendment issue, since petrs have not been prohibited from engaging in comparative advertising, and there is no 1st Amendment right to copy the trade dress of a product. The CA has simply prohibited petrs' intentional effort to facilitate "passing off" by furnishing retailers with an exact duplicate of resp's product. While the reliance on §32 may be somewhat novel, the CA's decision is consistent with cases applying §43 (a) or general unfair competition law. See William Warner & Co. v. Eli Lilly & Co., 265 U.S. 526 (1924); SK&F CO. v. Premo Pharmaceutical Laboratories, Inc., 625 F.2d 1055 (3d Cir. 1980).

Amicus National Ass'n of Pharmaceutical Manufacturers, a representative of the generic drug industry, contends that the practice of marketing generic drugs in the same color as that of brand name drugs is longstanding. Only since the advent of generic drug laws has the practice been challenged by brand-name manufacturers, who for the first time are subject to meaningful competition. The effect of the CA decision will be to suppress competition in the generic drug industry, contrary to the will of the 49 states which have passed generic drug laws.

Amici American Ass'n of Retired Persons and the National Retired Teachers Ass'n argue that the CA decision will have an adverse impact on the elderly, who benefit from competition between generic and brand-name manufacturers.

DISCUSSION: I find the CA decision troubling, essentially for the reasons put forth by petrs and amici (although I think the 1st Amendment claim is without merit). The theory of "contributory infringement" seems quite strained, and I am concerned that Ives has been given an unnecessary competitive advantage since there is little to indicate confusion among those who actually distribute cyclandelate--physicians and pharmacists. The issue is important and may affect a large number of persons who regularly take prescription drugs.

Nevertheless, I am not convinced that cert should be granted. With respect to the §43 (a) claim especially (on which the CA did not rule), much depends on the interpretation one places on the particular facts adduced at trial, including the results of various surveys and test shoppings. Petrs do not point to any substantial conflict among circuits, and amicus NAPM indicates it is likely that there will be future cases similar to this one. It might be wise to let a body of precedent develop in the CAs prior to taking the issue. On balance, I recommend denial.

There is a response.

7/31/81

Rosenblum

Opns in petn

e
D
B

PRELIMINARY MEMORANDUM

SEP 28 1981

~~Summer List 15, Sheet 3~~

No. 81-11

DARBY DRUG CO., ET AL.
(Drug Wholesalers)

Cert to CA2 (Lumbard, Mansfield;
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v.

IVES LABORATORIES, INC.

Federal/Civil Timely (w/ ext)

See memorandum in No. 80-2182.

7/31/81

Rosenblum

Opn in 80-2182 petn

Court
 Argued, 19...
 Submitted, 19...

Voted on, 19...
 Assigned, 19...
 Announced, 19...

No. 80-2182

INWOOD LABORATORIES, INC.

vs.

IVES LABORATORIES, INC.

HAB put on list. (9 agree case is interesting)
HAB thinks Mulligan's dissent is right. I see it very important in med. field CA 2 under-cut - almost nullified state law. I PS says there is revenue fed. Q

Grant
Relist
But relisted for Byron to take another look.

	HOLD FOR	CERT.		JURISDICTIONAL STATEMENT				MERITS		MOTION		ABSENT	NOT VOTING
		G	D	N	POST	DIS	AFF	REV	AFF	G	D		
Burger, Ch. J.			✓										
Brennan, J.			✓										
Stewart, J.			✓										
White, J.			✓										
Marshall, J.			✓										
Blackmun, J.			✓										
Powell, J.			✓										
Rehnquist, J.			✓										
Stevens, J.			✓										
O'Connor, J.													

Panel

Review 2/21 - good memo - tho I may not agree

jsw 02/21/82

BENCH MEMORANDUM

To: Mr. Justice Powell

February 21, 1982

From: John Wiley

Nos. 80-2182 & 81-11: Inwood Laboratories, Inc. v. Ives Laboratories, Inc.

Question Presented

Whether petrs are guilty of contributory trademark infringement under §32 of the Lanham Act because they both copied resp's pill shape and color and advertised this similarity.

Background

Ives, the resp, sued petrs because petrs were making generic substitutes for Ives' Cyclospasmol in pills that are identical -- in color and shape -- to Ives'. One theory Ives utilized was trademark infringement under §43 of the Lanham Act. Section 43 grants a right of action against anyone who falsely describes the origin of goods. It is the standard

trademark infringement cause of action.

Section 43 is not properly at issue in the case before the Court. The DC found that Ives failed to make out a §43 claim. Ives appealed that determination to the CA2. But the CA2 reversed on a different theory, one that the DC also had rejected: "contributory infringement" under §32 of the Lanham Act. The court remanded without reaching the DC's §43 holding. Consequently only the §32 issue properly is before the Court.

*Only § 32
is here*

The contributory infringement theory is that Ives' trademarked product name, "Cyclospasmol," has been infringed. But petrs are not the ones who directly infringed it. Petrs are competing drug manufacturers of "cyclandelate," which is the generic name describing the chemical ingredients in Cyclospasmol. Petrs truthfully label their products as chemical equivalents of and generic substitutes for Cyclospasmol.

*Drugs are
not Petrs
mfg.,
directly
infringe*

The primary infringing villains rather are alleged to be pharmacists. Ives claims pharmacists sell petrs' products instead of Cyclospasmol when physicians prescribe "Cyclospasmol" by name. Pharmacists have a motive falsely to describe petrs' cyclandelate as Ives' Cyclospasmol: the profit difference between the low purchase price for generic cyclandelate and the high sales price for Cyclospasmol. Under the §32 contributory infringement theory, petrs' sin is that they instigate or make possible suggest the pharmacists' dishonest substitution.

I see three primary issues in this case. First, does

§32 in fact encompass a "contributory infringement" theory? Second, if so, what are the mental element that this claim requires Ives to show? Third, did the CA2 correctly hold that Ives had shown a violation of this element?

In my view, only these three questions must be faced. I believe the CA2 erred in holding that Ives had proved that petrs were guilty of contributory infringement. If you disagree, there is a final issue about the appropriate remedy.¹ And as I have already mention, the §43 issue is not before the Court, despite some discussion of that section in the SG's brief.²

Discussion

1. Contributory infringement and §32

Parter assume §32 encompasses

The parties do not discuss this issue. All assume that §32 in fact encompasses the common law doctrine of contributory infringement. The Court has never so held. The statutory language raises a significant issue in this respect.

I append a copy of §32, which is prolix. Boiled down to essentials, however, the section grants a right of action

¹Although I do not discuss remedy issues in this memo, I agree with the SG that the remedy granted below is overly broad. If the Court reaches this issue, I think the injunction should be narrowed along the lines he suggests.

²I note that Ives requests an opportunity to submit additional briefing if the Court does decide to pass on the §43 issue. Red brief at 50 n. 32. This is a fair request.

against persons who "use" or "reproduce, counterfeit, copy or colorably imitate" a registered trademark without the owner's consent. But pharmacists are the ones who "use" or "imitate" the mark Cyclospamol in the situation at bar; they sell copies of Cyclospasmol pills when the prescription calls for Cyclospasmol by name. It will take some stretching of statutory language to say that petrs "use" or "imitate" the Cyclospasmol mark simply by suggesting that pharmacists misidentify the petrs' generic product (assuming that Ives has proved that petrs indeed have made such suggestions).³

But they do imitate

Such a stretching of Lanham Act language may not be improper. The trademark and unfair competition field has deep roots in common law. Much of the Lanham Act's interpretation has followed from common law principles. And there seems to be no doubt that contributory infringement was a living common law doctrine before the passage of the Lanham Act.⁴ It thus may

yes

common law

³Contributory activity might be attacked under a conspiracy theory. Of course, a conspiracy theory -- which Ives does not invoke -- would bring its own proof elements, such as the need to show agreement to infringe. This showing probably would be very difficult to make in this case. Moreover, I have some doubt whether there is a general theory of civil conspiracy based on statutory causes of action but independent of specific statutory authorization. The Court probably would have to discover any such conspiracy right of action from §32's text. This approach thus does not seem to advance the ball much over the method of directly reading a contributory infringement right of action into §32.

⁴Indeed, the only authority that Judge Friendly cited in the first CA2 decision in this case, see Inwood Cert Petn at 35a, for the elements of the contributory infringement doctrine was a pre-Lanham Act opinion: Coca-Cola Co. v. Snow Crest Bevereages, 64 Footnote continued on next page.

well have been Congress' intent in passing §32 to incorporate principles of contributory infringement.

My own opinion tends to the contrary. Absent some further indication of congressional intent (which may well exist in legislative history -- I have not checked), I would adhere more closely to the statute's language. To my eye the section's language makes no provision for a right of action on a contributory infringement theory.

But the lower courts in this case -- composed of very good judges -- simply assumed such a cause of action exists without discussion. The parties -- including the SG -- do not discuss the point. Consequently I will devote no further attention to the question in this memo. Having called the issue to your attention as a possible means of resolving the case, I suggest only that you allude to the point in oral argument. I would ask if the parties can explain how (or cite authority that analyzes whether) §32's language incorporates principles of contributory infringement. This also will alert the Court to the issue, if the other Justices have not already pondered the point. I will, of course, be happy to explore this question in more depth if you would like.

F.Supp. 980, 989 (D. Mass 1946) (Wyzanski, J.), aff'd, 162 F.2d 280 (CA1), cert. denied, 332 U.S. 809 (1947). Rather indistinctly, Snow Crest was based upon "registered federal and state trademark[k]" law and "common law rights under the Massachusetts or federal principles of unfair competition" 64 F.Supp. at 990.

2. Element of contributory infringement

Assuming §32 embodies a cause of action for contributory infringement, it is necessary to establish the elements of this cause. Conflicting policies frame the analysis.

First and most obviously, there is the policy of preventing the infringement of a federally recognized trademark right. It is important to assess the exact scope of this policy in this case. As mentioned, the right is to Ives' exclusive use of the name Cyclospasmol. The right does not include the exclusive right to manufacture cyclandelate itself. Ives' patent on this substance has expired. Neither does the right, in and of itself, cover the color and shape of Ives' pills. Ives' now-expired patent never included color or shape. And at this stage of the litigation Ives has failed to establish a trademark right to color and shape; the DC rejected Ives' §43 claim and the CA2 did not reach or disturb this holding.

no
trade
mark

But if
Ives'
pills
can be
"palmed
off"
because
of color
& shape
does this
not
imply a
secondary
meaning

The second policy is the exact opposite of the protection offered by patents, trademarks, or copyrights. That is protection of the right to copy. Absent trademark or similar protection, competitors have a federal right to copy exactly another's product (so long as the copy truthfully is identified as such and not as the real thing).

This federal right to copy is well established. In 1938, Kellogg Co was charged with copying Nat'l Biscuit Co's shredded wheat design. Justice Brandeis wrote:

Kellogg Company is undoubtedly sharing in the goodwill of the article known as "Shredded

Wheat"; and thus is sharing in a market which was created by the skill and judgment of the [Nat'l Biscuit Co's] predecessor and has been widely extended by vast expenditures in advertising persistently made. But that is not unfair. Sharing in the goodwill of an article unprotected by patent or trademark is the exercise of a right possessed by all--and in the exercise of which the consuming public is deeply interested.

Fed. right to "copy"

Kellogg Co. v. National Biscuit Co., 305 U.S. 111, 122 (1938).

See also Sears, Roebuck & Co. v. Stiffel Co., 376 U.S. 225, 230 (1964) ("when the patent expires the monopoly created by it expires, too, and the right to make the article--including the right to make it in precisely the shape it carried when patented--passes to the public") (emphasis added); Compco Corp. v. Day-Brite Lighting, Inc., 376 U.S. 234, 237-38 (1964) ("Here Day-Brite's fixture has been held not to be entitled to a design or mechanical patent. Under the federal patent laws it is, therefore, in the public domain and can be copied in every detail by whoever pleases.") (emphasis added).

Important policies animate this federal right to copy. Competition is the basic federal economic policy. The entire point of competition is to produce what consumers want at the lowest possible price. If some innovator produces a product that proves popular, consumers welfare is increased if other manufacturers duplicate the good and drive down price. Duplication of commercially successful goods thus is the lifeblood of the market process.

Exceptions to the right to copy are made in only two

relevant instances. First, when innovators meet the demanding standard of the patent laws, they are rewarded with a period of monopoly. Here that patent monopoly has expired for Ives' discovery of cyclandelate. Second, duplicators are not permitted to confuse the public about who in fact made the article; originators have the exclusive trademark right to identify their own products as such. Similarly, copiers cannot infringe this trademark right by misleading the public into thinking that their imitations are really made by the originator. But copiers are allowed to copy the good, to tell the public that it is a copy but just as good as the original, and to sell for less. Public welfare increases as a result.

Point
of
this
case

Both the protection of trademark and right to copy policies are important. For this reason I conclude that the cause of action to protect against those who contribute to trademark infringement is inherently desirable. By the same token, it must not be too broad. It should not be permitted to chill the truthful exercise of competitors' right to copy an originator's product.

To my mind, the SG does the best job of presenting the correct resolution of this conflict. He summarizes the proper contents of a contributory infringement action by stating "a person may be held vicariously liable for the trademark infringement of another person only upon a showing of a guilty state of mind." SG brief at 16 (emphasis added). This state of mind requirement permits courts to discriminate-

John
agrees
with
SG
- "must
show
intent"

ly between laudable exercises of the right to copy unprotected goods and the culpable encouragements of pharmacists to misdescribe the origin of generic cyclandelate (when a prescription demanded only Cyclospasmol). As the SG notes, explicit statement of this element is not inconsistent with Judge Friendly's opinion in the first CA2 Ives opinion. Rather it differs only as a matter of emphasis.

I now consider whether Judge Mansfield's second CA2 Ives opinion (the decision before the Court) correctly applies this state of mind element.

3. Ives' proof of petrs' guilty mind

Ives relies on four items of evidence to prove that petrs improperly encouraged pharmacists to infringe Ives' Cyclospasmol trademark: (1) petrs' manufacture of cyclandelate in identical pills; (2) petrs' catalogs; (3) 15 instances in which pharmacists illegally substituted cyclandelate for Cyclospasmol; and (4) a sample in which Ives' agents filled prescriptions for Cyclospasmol or a generic substitute at 83 different pharmacies. I discuss each item of proof in turn.

Evidence that petrs copied Ives' pill color and shape cannot, I think, properly be given much weight. This imitation is a pure example of the right to copy an unprotected feature of a competitor's product. As mentioned, Ives has not established that it has any trademark right to pill color. (My assessment of the DC rejection of Ives' §43 claim, which sought

Why?

to establish this right, is that the DC acted correctly.) Petrs therefore were within their rights by copying the unprotected pill shape and color of the market leader. This evidence does not show petrs had a guilty mind to encourage misidentification by pharmacists.

Petrs' catalogs present little additional evidence of a guilty mind. The catalogs did two things. They listed price comparisons between Ives' and petrs' products, and they identified the color of petrs' cyclandelate pills. These acts by petrs do no more, I think, than proclaim "our product is just as good as Ives, and it is cheaper." Such advertising logically is a proper incident to the right to copy. Indeed, there is a net social benefit to the extent that consumers can be made aware that the same product is available at lower cost. Like the pill design evidence, this evidence is consistent with a theory that petrs were doing no more than exercising their protected right to copy. Because it does not exclude an innocent -- and worthy -- motive for petrs behavior, it is of little value in proving petrs' guilty mind.

*Catalogs
of Petrs*

The final two pieces of evidence do not relate to petrs' actions at all. Rather they purport to show that the pharmacy industry is rife with trademark infringement. The implication would be that, given this context, only slight infringement encouragement by petrs should suffice to show their guilty minds.

My first reaction is that this whole effort is mis-

guided. If infringement really is rife in an industry where agents (like pharmacists) must be trusted to obey product selection orders (like physicians' prescriptions), then the agents are the proper target of attack. Vicarious attack on the manufacturers by lowering the standards needed to show the manufacturers' guilty minds trenches on their federal right to copy. The result to be feared is that, in attempting to cure one evil (the misbehavior of pharmacists), the Court would create another: elimination of the right to copy. The result would be that Ives would be permitted to enjoy an unwarranted monopoly in pill design. Consequently I think Ives should have devoted its efforts at trial to illustrating bad conduct by petrs, not by pharmacists. The easiest way to do this would have been to find smoking guns in petrs' files or testimony from pharmacists about actual hints from Ives that advocated substitution. Ives' actual strategy misses the point and threatens other important federal policies.

In any event, I agree with the DC that Ives failed to prove widespread infringement in the pharmacy business. The 15 examples of illegal substitution were insufficient even for the CA2 panel in the first appeal; the CA2 affirmed the DC's decision to deny Ives' request for preliminary relief. These 15 examples of unprincipled pharmacist conduct were not randomly selected. Instead they were drawn, by Ives, from the entire market in which Cyclospasmol is sold: presumably the nation, if not the world. In this light, 15 looks like a very small

number. This evidence does not show that misdescription of goods is unusually common or typical in this industry.

Second, Ives polled 83 pharmacists with prescriptions that explicitly permitted substitution of generic cyclandelate for Cyclospasmol. This study is flawed from the outset. First, 83 is larger than 15, but it still is tiny considering the market at issue. Second, Ives must show that it is common for pharmacists to give generic cyclandelate when they are asked specifically for Cyclospasmol. Only in this manner can it prove that pharmacists corruptly give way to the profit incentive of selling the cheap copy as the expensive original.

By contrast, this study asks pharmacists to give either the cheap copy or the expensive original. It tests their labelling accuracy, not their honesty. Any trademark infringement that is found can be merely technical, because by hypothesis customers are asking for Cyclospasmol or a substitute. Consumers consequently are not being misled about the origin of the pill they buy, since in their request they have specified that they are indifferent as to origin.

A disputed percentage (12% v. 29%) of the pharmacists dispensing the generic did mislabel in some manner. But only one of the 83 sold generic cyclandelate as "Cyclospasmol" and charged the brand name price. This evidence is strong. But it counts in petrs' rather than Ives' favor. It shows that the basic market condition that Ives is trying to prove -- common pharmacist willingness to cheat consumers by substituing copies

and charging for the original -- is quite rare.

Conclusion

In sum, I believe that Ives has failed to prove petrs' guilty mind. The CA2 erred in losing sight of the key mental element of contributory infringement. Its decision overprotects Ives' Cyclospasmol name and consequently impairs the strong federal interest in permitting competitors to duplicate otherwise unprotected features of popular products. Assuming that the Court decides that §32 does contain a right of action for contributory infringement, the Court should reverse; the CA2 has misapplied the proper standards governing relief under that theory.

Inclined to agree.

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.

(2) Notwithstanding any other provision of this chapter, the remedies given to the owner of the right infringed shall be limited as follows: (a) Where an infringer is engaged solely in the business of printing the mark for others and establishes that he was an innocent infringer the owner of the right infringed shall be entitled as against such infringer only to an injunction against future printing; (b) where the infringement complained of is contained in or is part of paid advertising matter in a newspaper, magazine, or other similar periodical the remedies of the owner of the right infringed as against the publisher or distributor of such newspaper, magazine, or other similar periodical shall be confined to an injunction against the presentation of such advertising matter in future issues of such newspapers, magazines, or other similar periodical: *Provided*, That these limitations shall apply only to innocent infringers; (c) Injunction relief shall not be available to the owner of the right infringed in respect of an issue of a newspaper, magazine, or other similar periodical containing infringing matter when restraining the dissemination of such infringing matter in any particular issue of such periodical would delay the delivery of such issue after the regular time therefor, and such delay would be due to the method by which publication and distribution of such periodical is customarily conducted in accordance with sound business practice, and not to any method or device adopted for the evasion of this section or to prevent or delay the issuance of an injunction or restraining order with respect to such infringing matter.

(July 5, 1946, ch. 540, title VI, § 32, 60 Stat. 437; Oct. 9, 1962, Pub. L. 87-772, § 17, 76 Stat. 773.)

§ 1114. Remedies; infringement; innocent infringement by printers and publishers

(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,

80-2182 INWOOD v. IVES

Argued 2/22/82

"Color & shape" of pills - generic products

Any other info's
using these colors?
What share of mkt

Bass (Petros)

Petros wants monopoly on color
Case is here on alleged violation
of § 32 of ~~Trade~~ Lanham. See 43(a) not
before us.

Petros are three drug manufacturers,
three wholesalers,

Only one other info's - it uses
different colors

Gonzalez (SG - supporting Petros)

1. Friendly's standard is OK.

2. Mansfield misapplied it

§ 43 would apply to a "secondary
meaning" case

SG suggests we should remand
on § 43.

SG says "guilty state of mind"

is necessary under

§ 32

Mr. B. Driscoll (Resp)

CA/APP disagreed with some of findings of DC. CA2 did not make contrary findings. It found no ev to support some of DC's findings.

CA2 applied U.S. v Gypsum in holding that rule 52 of Cr. Rules did not apply.

No inherent ~~fundamentality~~ functionality in color.

There was a "guilty state of mind" here as SG would require.

Rev & Remand 9-0

No. 80-2182

Inwood v. Ives

Conf. 2/24/82

The Chief Justice *Rev.*

The DC & Mulligan were right.

There is no misrepresentation.

CA 2 did not say DC's findings were clearly erroneous.

~~The~~ Reverse - but might not dissent if majority of Court remanded

Justice Brennan *Rev.*

DC was right, & CA 2 ignored Rule 52.

CA 2 ~~was~~ ~~erroneous~~ but we may have to remand on § 43. (The CJ ~~said~~ said we could Rev & Remand)

Justice White *Rev - could remand on § 43*

The second panel applied a different standard for first panel. This was error.

Mausfeld applied a neg. standard: "if Δ knew or should have known"; ~~§~~

CA 2 ignored Rule 52

Justice Marshall

Rev. - & on to Remand.

Justice Blackmun

Rev. & Remand,

That is "old battle".

~~Not~~

Resps have a valid req. Trade Mark on name

Exact

All parties agree no remedy on color. ?

Findings of DC were not clearly erroneous

The ³43 issue is basic one & would
go along with remand.

Justice Powell

Rev & probably remand on § 43

Agree that we should reverse as to
§ 32 & remand on 43.

Justice Rehnquist

Rev & Remand.
Friendly op. stated correct standards

Justice Stevens

Rev & Remand.
DC was right but would go along with
remand.
DC's findings were not found to be
clearly erroneous

Justice O'Connor

Rev & Remand

To: The Chief Justice
Justice Brennan
Justice White
Justice Marshall
Justice Blackmun
Justice Powell
Justice Rehnquist
Justice Stevens

LFA

From: Justice O'Connor

MAY 6 1982

Circulated: _____

Recirculated: _____

1st DRAFT

SUPREME COURT OF THE UNITED STATES

No. 80-2182

INWOOD LABORATORIES, INC., ET AL., v.
IVES LABORATORIES, INC.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF
APPEALS FOR THE SECOND CIRCUIT

[May —, 1982]

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.¹ Ives marketed the

¹ Under the Trademark Act of 1946 (Lanham Act), 60 Stat. 427, as amended, 15 U. S. C. § 1051 *et seq.*, the term "trademark" 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.*

Reviewed

Join

See Pm 11,

& my letter

to Sandra

Also see n. 19

& HAH's letter

2 INWOOD LABORATORIES *v.* IVES LABORATORIES

drug, a white powder, to wholesalers, retail pharmacists, and hospitals in colored gelatin capsules. Ives arbitrarily selected 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. (collectively the generic manufacturers), began marketing cyclandelate.² 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.³

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.⁴

²The 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, doctors, and pharmacies.

³Initially, 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 "NDC 285."

⁴Since 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 Drugs:

The generic manufacturers also follow a normal industry practice by promoting their products primarily by distribution 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.⁵ 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

The Generic Drug Substitution Laws, 67 Ky. L. J. 384 (1978-1979). The New York statutes involved in this case 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 1972 and 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; N.Y. Pub. Health Law § 206.1(o) (McKinney 1971 and 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.

⁵ Ives conceded that CYCLOSPASMOL and the petitioners' generic equivalents are bioequivalent and have the same bioavailability. See 455 F. Supp., at 942 and 488 F. Supp., at 396. 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).

from the container in which he receives them and dispenses them to the consumer in the pharmacist's own bottle with his own label attached. Hence, the final consumer sees no identifying marks other than those on the capsules themselves.

II

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).⁶

Ives' claim under § 32, 60 Stat. 437, 15 U. S. C. § 1114,⁷ derived from its allegation that some pharmacists had dis-

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

⁷Section 32 of the Lanham Act, 60 Stat. 437, 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.”

pensed generic drugs mislabeled as CYCLOSPASMOL.⁸ 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),⁹ alleged that the petitioners falsely designated the origin of their products by copying the capsule colors used by

Lanham Act

⁸The claim involved two types of infringements. The first was "direct" infringement, in which druggists allegedly filled CYCLOSPASMOL prescriptions 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.

⁹Section 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."

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*¹⁰ and that they had developed a secondary meaning for the consumers.¹¹

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, 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. 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 sufficient to justify preliminary relief. *Id.*, at 945. Ives had not established that the petitioners conspired with the pharmacists or suggested that they disregard doctors' prescriptions.

The Court of Appeals for the Second Circuit affirmed. 601 F. 2d 631. To assist the District Court in the upcoming trial on the merits, the appellate court defined the elements of a

¹⁰ 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. See *Sears, Roebuck & Co. v. Stiffel Co.*, 376 U. S. 225, 238 (1964); *Kellogg Co. v. National Biscuit Co.*, 305 U. S. 111, 122 (1938).

¹¹ 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 producer rather than the product itself. See *Kellogg Co. v. National Biscuit Co.*, *supra*, at 118.

Enso

Humbel

SONOCLIO

AMICO

Ind.

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Identifies the source

Checco/Kellogg

claim based upon §32 in some detail. Relying primarily upon *Coca-Cola Co. v. Snow Crest Beverages, Inc.*, 64 F. Supp. 980 (D. 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 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. 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.¹²

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

¹²The District Court also found that 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.

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 evidence 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 co-mingle 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 petition-

DC

ers violated § 32. The Court of Appeals did not reach Ives' other claims. We granted certiorari, — U. S. —, 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 distribution, 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 to the consuming public as a result of the deceit. 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 § 32.¹³ 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

¹³ 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 good will which he spent energy, time, and money to obtain. See Sen. Rep. No. 1333, 79th Cong., 2d Sess., p. 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, 79th Cong., 1st Sess., p. 3 (1946).

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*, — U. S. — (1982). 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.¹⁴

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. . . .”¹⁵

¹⁴ 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, at 636 with 488 F. Supp., at 397.

¹⁵ As the opinions from the lower courts reveal, more than one inference can be drawn from the evidence presented. Prior to trial, test shoppers 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 35 pharmacists who dispensed a generic

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." 638 F. 2d, at 543. In reaching its conclusion, the Court of Appeals was influenced by several factors. First, it thought 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.*¹⁶ Second, it disagreed with the trial court's finding that

drug included the word CYCLOSPASMOL on the label, although 4 of those 10 also included some form of the word "generic." Nine of the 10 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 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.

¹⁶The Court of Appeals cited no evidence to support its conclusion, which apparently rests upon the assumption that a pharmacist who has

the mislabeling which did occur reflected confusion about state law requirements. *Id.*, at 544.¹⁷ Third, it concluded that illegal substitution and mislabeling in New York are neither *de minimis* nor inadvertent. *Ibid.*¹⁸ Finally, the Court of Appeals indicated it was further influenced by the fact that petitioners did not offer “any persuasive evidence of a legitimate reason unrelated to CYCLOSPASMOL” for producing an imitative product. *Ibid.*¹⁹

been provided 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.

¹⁷The 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 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 398.

¹⁸In 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*, — U. S. —, at — (1982).

¹⁹To reach that conclusion, the Court of Appeals necessarily rejected the District Court’s finding that, on the facts before it, the capsule colors were functional. See p. 8, *supra*. Whether a particular feature of a product is functional is a factual issue. *E. g.*, *Vuitton et Fils S.A. v. J. Young Enterprises, Inc.*, 644 F. 2d 769, 775 (CA9 1981). 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 Prob-

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 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.

Additionally, 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, the District Court’s decision dismissing Ives’ claim that the petitioners violated § 43(a) must be independently reviewed. Therefore, we remand to the Court of Appeals for further proceedings consistent with this opinion.

Reversed and remanded.

lem of Functional Features: Trade Dress Infringement Under Section 43(a) of the Lanham Act, 82 Colum. L. Rev. 77 (1982), a finding of functionality can also be relevant to an action involving § 32. For instance, the trial court’s finding in this action that the capsule colors are functional provides an explanation for the petitioners’ decision to imitate the Ives product’s appearance.

jsw 05/06/82

Memorandum to Justice Powell

Re: SOC's draft in No. 80-2182, Inwood Labs

My general reaction to this draft is very favorable. SOC has written the case narrowly, as an application of the rules of appellate review as elaborated by the Court's recent decision in Swint. Although she has not devoted much space to finding that §32 does in fact cover the theory that the plaintiff advances, the attention SOC does devote refers back to the legislative history of the Lanham Act. See draft at 9 and n. 13. This satisfies the concerns I raised in my bench memo at 3-5.

My only substantive concern revolves around the draft's invocation of the concept of "functionality." This term is of relevance to trademark actions under §43(a) of the Act, as SOC notes in her final footnote 19. The draft, of course, avoids passing on the merits of §43. The functionality doctrine is not of direct relevance to the §32 action at issue in this case, as SOC also notes in that footnote. Importantly, the concept as developed in the lower courts is quite unclear and is the subject of conflicting definitions. (Indeed, the CA3 is in conflict with the CA2 regarding the color of the very pills in this case. The CA3's "functionality" definition led it to conclude that the pill color is not functional, while the DC in this case decided that color was functional.)

Lower courts

SOC defines the term "functionality" in acceptably broad and cautious terms in her note 10. Yet in her note 19 she states

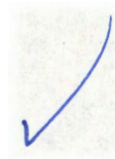
that the issue of functionality "is a factual question." This is true -- in part. But as the conflicting CA "functionality" definitions illustrate, there also is a question of law involved. Consequently SOC's criticism that the CA2 rejected the DC's functionality finding without stating it to be clearly erroneous is only partially justified. As a mixed question of law and fact, the CA2 could have simply disagreed with the DC's legal definition of functionality. The Court would have no legitimate grounds for criticizing the CA2's failure to adhere to the DC's factual finding -- if the CA2 in fact thought that the DC had utilized an incorrect legal definition of functionality.

Consequently SOC's footnote needs a little elaboration to avoid being accused of engaging in faulty criticism. She should point out that the CA2 either should have identified the DC's finding of functionality as clearly erroneous as a factual matter, or should have pointed out that the DC's functionality definition was incorrect as a legal matter. Because the CA2 did neither, it justifiably is open to criticism.

I have spoken to SOC' clerk on this case, and she seemed quite agreeable to correcting this problem. I recommend that you join the draft, but include in your note a comment to the effect that note 19 should be amended to reflect the fact that functionality is a mixed question of law and fact.

Supreme Court of the United States
Washington, D. C. 20543

CHAMBERS OF
JUSTICE JOHN PAUL STEVENS



May 6, 1982

Re: 80-2182 - Inwood Laboratories v.
Ives Laboratories

Dear Sandra:

Please join me.

Respectfully,

Justice O'Connor

Copies to the Conference

jsw 05/08/82

Memorandum to Justice Powell
Re: SOC n. 11 in Inwood Labs

*Jim
Gormley*

After looking through some treatises, it appears that no one case from this Court gives an all-inclusive definition of secondary meaning. The commentators seem to enjoy describing what an amorphous term "secondary meaning" is. But a typical definition is that given by McCarthy: "The prime element of secondary meaning is a mental association in buyers' minds between the alleged mark and a single source of the product." 1 McCarthy, Trademarks and Unfair Competition 516 (1973).

I think SOC's definition could be generalized in adequate fashion by simply replacing the word "producer" with "source of the product." This change is so minor that I doubt it would meet with resistance. In any event, because her present phrasing is a close paraphrasing of the opinion in the Kellogg Co. case, I do not think that it will do any harm or make any new law.

others soon after. Since during the life of the patents "Shredded Wheat" was the general designation of the patented product, there passed to the public upon the expiration of the patent, not only the right to make the article as it was made during the patent period, but also the right to apply thereto the name by which it had become known. As was said in *Singer Mfg. Co. v. June Mfg. Co.*, 163 U. S. 169, 185:

"It equally follows from the cessation of the monopoly and the falling of the patented device into the domain of things public, that along with the public ownership of the device there must also necessarily pass to the public the generic designation of the thing which has arisen during the monopoly. . . . To say otherwise would be to hold that, although the public had acquired the device covered by the patent, yet the owner of the patent or the manufacturer of the patented thing had retained the designated name which was essentially necessary to vest the public with the full enjoyment of that which had become theirs by the disappearance of the monopoly."

It is contended that the plaintiff has the exclusive right to the name "Shredded Wheat," because those words acquired the "secondary meaning" of shredded wheat made at Niagara Falls by the plaintiff's predecessor. There is no basis here for applying the doctrine of secondary meaning. The evidence shows only that due to the long period in which the plaintiff or its predecessor was the only manufacturer of the product, many people have come to associate the product, and as a consequence the name by which the product is generally known, with the plaintiff's factory at Niagara Falls. But to establish a trade name in the term "shredded wheat" the plaintiff must show more than a subordinate meaning which applies to it. It must show that the primary significance of the term in the minds of the consuming public is not the product but the producer. This it has not done. The

showing which it has made does not entitle it to the exclusive use of the term shredded wheat but merely entitles it to require that the defendant use reasonable care to inform the public of the source of its product.

The plaintiff seems to contend that even if Kellogg Company acquired upon the expiration of the patents the right to use the name shredded wheat, the right was lost by delay. The argument is that Kellogg Company, although the largest producer of breakfast cereals in the country, did not seriously attempt to make shredded wheat, or to challenge plaintiff's right to that name until 1927, and that meanwhile plaintiff's predecessor had expended more than \$17,000,000 in making the name a household word and identifying the product with its manufacture. Those facts are without legal significance. Kellogg Company's right was not one dependent upon diligent exercise. Like every other member of the public, it was, and remained, free to make shredded wheat when it chose to do so; and to call the product by its generic name. The only obligation resting upon Kellogg Company was to identify its own product lest it be mistaken for that of the plaintiff.

Second. The plaintiff has not the exclusive right to sell shredded wheat in the form of a pillow-shaped biscuit—the form in which the article became known to the public. That is the form in which shredded wheat was made under the basic patent. The patented machines used were designed to produce only the pillow-shaped biscuits. And a design patent was taken out to cover the pillow-shaped form.⁴ Hence, upon expiration of the patents

⁴ The design patent would have expired by limitations in 1909. In 1908 it was declared invalid by a district judge on the ground that the design had been in public use for more than two years prior to the application for the patent and theretofore had already been dedicated to the public. *Natural Foods Co. v. Bulkley*, No. 28,530, U. S. Dist. Ct., N. Dist. Ill., East. Div. (1908).

Supreme Court of the United States
Washington, D. C. 20543



CHAMBERS OF
JUSTICE BYRON R. WHITE

May 10, 1982

Re: 80-2182 - Inwood Laboratories, Inc.
v. Ives Laboratories, Inc.

Dear Sandra,

I vote to reverse primarily because (1) I thought the Court of Appeals' interpretation of the Lanham Act was wrong -- that it permitted a finding of contributory infringement based on the use of non-functional colors without knowledge or intent that passing-off was occurring, unduly watering down what is necessary to prove contributory infringement; and (2) because I was not sure that the Court of Appeals employed the proper standard of review with respect to functionality. I would not have voted to grant on the basis of our own reassessment of the facts under the proper statutory standard or the proper standard of review, and I would rather not reverse on this basis. I am considering writing separately.

Sincerely yours,

B. Ne
cpm

Justice O'Connor

Copies to the Conference

cpm

May 11, 1982

80-2182 Inwood Laboratories v. Ives Laboratories

Dear Sandra:

Please join me in your opinion for the Court.

I would have no objection to the substitute for footnote 19 suggested by Harry. It seems to me to be helpful.

Sincerely,

Justice O'Connor

lfp/ss

cc: The Conference

P.S. In footnote 11, p. 6, it may be more accurate to substitute "source of the product" for the word "producer" in the third line of the footnote. Although your quote comes from Kellogg, a product may have a secondary meaning without actually identifying the "producer".

Supreme Court of the United States
Washington, D. C. 20543

CHAMBERS OF
JUSTICE HARRY A. BLACKMUN


May 11, 1982

Re: No. 80-2182 - Inwood Laboratories v. Ives Laboratories
No. 81-11 - Darby Drug Co. v. Ives Laboratories

Dear Sandra:

Thank you for your response of May 10. I, of course,
now join your opinion.

Sincerely,



Justice O'Connor

cc: The Conference

Supreme Court of the United States
Washington, D. C. 20543

CHAMBERS OF
JUSTICE LEWIS F. POWELL, JR.

May 11, 1982

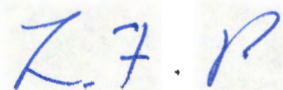
80-2182 Inwood Laboratories v. Ives Laboratories

Dear Sandra:

Please join me in your opinion for the Court.

I would have no objection to the substitute for footnote 19 suggested by Harry. It seems to me to be helpful.

Sincerely,

Handwritten signature in blue ink, appearing to read "L.F.P."

Justice O'Connor

lfp/ss

cc: The Conference

Supreme Court of the United States
Washington, D. C. 20543

CHAMBERS OF
THE CHIEF JUSTICE



May 19, 1982

Re: No. 80-2182 - Inwood Laboratories Inc. v. Ives Labs., Inc.
81-11 - Darby Drug Co., Inc. v. Ives Laboratories, Inc.

Dear Sandra:

I join.

Regards,

Justice O'Connor

Copies to the Conference

Supreme Court of the United States
Washington, D. C. 20543

CHAMBERS OF
JUSTICE WM. J. BRENNAN, JR.

May 20, 1982



RE: No. 80-2182 Inwood Laboratories, Inc. v.
Ives Laboratories, Inc.

Dear Sandra:

I agree.

Sincerely,

Justice O'Connor

cc: The Conference

THE C. J.	W. J. B.	B. R. W.	T. M.	H. A. B.	L. F. P.	W. H. R.	J. P. S.	S. D. O'C.
John D. O.C. 5/19/82	agree 5/20/82	considering writing separately 5/10/82	John John B. W. 5/20/82	John D. O.C. 5/11/82	John D. O.C. 5/11/82	1st draft con opinion 5/10/82	John D. O.C. 5/6/82	3/8/82 1st draft 5/6/82 2nd draft 5/12/82 3rd draft 5/19/82 4th draft 5/28/82
		1st draft con opinion the plaintiff 5/18/82						
		2nd draft 5/24/82						
				80-2182	Inwood Lab. v. Ives Lab.			