In the

ORIGINAL

Supreme Court of the United States

In the Matter of:

INWOOD LABORATORIES, INC., ET AL.,

Petitioners

v. NO. 80-2182

IVES LABORATORIES, INC.; and

DARBY DRUG CO., INC., ET AL.,

Petitioners

v. NO. 81-11

IVES LABORATORIES, INC.

Washington, D. C.

February 22, 1982

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IVES LABORATORIES, INC.		

Washington, D.C.

Monday, February 22, 1982

The above-entitled matter came on for oral argument before the Supreme Court of the United States at 10:56 a.m.

APPEARANCES:

MILTON A. BASS, ESQ., New York, N.Y.; on behalf of the Petitioners.

JERROLD J. GANZFRIED, ESQ., Office of the Solicitor General, Washington, D.C.; as amicus curiae.

MS. MARIE V. DRISCOLL, ESQ., New York, N.Y.; on behalf of the Respondent.

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C O N T E N T S

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P R O C E E D I N G S

CHIEF JUSTICE BURGER: We will hear arguments next in Inwood Laboratories against Ives Laboratories and the consolidated case.

Mr. Bass, I think you may proceed whenever you're ready.

ORAL ARGUMENT OF MILTON A. BASS, ESQ.,

ON BEHALF OF THE PETITIONERS

MR. BASS: Mr. Chief Justice, and may it please the Court:

In this dispute between generic manufacturing companies and brand name companies, the generic manufacturers are seeking to get a larger share of the drug industry, of the drug market. The brand name companies are seeking to retain or increase their dominant position in the prescription drug market. It has been variously reported that they have approximately 90 percent of the prescription drug market at this time.

What the brand name companies are asking, what they're asking for the Court to give them is a monopoly on color. They're asking this for a competitive advantage, and that's why we are here.

Both sides in this dispute claim they speak in the public interest. We believe that our position weighs more heavily in the public interest than that of

the brand name companies.

If the brand name companies are given a monopoly on color, I respectfully submit they will be able to use that advantage for unfair competition whether or not it is found by this Court that there is functionality present.

The question of whether there is functionality will depend upon the definition that this Court lays down. But irrespective of whether there is a fact of functionality, even then I believe it will be used to the great advantage of the brand name companies and to the disadvantage of the generic companies for this reason.

The Respondent and the PMA, the association that represents the brand name companies, have submitted briefs to this Court, and they have said to this Court color serves no function other than to deceive the consumer. They have said that to this Court in order to get the color monopoly they seek.

But when they speak outside of this Court, they do not say color has no purpose or no function. On the contrary, we have found that one company, for example, issued a document to its salesmen for discussion with physicians to convince them that they should prescribe the brand name product and not the

generic product. And they said -- they didn't say what they told the courts, color has no function; they said color has advantages. If you change, some patients may become concerned that it's been changed. They said particularly in the hospitals, if you change the color, if you don't keep prescribing the brand name product, you'll have problems with all personnel handling the medications. Explanations alone will be time consuming. They'll require additional checks. Possible confusion and additional effort will result.

Now, that's --

QUESTION: Isn't there a statute involved in this case?

MR. BASS: A statute?

QUESTION: The Lanham Act?

MR. BASS: Yes, Your Honor.

QUESTION: On that point, Mr. Bass, aren't we really concerned with whether there is a Section 32 of the Lanham Act violation?

MR. BASS: Correct.

QUESTION: We're not concerned properly, are we, with the 43a question, would you agree?

MR. BASS: That is correct, Your Honor. The case comes up on an alleged violation of Section 32, and more precisely, whether the defendant manufacturers are

guilty of contributory liability or contributory violative conduct.

But I would respectfully submit, Your Honor, the question of functionality is essential, in my view, to a consideration of this problem because when these cases have been presented in the district courts, in the lower courts, that is the argument that has been presented to the court time and time again: color has no purpose except to deceive. And I believe that is the reason we're here today; that the lower courts have accepted that proposition.

And therefore, with due respect, I merely wish to point out that no matter what Your Honor decides is the definition of functionality, well, I believe this itself is functionality, that our ability to effectively compete -- I'm not saying we cannot compete -- to effectively compete will be damaged if they can say to the doctor do not prescribe the generic because you'll cause confusion, mistake, error, patient resistance, whether that's true or not, even though we will submit, as I will discuss now, it is true.

So that the strict legal question, Your Honor, you are correct, is are we guilty of contributory violative conduct. But I --

QUESTION: Shouldn't we focus on what standard

of review the Court of Appeals invoked in reviewing the District Court findings?

MR. BASS: Yes, Your Honor. I believe that must be done, and I can do it now, or I intended to address it. The reason I wanted to --

QUESTION: It just seemed to me that maybe a lot of time was spent in the briefs arguing something that we wouldn't end up resolving if we stuck to the question that we were supposed to resolve.

MR. BASS: Well, that is true, Your Honor, but there is one other factor that is relevant. Inherent in applying the standard that the Second Circuit discussed both in Ives II and Ives IV, both the first decision written by Judge Friendly and the second by Judge Mansfield, one of the rules laid down is that you will find contributory liability if you suggest even by implication that you should commit illegal substition or mislabeling. The second part that Judge Friendly mentioned was if you continue to sell to someone you know is illegally committing these acts.

In discussing the question of whether you come within the first prong of that rule, if that is the rule this Court should adopt, that if you suggest even by implication, whether or not there is functionality becomes relevant, separate and apart even from the

question of relief. But even liability itself will hinge on whether there is a complete absence of functionality.

And the reason why the Respondent and the other briefers make great moment of that question is precisely because I believe they cannot sustain any position unless they can convince this Court that color serves no purpose. If color serves a purpose, they have then lost their basic position to get a color monopoly, because that is what they are saying to the Court constituted the suggestion.

Now, I will, Your Honor, be happy to address it right now. When Judge Friendly in Ives II said the standards we're using are twofold -- either you suggest even by implication that you should commit the wrongful act, or you continue selling -- he said also he was adopting Judge Wyzanski's discussion and rule in the Coca-Cola-Snow Crest case. When it came to the Ives IV decision in which the majority opinion was written by Judge Mansfield, he said he was applying that rule, and to come within that rule he said there were a number of factors. He said the color, which was the same. He said there were catalogs and price lists which compared prices and mentioned the color of both products.

Significantly, when the Respondent submitted

its brief in this case, it did not adopt what Judge Mansfield said, even though he ruled in their favor. They are trying to contend and argue that color alone, color alone comes within the rule to constitute the suggestion. And I would respectfully submit, Your Honor, twofold: first, that is not a proper rule to be adopted; and secondly, that this Court of Appeals did not properly apply the rule in terms of showing that there was compliance with the requirement laid down in Ives II, if that is the rule this Court agrees with.

Because when Ives II came before the Court of Appeals, the court effectively said color is not enough to constitute a suggestion by implication or otherwise that you should commit an illegal act, violate the criminal code because we sell it in the same color, because if that were adequate, the Court would not have sent it back and said a trial will have further evidence to see what each side can introduce to try to come within or negate compliance with that rule of liability.

And in that regard I would like to point out what is relevant and significant. When Judge Friendly sent the case back for trial, he said you've give us 15 instances of illegal substitution. I don't think this is of any moment. This is not extensive. Though I might point out we later found out there were really

only four; they found four cases of illegal substitution in the United States -- one in Philadelphia, Pennsylvania, one in Tylertown, Mississippi, and two in New York City.

And what did they do when they came back with the additional evidence? They did not conduct a study, which Judge Friendly asked them to do, to try to show more extensive illegal substitution. They showed -- there was an indictment against six pharmacists for illegal substitution. That was all they showed. But the study they conducted, allegedly to follow the direction of the Court of Appeals, was on legal substitution.

And, Your Honors, I respectfully ask how can legal substitution be connected with or related to contributory violative conduct? In other words, if the substitution isn't legal under the law, how can we say the manufacturer is suggesting to the pharmacist that he comply with the law, sell my product, the generic product but put his trademark on it?

Why? What motive is there for the manufacturer to tell the pharmacist you have the legal right, the law says you can legally substitute? Ives isn't losing a sale. It's not its sale. Under the substitution law it's mine, the generic companies. So

what they did to try to prove what the Ives II court asked them to do was come in with a survey on legal substitution. And I would respectfully submit there was a complete failure of proof.

But what we are trying to ask this Court today is not --

QUESTION: But, Mr. Bass, may I interrupt a minute?

MR. BASS: Yes, sir.

QUESTION: The concept of legal substitution means legal as a matter of state law, don't you?

MR. BASS: That's correct. And, Your Honor --

QUESTION: Well, but the fact that it's legal as a matter of state law doesn't necessarily mean there was no infringement or unfair competition, does it?

MR. BASS: Absolutely, Your Honor. But what I am suggesting is this: they are trying to put in evidence to prove that the manufacturer is guilty of contributory trademark infringement, and they are trying to do it by saying the manufacturer sells his product to the pharmacist in the same color. And they say he's telling him you commit the wrongful act of writing their name on your label to the consumer. And what I am saying, Your Honor, is how do we get that causal connection? What nexus can there be, what motivation?

QUESTION: The only thing I'm suggesting is I don't think your argument turns on whether -- the mere fact that there was legal substitution isn't what's critical. The fact is that there was no wrongful intent or not sufficient knowledge of the likelihood of deception or something of that character.

MR. BASS: Yes. There has to be a showing or proof of culpability on the part of the manufacturer.

QUESTION: But I mean that could exist even though the substitution was lawful. It just seemed to me you're emphasizing a point that is not critical to your argument.

MR. BASS: It is conceivable or theoretically possible, Your Honor, but I think it would be rather difficult to conceive of a generic company acting with guilty intent or wrongful intent or have any thought of wanting to tell the pharmacist by any means -- by telegram, letter, or using the same color here as they're claiming -- to go and commit a trademark infringement when I'm selling a product for a legal sale, and it's being sold legally.

Their theory, Your Honor, was originally that an illegal substitution -- the pharmacist is palming off my product -- so they're saying the manufacturer is trying to get more sales to have his product substituted

illegally. That was their theory, reading into his mind that state of mind.

And I'm suggesting for whatever reason they had, they didn't go out and try to prove more extensive illegal substitution, which Ives II court found no showing of any moment.

But I appear, Your Honors, not primarily to say to you it was applied incorrectly, which I believe the case was decided incorrectly --

QUESTION: Mr. Bass.

MR. BASS: Yes, sir.

QUESTION: May I ask you a factual question? Are the four drug manufacturers that are here in this case the only ones who market this particular drug?

MR. BASS: No, Your Honor.

QUESTION: How many others are there?

MR. BASS: We don't have the exact figure of pharmacists. There's been an estimate of approximately 100,000 users, maybe 25,000 pharmacists.

QUESTION: I'm asking --

MR. BASS: I mean doctors. We don't --

QUESTION: I'm asking only about drug manufacturing companies that manufacture this particular drug.

MR. BASS: How many today?

QUESTION: There are four before us in this case. Are there others in the United States that market -- manufacture and market this drug?

MR. BASS: Yes, Your Honor.

QUESTION: How many?

MR. BASS: The only one I know of, there's a Hauck, there's a regional manufacturer in Georgia. I don't -- there would be some others, Your Honor. I'm not certain of which others.

Incidentally, I must amend, though, the answer, sir. In this case two of -- the two manufacturers, Premo and Inwood, are not presently manufacturing it pending the decision of this case.

QUESTION: So there are only two parties before the Court that are presently manufacturing this drug?

MR. BASS: Ives, yes, that I know of. Actually it's Ives basically would be the one manufacturer.

QUESTION: Do you know whether the company in Georgia that you mentioned markets the drug with the same color and shape distinctions that you are discussing?

MR. BASS: No, they do not. They use a red capsule for their product.

QUESTION: Are there any others who use different colors?

MR. BASS: Not that I'm aware of. I mean right now, yes. After the decision when they were compelled to change --

QUESTION: Yes.

MR. BASS: Yes. The company would have to change.

QUESTION: What is the purpose of using identical colors?

MR. BASS: The purpose of identical colors, Your Honor, is to maximize the ability to compete. One example --

QUESTION: Does that mean the purpose is to cause the public to think that they're produced by the same manufacturer?

MR. BASS: No, sir.

QUESTION: Why not?

MR. BASS: The purpose is to make them think it's the same drug, not the same manufacturer. The purpose -- I'll have to use plural, Your Honor, if I may, with due respect -- the first purpose I tried to refer to is that if we do not make it in the same color, they go to the doctors, who is the purchaser here, who prescribes the product, as I mentioned earlier, and they

say color is important; you'd better prescribe my product or otherwise there will be problems and confusion.

Second, doctors say that. There was an amicus brief by an organization of doctors who also said to this Court color isn't important. But when they issue their own papers here, they say in a poll in Florida there were 99 percent of the people who said if they had a different color they'd call their doctor, and they would have those calls.

Color is important, Your Honor, for doctor-patient communication. When the doctor -- if a person is taking a number of medications and the doctor tells the patient you'll take the red one at 2:00, the green one at 4:00, it's an aid for identification. In that respect it's an aid with respect to co-mingling. When an individual is taking a number of medications, Your Honor, they carry them in a vial. They identify the product by color -- not the manufacturer, by the color.

To the same extent, Your Honor, there is an aid in an emergency situation -- not a final determination but an aid to have the color. Color prevents confusions at all levels -- pharmacy, in the hospitals who handle drugs. Color is an important

factor. It is an important competitive factor because they make it so and because there is resistance.

QUESTION: But from your point of view it aids confusion. Otherwise you wouldn't have copied theirs.

MR. BASS: No. The reverse, Your Honor. For example, the premise determines the answer to Your Honor's question. If it distinguishes the medicine, if we say it's either the same medicine or a different medicine, then it's aiding identification preventing confusion. If it identifies source, then there would be confusion, Your Honor. But that's the key to the issue.

Now, take Ives. When Ives sells its products, it really doesn't use color as a source. It puts out one product in blue, one in orange, one in yellow, and one in green; and it says each color says I am Ives. Lily has a green product, blue product, yellow product that says each color is -- I am Lily.

Is that a rational way to try to identify me as the source? If they really wanted to identify source, Your Honor, they would take a symbol, a star. If they want to put on that capsule a blue star which then they advertise says I am an Ives product on all their products, I think they're right and should do it to identify the source. But the color doesn't do it.

Look at the products in this case. In the 200

milligram they make it in blue. In the 400 milligram they make it in red and blue. Each one -- does that each one say I'm Ives? It will confuse the patient if it was talking about source; but it does tell the patient the truth: I am a different medicine. I, the blue, am 200 milligrams. I, the red and blue, are 400 milligrams.

And, Your Honor, you've touched one of the very problems we have. What they're saying to the Court is give me the color monopoly; force him to change the color so I will be saying to the patient you've got a different medicine, because I speak, color is speaking, saying I am the same medicine or I am different. And if I have to put a different color --

QUESTION: Mr. Bass --

MR. BASS: -- That patient --

QUESTION: Maybe the patients aren't confused, but I am.

MR. BASS: Yes, sir.

QUESTION: You say if they put a star on it it's all right.

MR. BASS: If they want to --

QUESTION: But if they put color on it it's wrong.

MR. BASS: Here's the distinction.

QUESTION: Is that your position?

MR. BASS: That was an example. Let me explain, Your Honor.

My position is the color of the capsule or the pill identifies the product and either says to the patient I --

QUESTION: Well, does somebody go in the drugstore and say I want some red pills?

MR. BASS: No, sir. They don't even say I want anything, Your Honor. That's the point about this industry. In this industry the patient doesn't choose; the doctor is the purchaser. He prescribes and the patient doesn't even see it until he goes home, Your Honor.

But let me explain the star because I'm going to change the star to the name, when I was answering Justice Rehnquist. When the patient picks up the 200 milligram blue from Ives, it has the name Ives on it, the source. When he picks up the red and blue, it has the name Ives, too. So if he wants to use Ives to identify the source, or a star, Your Honor, that's fine. But the appearance, the basic appearance, the basic color speaks to the patient I am the same medicine or a different medicine.

QUESTION: What happens to the color-blind

patient?

MR. BASS: The color-blind patient, Your Honor, will need another method for identification, communication and other purposes. Unfortunately, we cannot solve the whole problem. In fact, one of the unfortunate things, Your Honor, is in my view we should have a requirement that all medications in their overall appearance as to color, shape and size should be the same to prevent confusion and to help in terms of the patient, doctor, pharmacist and nurse in their use of the products, and if there's a sincere need or desire.

QUESTION: But that's not before us.

MR. BASS: It is not before us, but we are trying to accomplish part of the result. The answer is, Your Honor, when I started, why are we here? It's why is because they want to counter the drug substitution laws. Forty-nine states in this country the state legislatures have passed substitution laws stating the public interest be to encourage substitution.

QUESTION: Yes, but, Mr. Bass, those laws don't say anything about color.

QUESTION: Which is the other state?

MR. BASS: Indiana, Your Honor.

Now --

QUESTION: May I ask you a question, Mr. Bass,

about your star example?

MR. BASS: Yes.

QUESTION: You said well, they could use a star, but unless they got a trademark on it, that wouldn't be a different case, would it?

MR. BASS: Yes.

QUESTION: If they do not trademark the star, couldn't you copy the star as well as the color?

MR. BASS: If they don't trademark it, they could get secondary meaning and use it, Your Honor, for identification of source. We would have no problem with that. Our only dispute is that they are trying to get a monopoly upon and appropriate the whole appearance.

QUESTION: Well, do you deny that color can give rise to a secondary meaning?

MR. BASS: No, I don't deny it can.

QUESTION: Well, what's the difference between color and a star then?

MR. BASS: All right. First, I would like to equate the star with the name. The name Ives to identify source or some distinctive little star I would put in the same category. The color is the overall appearance that the patient sees to identify his medicine, as I see it, Your Honor, and I separate what functions they're playing.

You see, in this industry there's something very unique. We are not looking at products that are sitting on a shelf, and a consumer comes in and chooses a product, and there's a question of deception or palming off when he chooses one product against another.

In the prescription drug industry he doesn't even seen it until he goes home after he picked it up at the pharmacy. The doctor prescribes the product and decides what he'll get. So that the overall appearance and color plays no function in the purchase. The whole classic or historical purpose is not present here, so there is a basic distinction, Your Honor, in what we are contending here today.

In answer to Justice Powell's question of functionality, though, if I might state, although we submit that all of these elements that constitute functionality -- questions of patient-doctor communication, the co-mingling problem, the confusion problem, or even what Parke-Davis calls the psychological problem in which they actually issued a paper that color itself answers a positive or negative action. You wouldn't have a certain kind of black pill or a certain kind of other negative pill, Your Honor. We think the emergency aid. We think these are functional, but our submission, as stated earlier, even

if the rule or definition of functionality does not encompass all of those, the reality of the commercial dispute that competition exists here will still exist, and we know that that is not speculation but actually the fact of what is occurring.

Thank you.

CHIEF JUSTICE BURGER: Mr. Ganzfried.

ORAL ARGUMENT OF JERROLD J. GANZFRIED, ESQ.,
AS AMICUS CURIAE

MR. GANZFRIED: Thank you, Mr. Chief Justice, and may it please the Court:

The United States contends that the Court of Appeals incorrectly found contributory infringement in the trade name Cyclospasmol. I'd like to explain why.

QUESTION: What's the Government's interest in this case?

MR. GANZFRIED: This case presents important questions as to federal competition policy, on the one hand between the policy favoring product imitation, which will ultimately hopefully allow for reduced prices to consumers; and on the other hand, the federal policy favoring competition by product differentiation.

QUESTION: Do you think the Lanham Act is the federal policy favoring competition by differentiation?

MR. GANZFRIED: It states so in the

legislative history, in the Senate report that we cited in our brief. It is certainly one aspect of the federal policy favoring competition by product differentiation, so long as there is a distinctive trademark or so long as the company that is seeking the protection has established that the symbol it seeks to protect has acquired in the minds of consumers an identification with the producer.

Now, in this case the only trademark that's involved is the name Cyclospasmol, and any claim of infringement under Section 32 must be rooted in the misuse of that particular word. Keeping this as a central fact in the case in mind, we approach the issues presented under the legal standard described by Judge Friendly in the first appeal in this case and nominally applied by the majority in the second appeal.

Now, that standard that Judge Friendly announced has been referred to by counsel. We contend that the problem with the majority's opinion on the second appeal is that in effect it read the intent element out of the standard and found liability on a lesser showing that Petitioners merely facilitated infringement. In addition, there was error in the Court of Appeals' conclusion -- Justice O'Connor's question earlier as to the standard of appellate review. They

did not find that any of the findings of the District Court were clearly erroneous. Rather, the words they used were "unconvincing" and "unpersuasive." That, we submit, is not an appropriate standard for reversing findings of fact.

Now, as to the question of what the Court of Appeals did find on the second appeal, there was indeed evidence of trademark infringement by a small number of retail druggists. However, the record is absent any proof that the Petitioners in fact suggested or implied this course of conduct to the druggists. To the contrary, the record does support, and the District Court found, that the generic manufacturers label their bottles only with the generic name cyclandelate, never with the trade name Cyclospasmol. And each bottle manufactured by the manufacturing Petitioners clearly states the name of the appropriate manufacturer; thus, there was no direct infringement by the manufacturers.

There was, however, direct infringement when those few retailers mislabeled the generic name as the brand name and failed to inform customers. But the Petitioners could be vicariously liable for these isolated acts of druggists as contributory infringers only if they have the knowledge or intent required by Judge Friendly and the cases recited in our brief. And

as I previously indicated, Ives has no evidence on that particular issue. It merely showed facilitation and relied on the assumption that when presented with identical capsules, pharmacists as a group will be so tempted that they will disregard their professional obligations and statutory responsibilities simply in order to make a fast buck.

Now, this is a pessimistic assumption that's similar to one that the Court was asked to make in Virginia Board of Pharmacy, and the Court properly refused to do so, because in any event this temptation to deceive, which is presented when any product is imitated, whether it be a Singer sewing machine, or Shredded Wheat, or cocoa quinine, or Hungarian bitter water -- whenever a product is copied, there is some temptation presented to those further down the line in distribution to pass it off. But this has never been held to be a sufficient nexus between the manufacturer, who makes no suggestion, merely facilitates, and the ultimate infringement by the retail person.

In fact, the language of the Court of Appeals in the Coca-Cola-Snow Crest case -- I realize that Judge Wyzanski's opinion tends to get a lot of comment, but there is some language in the Court of Appeals decision in that case which bears on this very issue. And that

is that the court said that all that Snow Crest did to make substitution possible was to make their product identical, which it had a right to do.

QUESTION: Counsel, does the Government take a position on the question of functionality of color?

MR. GANZFRIED: The Government takes the position that on this record -- the record is rather sparse as to functionality. I think on this record we'd have to say that the District Court made findings of fact which are in fact not clearly erroneous. As to whether another finder of fact would have found differently is hard to say. The record indeed is sparse. We don't argue --

QUESTION: And the Government takes no broader position than that?

MR. GANZFRIED: We argue that --

QUESTION: On the color question.

MR. GANZFRIED: -- Color can have functionality. We submit that the record here is insufficient to state that in fact functionality has been proved, or for that matter that nonfunctionality has been proved.

QUESTION: And what were the findings of the District Court on functionality here?

MR. GANZFRIED: That the color was functional

and therefore could be copied. In particular, the functionality that the District Court found was the possiblity of avoiding patient anxiety, identifying the capsules in cases of consumers who co-mingled them with other capsules they --

QUESTION: Do I understand the Government either supports that finding or says in any event it was not clearly erroneous?

MR. GANZFRIED: The Government says it was not clearly erroneous. We don't argue, however, that color is always functional or that it is always nonfunctional.

QUESTION: Well, are you -- let me try this out on you.

MR. GANZFRIED: Okay.

QUESTION: Suppose someone came out with a new aspirin, which could readily be done, I assume, and they had the same shape and size but it's tinted pale green. Are you suggesting that that would -- that people are so accustomed to aspirin and bufferin and the related things --

MR. GANZFRIED: We don't know.

QUESTION: -- Being white that the green would --

MR. GANZFRIED: We don't know. That is what the Petitioners argue. As to the evidence on aspirin,

or frankly for any other particular drug, we don't know. But the question is simply, as to functionality, is it a value apart from an identification of the source.

QUESTION: Well, what --

MR. GANZFRIED: For example, if I may take one that appears before me, a question of judicial robes. If there were one company that made judicial robes and made them black, would the second company that made them have to make them green? The question is do you identify the color with the product or do you identify it with the producer; and that is the issue in this case.

QUESTION: Well, in common human experience what would be, in your view, the reaction to people being handed green aspirin?

MR. GANZFRIED: My personal view?

QUESTION: Yes.

MR. GANZFRIED: They would think it was something other than aspirin.

QUESTION: Well, common human experience which you share.

MR. GANZFRIED: I frankly couldn't base it on anything other than that. I think that's right.

QUESTION: Well, that's not what Judge Friendly said in the original opinion. He gave certain

tests, didn't he?

MR. GANZFRIED: As to functionality.

QUESTION: Yes.

MR. GANZFRIED: And as to secondary meaning.

QUESTION: And they were not followed.

MR. GANZFRIED: Well, the Respondents did not satisfy the tests that Judge Friendly set down, and the panel on the second appeal in effect read the intent element out of the test.

QUESTION: I understand.

MR. GANZFRIED: Now, let me separate this question of Section 32 and the question of Section 43. Section 32 is the only issue that is presented to this Court. We submit that 43 should be remanded. But 32 is the one that is rooted in the trademark, the name, and the misuse of that name. Are the Petitioners contributorily liable?

Section 43 would be an issue relating to the non-trademark features, namely the colors. So the discussion of functionality, the discussion of secondary meaning is largely an analysis that would come within Section 43 rather than Section 32 which is the issue presented to this Court.

QUESTION: Counsel, the Court of Appeals relied also on the distribution of the comparative

prices?

MR. GANZFRIED: That's correct.

QUESTION: Isn't that right?

MR. GANZFRIED: The Court of Appeals did refer to that. We submit two points on that. One is that in the previous cases that has not amounted to sufficient conduct to constitute suggestion or active inducement and thereby to bring someone contributorily liable.

QUESTION: Well, in fact, how are you going to get competition if you don't --

MR. GANZFRIED: You have to do it.

QUESTION: -- Comparing prices.

MR. GANZFRIED: You have to do it. It is protected speech. It is precisely the speech that was at issue in Virginia Board of Pharmacy. Can you provide price information: I will sell X to you for Y.

There is an interesting issue about that and that is an apparent factual mistake in Judge Mansfield's opinion. The only price list that listed both the brand name and the generic prices side by side was one price list. It was not of a manufacturer; it was of a distributor who in fact sold both the brand name and the generic.

Now, I submit on the cases that that is not sufficient to constitute the inducement to make out a

case of contributory infringement.

QUESTION: Is there any controversy about that here?

MR. GANZFRIED: Excuse me?

QUESTION: At this point?

MR. GANZFRIED: Very little has been said about the advertisements. They don't seem to be relied on as a basis for upholding the Court of Appeals decision, and I submit that in fact they cannot properly be used as a basis for that because it is simply adding information that gets ultimately to the druggist and allows him to buy what he would like.

QUESTION: Before you sit down, I just want to be sure I understand your argument on functionality or nonfunctionality. Your submission is that even if color has no function to play, there still is not sufficient evidence of intent to cause the retailer to infringe.

MR. GANZFRIED: The function of the color is something that has to be removed entirely from Section 32, because the color was not the trademark feature that was the basis of the finding of contributory --

QUESTION: Really, the Government's position just boils down to a suggestion that there was a failure of proof of --

MR. GANZFRIED: There was a failure of proof.

QUESTION: There's no really big issue in the case.

MR. GANZFRIED: Under the standards that Judge Friendly set down we submit that the standard that Judge Mansfield ultimately used as to Section 32 read the intent element out and was incorrect in that respect. There was also the question of --

QUESTION: Let me ask you this. Under Judge Mansfield's standard suppose they used a different color, but they had everything else the same. Do you think there would be contributory infringement?

MR. GANZFRIED: Under Judge -- and there were no suggestion?

QUESTION: Just the -- everything's the same except they have different colored products. Under Judge Mansfield's standard would the generic druggist -- generic manufacturer be guilty of contributory infringement?

MR. GANZFRIED: Presumably not, because Judge Mansfield apparently assumed the fact of suggestion from the identity of the color.

QUESTION: Suggestion to whom?

MR. GANZFRIED: Excuse me.

QUESTION: Suggestion to the retailer?

MR. GANZFRIED: Yes. Judge Mansfield assumed

that by using the identical colors, the manufacturers were thereby suggesting to the retailers that they pass off. And in our view that is insufficient proof, and that is an inappropriate standard for judging liability under Section 32.

QUESTION: I understand your brief to say that the case should have been decided under Section 43b rather than 32.

MR. GANZFRIED: 43a.

QUESTION: 43a.

MR. GANZFRIED: That's correct. That was the chief issue of trial. That was the chief issue on the appeal.

QUESTION: Is it your suggestion the case should be remanded to be decided on that statute?

MR. GANZFRIED: We believe that that is really what is at issue here, and clearly there should be a remand for a finding under Section 43a. It's not been briefed in this Court by the parties. There is a complete record in the Court of Appeals, however. Our suggestion was that it would be most suitable in the circumstances for a remand on that issue and for a reversal of Section 32.

Thank you.

CHIEF JUSTICE BURGER: Ms. Driscoll.

ORAL ARGUMENT OF MARIE V. DRISCOLL, ESQ.,

ON BEHALF OF THE RESPONDENT

MS. DRISCOLL: Mr. Chief Justice, and may it please the Court:

I think I, too, should begin with informing the Court just why we are here today and why the finding of contributory trademark infringement was in fact clearly supportable on the record.

I have lodged with the Clerk of Court, and you may wish to look at what actually is involved in this case. We have vivid blue capsules made by Ives. The defendants -- and this an exhibit in the record -- had tens of thousands of color combinations from which to select, and they selected exactly the same colors when they decided to sell generic cyclandelate.

QUESTION: For the same content?

MS. DRISCOLL: The same active ingredient, Your Honor.

QUESTION: The same -- well, active ingredient. The same total content?

MS. DRISCOLL: There is not at issue in this case, because we did not raise an issue, as to what in addition to the active ingredient they may have in their product. That has been involved in some other cases as to whether the binders and excipients are the same. But

we have not claimed in this case that for purposes of, for example, the substitution law in New York which is involved, that these products are not in fact equivalent.

QUESTION: The capsule is the same size?

MS. DRISCOLL: The capsules are exactly the same size, and the defendants' capsules, to make things even worse, are completely, or were at the beginning of this suit, completely anonymous. Their own executives at depositions looked at their capsules, and they couldn't tell where there product came from.

QUESTION: Did you say, Ms. Driscoll, copies of that are around here?

MS. DRISCOLL: Yes, Your Honor. I believe they're lodged with the Clerk. I had ten facsimiles made.

QUESTION: I thought that was corrected, though, wasn't it? I mean your case doesn't depend on that. They could have their own name on it.

MS. DRISCOLL: They have -- well, you will see, Your Honor, also that I have included in the upper righthand samples of their capsules which have markings on it, the names or MDC number; and in each case - and there have been many cases brought recently involving the duplication of color of prescription drug capsules -- it's been held that the imprint is so small -- and I

think the Court will agree -- it is so small --

QUESTION: Well, but isn't it your legal position that even if the imprint were large, you would still make the same claim about their using the color?

MS. DRISCOLL: Yes, I would.

QUESTION: So now why are you arguing that it's significant that it's not legible.

MS. DRISCOLL: That it is not -- I'm not saying it's significant. I'm saying it's so small --

QUESTION: It's just a matter of interest.

MS. DRISCOLL: It's so -- yes. And also in this exhibit you will see at the lower right the capsules of W.E. Hauck Company. That is the company to which reference was made in Mr. Bass' argument. That company sells generic cyclandelate, but it is not a copycat.

QUESTION: Let me give you a hypothetical practical question. Suppose you have a patient with diabetes, for example, or something of that kind where they lifelong or for a long period of time take a particular prescribed medicine. And at some point either the pharmacist acting on his own under this dual prescription of the New York law or the physician himself in order to save the patient money says give them the generic drug; it's the same thing.

Now, if it comes in a different color, do you say that creates no problem, psychological or whatever, for the patient?

MS. DRISCOLL: No. There has been extensive evidence on this, Your Honor. Physicians testified. We have physicians totaling, if you count up the plaintiffs' and the defendants' physicians, with 125 years of experience total in treating patients where they have had color change. Color change comes about fairly frequently in this industry because there are many companies that sell generics that do not duplicate the appearance of the pioneer or market leader.d

And while the patients may inquire and may say I notice why is this green this month, it's always been red, hasn't it, the testimony is when the pharmacist or the physician explains you're getting a generic because it's the same product, we believe it's cheaper, patients accept that. There was one patient who refused to accept a change -- we do not know whether it was because of color or because he simply didn't want a generic -- from one of the doctors that the defendants produced.

On the other hand, we have significant evidence that color changes all the time, for example, in institutional settings. Hospitals and government institutions for years have bought generics, and they

buy on the basis of the best price, also quality, and their colors change frequently. Patients in the hospitals are used to this, and these would be the same patients who at home may be getting a different color. When they go to the hospital they get a different color generic. The testimony was there really is no problem.

The government does not require that color be part of the bidding process, for example..

QUESTION: Well, would you agree that there's a difference between the patient in the hospital and the patient taking a medication long-term at home without constant medical guidance; that is, there's a nurse or an intern or a doctor or a resident in the hospital to explain the change.

MS. DRISCOLL: That's true.

QUESTION: At home the patient is --

MS. DRISCOLL: You can make a phone call, that's correct, which does happen. That's right.

QUESTION: Do you acknowledge that there is a difference, that it's more readily explained to the patient in the hospital than it is to the other patient?

MS. DRISCOLL: Well, there are more people to explain it. Once the explanation is made I'm not sure it's more readily accepted one place or another. There doesn't seem to be a distinction on that.

And I might add that the particular product involved in this case is a long-term medication for poor circulation.

QUESTION: Ms. Driscoll, you're arguing the facts, which I think you're really entitled to do, but you started out by saying you thought there was -- or early in your argument you said you thought there was support in the record for the finding that there was a Section 32 violation.

MS. DRISCOLL: That's right.

QUESTION: Whose finding were you talking about, the Court of Appeals?

MS. DRISCOLL: The Court of Appeals application of the law, yes.

QUESTION: Well, the District Court had found no Section 32 violation and had a series of factual findings. Did the Court of Appeals set aside any of the District Court's findings?

MS. DRISCOLL: Yes.

QUESTION: And did it do so on a clearly erroneous standard or not?

MS. DRISCOLL: While the Court of Appeals did not specifically use the words "clearly erroneous," it would be a matter of semantics to say that it was not applying such a standard, because the Court of --

QUESTION: Well, you agree that it should have, and that it did furthermore.

MS. DRISCOLL: And that it did, yes, because it said, for example, on the question of the mislabeling that occurred, there was no support --

QUESTION: Well, you're not suggesting that the Court of Appeals was free to arrive at its own independent finding?

MS. DRISCOLL: No, I'm not suggesting that, nor do I believe it did. The language is very strong, and I'll quote. There's no support in the record for the defendants' claim that the mislabeling that occurred was because of confusion. There's no persuasive evidence on this point. Arguments that the defendants made and testimony on another point are unconvincing. There's no evidence of patient confusion. There's no evidence that doctors or druggists refused to explain --

QUESTION: Well, do you suggest that the Court of Appeals -- or I'll just ask you directly. Do you think the Court of Appeals applied a different standard of law with respect to a Section 32 violation than did the District Court?

MS. DRISCOLL: It's hard to tell what standard of law the District Court applied because --

QUESTION: Well, did it require an intent, or

did it not?

MS. DRISCOLL: It appeared on both the motion for preliminary injunction and after trial to require not only intent but almost active participation. The language is not that clear.

QUESTION: You mean the District Court.

MS. DRISCOLL: The District Court, yes.

QUESTION: But how about the Court of Appeals?

MS. DRISCOLL: Well, the Court of Appeals did not specifically use the word "intent," but in determining whether or not Section 32 has been violated and whether there's been a trademark infringement, specific intent to infringe is never an element of tradement infringement.

QUESTION: So if you say the District Court had an intent requirement in its appraisal of the facts --

MS. DRISCOLL: That would be incorrect.

QUESTION: You -- that would be incorrect, and you suggest the Court of Appeals did not adopt a -- did adopt a different standard than the District Court.

MS. DRISCOLL: Yes, unless you can interpret the --

QUESTION: Well, then, if that's so, if there was an error of law in the District Court, why wouldn't

it have been the proper proceeding, proper procedure to remand for a new trial under the right standard rather than the Court of Appeals arriving at its own independent view of the facts?

MS. DRISCOLL: Well, as I say, it is not possible to tell whether the court in fact was reversing on a clearly erroneous basis or whether it was applying the law differently. It had the complete record in front of it.

QUESTION: Well, you just -- I thought you just conceded or just said that the Court of Appeals standard was different from that adopted by the District Court, legal standard. The District Court had an intent standard. You say that was wrong, and the Court of Appeals said it was wrong.

MS. DRISCOLL: No. No. It is possible that when the Court of Appeals held that the defendants were liable for the clear acts of trademark infringement by the pharmacists that the Court of Appeals was also applying an intent standard, the intent being the intentional copying of the color, the intentional hiding of the source of the product, the intentional distribution of pamphlets in which the defendants indicated to whoever purchased their product, look, this is the same color.

QUESTION: Well, you say the standard the District Court applied was wrong. You just said so a moment ago.

MS. DRISCOLL: The result was wrong. The result was wrong.

QUESTION: Well, you said the standard was wrong. You said they applied an intent standard that was wrong.

MS. DRISCOLL: The District Court standard went beyond intent because it implied there had to be almost an actual participation.

QUESTION: Well, however -- whatever standard it was, you say it was wrong.

MS. DRISCOLL: That's right.

QUESTION: And you say the Court of Appeals corrected it.

MS. DRISCOLL: Corrected the result, yes. Whether it --

QUESTION: Corrected the standard.

QUESTION: Can you suggest any reason why there is no reference to Rule 52 in the Court of Appeals opinion?

MS. DRISCOLL: Well, all I can suggest is the Court was applying the standard in United States against Gypsum which indicated that a finding can be reversed

when the reviewing court on the entire evidence, and this Court has said, is left with the definite and firm conviction that a mistake has been made. And this standard has been repeated in U.S. against Singer.

There were many undisputed facts in this case. There were many elements of proof in this case that the defendants never produced at all. So in other words, it wasn't even a finding. There was nothing put in. There was no testimony as to patients. No patients appeared. No survey was put in by the defendants indicating patient concern about color change. And the applicable standards as applied to the facts were considered incorrect by the majority of the Court of Appeals.

I don't think it had to specifically refer to Rule 52 or specifically use the words "clearly erroneous."

QUESTION: With respect to this whole subject, could I focus your attention specifically to the District Court's finding that color is functional and that it has no secondary meaning in these circumstances. What is there in the record to suggest that the District Court clearly erred in making that finding?

MS. DRISCOLL: If the record is reviewed, and

I'll take first the function record, the record on whether this is functional or not, we have a situation where it's undisputed that the drug in question is a white powder. Color has nothing to do with it, if we go back to the normal standards of what function means.

Initially, Ives could have made this drug in any color. It, for a purely arbitrary reason, chose the blue and the blue-red. So there is no inherent functionality, and that is undisputed, and I believe even the District Court admitted that there's no inherent functionality.

Judge Friendly on the first appeal agreed that this was arbitrary, had no relationship to the underlying drug, and indicated that whether or not the colors had become functional, had somehow acquired functionality, would depend on proof offered by the defendants.

Now, if you look at the proof offered by the defendants, you find that there are three physicians who testified before the defendants; and I'm assuming now that although there was no finding as to credibility, we'll eliminate completely all the plaintiffs' evidence on this, but let's just look at what the defendant put in on functionality through its physicians.

They all agreed that there are many non-look

alike generics on the marketplace, and that they had had experience with them; that if their patients inquire why is there a color change, the patient accepts the explanation for the color change. One physician who sees approximately a thousand patients a year and has practiced for 16 years -- that's the defendant's Dr. Bloom -- said that once, once in his entire practice a patient did not accept his explanation and asked to go back to the original drug.

A second doctor, Dr. Schinback, couldn't recall of a single instance in his practice where the explanation wasn't accepted. In other words, if you say it's a different color because I'm giving you a generic, I want you to get a less expensive drug, patients accept that.

The third doctor, who hadn't practiced for several years and is now with the New York Health and Hospital Corporations, testified that several years ago some of her patients who had Parkinson's disease did not want to change the source of their medication; and it was not clear that color had anything to do with that, but whether they might have been concerned about the true source of the medication. And at the Health and Hospitals Corporation where that witness of the defendant was then employed, it was clear that all

purchasing decisions as to whether generics are to be accepted are made not on the basis of color but price.

Color simply is really not a determining factor in whether institutional sales can be made. The FDA, which has primary jurisdiction over the safety and efficacy of drug products, has specifically said in response to pressures by the generic drug industry to have a color requirement that they do not believe that safety and efficacy require that the drug color be the same.

QUESTION: Ms. Driscoll, may I ask a question about the examples of infringement on page 10 of your brief? As I understand it, the thing you objected to primarily was that the retail druggist would use the name Cyclospasmol and then put something additional that was a little bit ambiguous, like they might put the word "generic" or "gen" or something like that, and those are examples of the infringement of which you primarily complain.

MS. DRISCOLL: Yes. There are several types, Your Honor. We had collected and put in evidence at trial approximately 34 instances --

QUESTION: Right.

MS. DRISCOLL: -- Where a bottle containing a generic look-alike had the Ives trademark on the label

put on there by the pharmacist.

QUESTION: The word "Cyclospasmol." I take it you object to any use of the word "Cyclospasmol" by the druggist?

MS. DRISCOLL: I object to the uses in this case.

QUESTION: Well, but in any event, could not the generic manufacturer and the druggist continue to do exactly what they've done here even with different colored capsules?

MS. DRISCOLL: Yes, but they'd be less likely -- they'd be more likely to --

QUESTION: So it's a question of probabilities.

MS. DRISCOLL: Yes.

QUESTION: Well, how -- of course, your case is one where the patient used the same drug over and over again. But with the first subscription why would the patient have any knowledge about it?

MS. DRISCOLL: The very first time someone gets a drug is simply not at issue in this case, because there would be no recognition by the patient, no understanding by the patient that he should --

QUESTION: So the color wouldn't make any difference in that situation.

MS. DRISCOLL: However, it could make a

difference if the pharmacist --

QUESTION: Does the record show these were all refills?

MS. DRISCOLL: No. Most -- many of these, Your Honor, would have been situations where we sent a shopper out.

QUESTION: As though he were getting his first prescription filled.

MS. DRISCOLL: Yes.

QUESTION: And he would have been equally misled if the color were not the same.

MS. DRISCOLL: Yes, but the pharmacist wouldn't know that it was the first prescription. They could have had a prescription from another doctor.

QUESTION: Well, the pharmacist can usually tell by the date whether it's a refill or not, can't he?

MS. DRISCOLL: I'm not sure of that, Your Honor. It could have been a different pharmacy from the one before and a different community.

QUESTION: But I mean the doctor's prescription is usually dated, isn't it?

MS. DRISCOLL: Dated? Yes.

QUESTION: Does your argument draw any distinction between the kind of drug you have where it's largely refills and the same situation in which it was

kind of just one prescription drugs?

MS. DRISCOLL: No. The likelihood of abuse I believe is worse in the case of maintenance drugs because of the recognition.

QUESTION: I should think that it would be the other way around, that the one who only gets the drug once wouldn't know what it looked like or anything right then. He'd have no way of protecting himself against a complicated name followed by "Gen" or something like that.

MS. DRISCOLL: That's true, but he may not -- he certainly would be -- he would be unlikely to detect a problem, but so would my person be unlikely to detect a problem if it's in the same exact color.

A patient -- and this goes --

QUESTION: What I'm trying to suggest to you is the problem, as long as you're selling the same drug and advertising it as performing the same function biotically and so forth and so on, the problem's always going to be there, isn't there?

MS. DRISCOLL: That's true.

QUESTION: That there's a risk that the druggist who is unscrupulous will say look, I can give you something cheap -- well, may not even say that -- that will sell it more cheaply but just put that kind of ambiguous legend on that a lot of people really don't

understand very well anyway.

MS. DRISCOLL: That's true. And the problem is --

QUESTION: So I'm just wondering if color really is the critical problem, or is it selling generic drugs?

MS. DRISCOLL: Color is critical because it makes it -- and it's been admitted in this case and stipulated that it makes it more likely for the pharmacist to do this because he doesn't think he's going to be detected, whether by, for example --

QUESTION: Do we know that any of these pharmacists had that particular decisionmaking process?

MS. DRISCOLL: No, we don't. We just know that they dispensed --

QUESTION: It just seemed reasonable to the judge --

MS. DRISCOLL: -- Dispensed a look-alike drug and called it Cyclospasmol.

QUESTION: May we return just a moment to the standard? The Solicitor General suggested, as I recall, that a guilty state of mind -- excuse me -- was necessary, was a necessary element to prove a case under Section 32.

MS. DRISCOLL: Well, I believe we do have a

guilty state of mind, and we look back again to Judge Wyzanski's decision, which has been cited so frequently, and that Judge Friendly characterized on the first appeal as providing the proper criteria. And that is, is the person furnishing this look-alike, does he know he's dealing with customers who are peculiarly likely to use the product wrongfully?

And we have a very unfortunate history, both in cases, in FTC reports, and really in knowledge generally available to the drug industry, that pharmacists have an unfortunate history -- not all of them, but enough of them to be a serious problem -- of in fact dispensing cheaper products in filling prescriptions for another product and pocketing the monetary difference.

And on this point of --

QUESTION: You mean by that charging for the brand name but actually delivering the generic drug? Is that what you're saying?

MS. DRISCOLL: Either that, Your Honor, yes, and that does happen, or charging more for the generic than they might otherwise do because the patient is not going to know when he sees something that looks just like the Ives capsule that he should be getting a price break.

And you'll see in the Attorney General -- State of New York Attorney General report, which is in evidence in this case, that very often in New York pharmacists are in fact filling generic prescriptions and charging more than other pharmacies charge for the brand name. The pricing patterns are erratic, but certainly there is no pass-along of the full generic saving or even much of the generic saving to patients who are getting prescriptions filled in that state and I believe in others, but certainly not in New York.

And a change in color in this instance, if it would alert the patient to inquire of the pharmacist why is the capsule green this time instead of blue, the patient would also be able to detect the economic problem and ask the pharmacist why am I paying the same amount as I always paid for the name brand.

QUESTION: Does the record tell us what percentage of retail druggists engage in this kind of practice?

MS. DRISCOLL: As to the straight mislabeling --

QUESTION: Just say infringement, the whole category of infringment.

MS. DRISCOLL: Okay. Of the mislabeling as opposed to the illegal substitution, our survey, which

was projectable to pharmacies in New York State, indicated there was a 29 percent of the pharmacists put our trademark on their look-alike.

CHIEF JUSTICE BURGER: We'll resume there at 1:00, counsel.

(Whereupon, at 12:00 p.m., the case in the above-entitled matter was recessed for lunch, to be reconvened at 1:00 p.m., the same day.)

AFTERNOON SESSION

(1:00 p.m.)

CHIEF JUSTICE BURGER: Ms. Driscoll, you may continue.

ORAL ARGUMENT OF MARIE V. DRISCOLL, ESQ.,

ON BEHALF OF RESPONDENT -- Resumed

MS. DRISCOLL: I believe I was in the middle of an answer to a question from Justice Stevens about the frequency of the infringements, and we have to look at those infringements in a few ways.

When we're talking about the legal substitution but followed by mislabeling or passing off, our survey showed that this occurred 29 percent of the time in the pharmacies in New York where the shopping was done. In this particular case, while we have many instances of illegal substitution and mislabeling, that is not projectable. There was not a projectable survey done on that. So I cannot say what the percentage is, but it's clear from the history of the pharmaceutical industry, from the FTC report that is referred to many times in the briefs, and from other look-alike cases, of which there have been many recently, that there is a substantial amount of illegal substitution and therefore infringement involved. In the FTC report I believe it was said to be as high as 25 percent of the time.

QUESTION: I meant to ask you also, if I could, is it your view that any time the word "Cyclospasmol" is used on the label there's an infringement? Supposing, for example, a druggist said this product is a generic equivalent to Cyclospasmol; he spelled it all out. Would that --

MS. DRISCOLL: No. I would have to take the position that if there were a clear and unequivocal statement like that, there would not be an infringement because there would not be a chance of misunderstanding.

QUESTION: Well, supposing in each of these cases where you just have the "Gen," say the druggist had explained; he said you understand, don't you, the doctor said we can substitute, and that's what we've done?

MS. DRISCOLL: Well, that would put us once again at the mercy of the pharmacists. In the particular shoppings we did the only reason the pharmacist disclosed anything to the shoppers that went in was that our shoppers were instructed as part of the survey instructions to ask whether or not a generic had been dispensed. But because of the peculiar way in which prescription drugs reach the public and because of the fact that the pharmacists are passing off these look-alikes, we do not want to be in a position where we

are relying on the good faith of the pharmacists, because we see this problem already.

QUESTION: Well, I understand that, but I'm not clear what your answer to my question was. Supposing that the pharmacist says this is a generic equivalent to Cyclospasmol, and he just has the writing, you say. Would that be infringement then?

MS. DRISCOLL: Well, the person receiving the bottle presumably would not be confused, and to that extent there would be no infringement; but anyone else who saw the bottle, for example, such as the physician should something have gone wrong with the product and the patient said this doesn't seem to be working the same way, here's my bottle, to that extent anyone else who saw labeling like that would in fact --

QUESTION: Well, the doctor wouldn't be confused. He would know what the "Gen" meant, wouldn't he?

MS. DRISCOLL: Not necessarily. He may.

QUESTION: You mean the doctor doesn't understand --

MS. DRISCOLL: Some of these designations, "Gen" may mean something. A "G" or an "EQ" may not. There are all sorts of gradations.

QUESTION: But if -- if a doctor -- if a

doctor participates in this process of permitting a druggist to substitute, is he -- can he be liable, too, under the -- under 32 or under -- I guess he couldn't be under -- couldn't be under -- but he could -- how about 32?

MS. DRISCOLL: No. See, the physician is in an unusual circumstance in most states, Your Honor. In most states substitution is not mandatory so that when a physician, for example, writes a prescription and indicates that a generic can be dispensed, that does not mean that the pharmacist must dispense a generic.

QUESTION: Well, I know, but isn't he like the manufacturer putting the druggist in a position to pass off?

MS. DRISCOLL: No, he's not, because he is not providing the druggist with the means by which the patient is fooled.

QUESTION: Well, he's -- he could have prescribed a trade name product, though, I suppose.

MS. DRISCOLL: Yes, he could have, but he has no control over what's finally given to the patient or what the labels given to the patient say.

QUESTION: Well, he has more control --

MS. DRISCOLL: Except in a mandatory --

QUESTION: He has more control than the

manufacturer.

QUESTION: I would think so.

QUESTION: Without the prescription the druggist can't even do it.

MS. DRISCOLL: No, but he has no control over -- let's talk about these look-alikes.

QUESTION: Yes, but if the druggist follows his instructions, the doctor has quite a bit of control.

MS. DRISCOLL: If his instructions are followed, and he, of course, has no way of knowing whether his instructions are followed because he is unlikely ever to see, unless there is a problem, what has been dispensed.

QUESTION: Well, neither does the manufacturer, but the manufacturer gets -- is being held liable on the grounds that he impliedly -- that he facilitates the passing off.

MS. DRISCOLL: That's right, because there is no independent reason for that manufacturer to make these products in the look-alike form. They could just as easily make those products in the colors that, for example, Hauck uses where the opportunity for wrongdoing or the likelihood of wrongdoing would be far less, whereas the physician has presumably independent and good reasons for prescribing either the branded product

or the generic. These people have furnished, as the Court of Appeals indicated, no good reason whatsoever for copying the appearance. Many other manufacturers are on the market with non-look alikes, and with non-look alikes you give the patient an opportunity to know that something has been changed. The change isn't concealed. As a matter of fact, if --

QUESTION: The question is whether the statute imposes a duty on them to have a reason. I mean there's no sort of general law that you've got to have a reason for making something blue instead of red.

MS. DRISCOLL: No, but you do have an obligation not to be the person who facilitates, makes more likely, or allows these pharmacists in many more instances to --

QUESTION: But if that's the test of secondary infringement, the doctor is clearly guilty, if he just makes it more likely or makes it possible.

MS. DRISCOLL: But he hasn't furnished the look-alike that prevents the patient from finding out.

QUESTION: He's given the authorization to purchase it.

MS. DRISCOLL: Well, Your Honor, I can't see that the analogy flows, because the doctor is not providing --

QUESTION: In fact, his authorization would apply even if the thing is a different color.

MS. DRISCOLL: Yes.

QUESTION: He would make it possible for -- in any generic drug to make it possible for the unscrupulous druggist to substitute.

MS. DRISCOLL: That's right.

QUESTION: And write the word, whatever the word is plus "Gen."

MS. DRISCOLL: That's right. And if it is in fact a different color, the patient will do exactly what --

QUESTION: And the patient has never even seen the drug before in most cases, so how would he know what the color is?

MS. DRISCOLL: Well, in this -- in this case because it is a maintenance drug, the patient is very likely --

QUESTION: Well, your case really rests on the fact that it's a maintenance drug then.

MS. DRISCOLL: Well, it is more likely that a patient will be alerted to the fact that he should inquire about a color change if it is a maintenance drug, yes.

QUESTION: But all that seems to me is that

it's more likely that there will be confusion or misunderstanding if it's not a maintenance drug, because they don't know what color to expect. All they get is a prescription, and they go in, and the druggist gives them a generic substitute.

MS. DRISCOLL: Well, to that extent those patients have less of a way to protect themselves. However, the pharmacist --

QUESTION: He'd have to rely on the druggist and the doctor.

MS. DRISCOLL: But the pharmacist doesn't necessarily know this. And if a pharmacist has a look-alike, the pharmacist admittedly in this case is more likely to take the chance of passing off and take the chance of illegal substitution because it is so much less likely that he will -- that his subterfuge will be detected.

QUESTION: Particularly if nothing happens to him when he does the substitute, and I guess nobody ever goes after the pharmacists.

MS. DRISCOLL: The Attorney General's report in the State of New York indicated that violation of the New York substitution law, for example, is given a very low priority.

QUESTION: Ms. Driscoll --

QUESTION: To what extent --

QUESTION: Go ahead.

QUESTION: To what extent does your case turn on proof of intent to deceive?

MS. DRISCOLL: Specific intent to deceive by the manufacturers, it does not turn on the specific intent to deceive. What it does turn on is the manufacturer's knowledge that in the prescription drug industry there is a very special circumstance, namely there is an individual intermediary, the pharmacist, who unfortunately as widely known in the industry and all the cases, has a proclivity toward trying to get away with something to make himself more money, either through illegally substituting or just through -- even through in this case legally substituting but misbranding and charging more money.

In the circumstances, given the fact that these were identically copied -- they didn't have to be; they could have done what Hauck did -- given the fact that they all admit that the identical copying of the color in fact made illegal substitution and misbranding more likely to occur and far less likely to detect, and given the fact they knew they were dealing with a very particular industry -- and I also suggest that it would not be offensive to hold these prescription drug

manufacturers to a very high standard to make sure there isn't deception. Public policy certainly is to hold prescription drug manufacturers to very high standards. They're the only industry I can think of who can't even sell their products without prior approval. These people --

QUESTION: Ms. Driscoll, why doesn't the clear marking on the capsule go a long way toward solving the problem of druggist misconduct. Mislabeling is very easy to detect when it's printed right on it Ives.

MS. DRISCOLL: Well, these drugs are taken principally by elderly people, and there is no evidence that --

QUESTION: Well, now we're talking about pharmacist misconduct on which you have been relying. Certainly the pharmacists can read, and they understand that if it says Ives, it's not something else.

MS. DRISCOLL: Yes. And the pharmacists can also read the original manufacturers' bottles and know what they're dispensing. It's not that the pharmacists are making mistakes, but the pharmacist, even when there is an imprint on this capsule, knows that people don't pay that much attention to the imprint. These are very small imprints because of the nature of the product. Obviously it's a small capsule.

QUESTION: Well, if Ives is so concerned, I suppose they could print a bigger name on the capsule.

MS. DRISCOLL: It's almost -- it's very difficult to do much more than what is done and still have it visible. And there's no evidence that the public would derive -- would really look at this. They look at the colors.

We did a survey of patients in this case, Justice O'Connor, in which we showed the patients a -- containers, three containers, one of which had -- two of which had completely anonymous capsules which the District Court opinion in this case would sanction, and the third of which had capsules clearly imprinted with the name Premo. And when asked what those capsules were, even the imprinted ones, patients still thought they were the Ives Cyclospasmol. The imprint does not, and has been held in all these cases not to have an effect. Even the District Court in this case said that because of the size of the product we're dealing with and the fact that we do have elderly patients who might not see as well that the imprint simply does not make an effect.

CHIEF JUSTICE BURGER: Your time has expired now, counsel.

Do you have anything further, Mr. Bass?

ORAL ARGUMENT OF MILTON A. BASS, ESQ.,

ON BEHALF OF THE PETITIONERS -- Rebuttal

MR. BASS: Thank you, Mr. Chief Justice. I do.

I would like to first note, Justice Stevens, that in the question that's been answered as to the survey and the projectability of this 29 percent, that survey of mislabeling where the generic was dispensed as permitted in the prescription, they had 10 pharmacists who used the name Cyclospasmol in some form on the label. Nine of those 10 told the patient you're getting a generic. And when they charged the patient, the average price charged was $6.50; when they gave the brand name it was $13 in that study. That is the study counsel was referring to, Your Honor, in the projection --

QUESTION: But isn't it true that when they told them it was the generic, it was in response to a specific question?

MR. BASS: Yes, but not the question counsel said. She said they asked did you give me a generic. That was not the question in the protocol. They asked do you carry a generic after he gave them the prescription and charged them the lower price, and he answered I gave you a generic.

QUESTION: I see.

MR. BASS: Also, Justice O'Connor, your question about the name Ives on the capsule is most appropriate, because not only do my over-50 eyes read that Ives, but they refused to include the Ives pill in those pills she showed the patients when the very company doing the survey recommended they put the Ives there; but we can only surmise why they didn't want to include for those test subjects the word Ives.

Now, Justice Powell, I'd like to correct an answer I gave you because I misunderstood your question earlier. You asked me about manufacturers of Cyclospasmol in the same color. I thought you were asking me today, and I answered as I did. However, I am told you asked in more general form.

Prior to the decision in the Second Circuit there were about 22 companies selling Cyclospasmol in the same color. One company, this Hauck from Georgia, sold it in red. This is a practice and this record that shows goes back 40 years, the generic companies selling the products in the same color.

Counsel has referred in answer to your question, Justice Stevens, about Judge Wyzanski's decision in the Court of Appeals decision in Snow Crest and Coca-Cola, and she referred again numerous times this afternoon about the pharmacists. And I would only

humbly suggest it is misplaced.

Judge Wyzanski said bartenders are not so unique that they would be deemed to be people who would commit a wrongful act in substituting another cola for Coca-Cola. There's nothing in this record that shows that pharmacists should be denominated worse than bartenders and should be considered unique to commit criminal acts to have premised their argument made to this Court today.

QUESTION: Mr. Bass, I notice we've talked about the standard this morning that the Court of Appeals used and about whether the court followed the clearly erroneous rule. I note that your petition for certiorari didn't raise either question.

MR. BASS: No, sir.

QUESTION: Do you agree, or don't you, that the Court of Appeals properly applied the clearly erroneous rule?

MR. BASS: No. I think they tried to avoid it, as the dissenting opinion of Judge Mulligan states.

QUESTION: Well, you didn't raise it in a petition -- in your -- as a question.

MR. BASS: No.

QUESTION: And do you think the Court of Appeals applied a different standard of law under

Section 32 than the District Court did?

MR. BASS: Definitely not, Your Honor. Ives II said to the District Court you didn't apply --

QUESTION: So you -- you -- you -- all -- you say that the Court of Appeals agreed with the standard of law that the District Court used and just disagreed with the factual application.

MR. BASS: In Ives IV. In Ives II they said you used the wrong standard. Then it went back to the District Court for trial. In Ives IV the court said we disagree that he didn't give weight to certain evidence like the catalogs.

But the standard, Your Honor, is precisely what you said this morning. The standard was not the issue the Court took with the District Court in Ives decision IV and in Judge Mansfield's decision, no, sir.

CHIEF JUSTICE BURGER: Thank you, counsel.

The case is submitted.

(Whereupon, at 1:17 p.m., the case in the above-entitled matter was submitted.)

CERTIFICATION

Alderson Reporting Company, Inc. hereby certifies that the attached pages represent an accurate transcription of electronic sound recording of the oral argument before the Supreme Court of the United States in the matter of:

Inwood Laboratories, Inc., Et Al., Petitioners v. Ives Laboratories, Inc.; and Darby Drug Co., Inc., Et Al., Petitioners v. Ives Laboratories, Inc.

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BY Sharon Ryan Connelly