

1990

ILO Marie Grundberg and Janice Gray and the estate of Mildred Lucille Coats v. Upjohn Company : Petition for Rehearing

Utah Supreme Court

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DECKET NO. 900573

DECKET

IN THE SUPREME COURT OF THE STATE OF UTAH

.....
ILO MARIE GRUNDBERG, and
JANICE GRAY, and the estate of
Mildred Lucille Coats,

Respondents,

vs.

THE UPJOHN COMPANY,

Petitioner.
.....

.....
: U.S. Dist. Crt. No. 89-C-274-G
:

: Utah Supreme Court No. 900573
:

: Priority No. 12
:
:

.....
PETITIONER THE UPJOHN COMPANY'S
PETITION FOR REHEARING TO CLARIFY HOLDING
.....

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JUN 11 1991

CLERK SUPREME COURT
UTAH

IN THE SUPREME COURT OF THE STATE OF UTAH

ILO MARIE GRUNDBERG, and
JANICE GRAY, and the estate of
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**PETITIONER THE UPJOHN COMPANY'S
PETITION FOR REHEARING TO CLARIFY HOLDING**

COMES NOW petitioner, The Upjohn Company (hereinafter "Upjohn"), pursuant to Rule 35 of the Utah Rules of Appellate Procedure, and petitions this Honorable Court for a rehearing for the limited purpose of clarifying the holding in its opinion of May 14, 1991 ("Slip op."). Although this Court held that plaintiffs in this civil action for personal injury involving an FDA approved prescription drug could not proceed on a theory of design defect, the United States District Court Judge has interpreted this Court's opinion of May 14, 1991 to allow plaintiffs to proceed to trial on a strict liability design defect theory. Clarification is necessary and would benefit these litigants, the Tenth Circuit Court of Appeals when and if it reviews the rulings of the District Court Judge, and future litigants in Utah.

I. PROCEDURAL BACKGROUND

Respondents (hereinafter "plaintiffs") commenced this civil action against Upjohn, alleging that Mildred Lucille Coats died at age 83 from gunshot wounds inflicted by her daughter, Ilo Grundberg, on June 19, 1988. Grundberg and Janice Gray, the personal representative of Coats' estate, brought this action alleging that Grundberg shot her mother as the result of ingesting the drug Halcion, a prescription drug approved by the United States Food and Drug Administration for the short-term management of insomnia.

Plaintiffs' Complaint stated several causes of action, including common law negligence, strict liability and breach of express and implied warranty. Upjohn challenged a number of plaintiffs' claims by motions for partial summary judgment. Judgment was entered for Upjohn on all plaintiffs' breach of warranty claims. Order of October 17, 1990. Plaintiffs' manufacturing defect claim was dismissed. Order of December 19, 1990. Plaintiffs did not plead an independent cause of action for fraud on the FDA. Transcript of Proceedings, April 15, 1991.

At the time questions were certified to this Court, plaintiffs were scheduled for trial on their failure to warn claim. Slip op. at 2. The availability to plaintiffs at trial of their design defect theory depended on this Court's resolution of certified questions. Id.

Upon certification, this Court specifically addressed the question of whether Utah adopts the "unavoidably unsafe products" exception to strict products liability as set forth in comment k to Section 402A of the Restatement (Second) of Torts. On May 14, 1991, this Court held that all FDA-approved prescription medications are "unavoidably unsafe." This Court further held that manufacturers of unavoidably dangerous products should not be liable for a claim of design defect.

In light of the strong public interest in the availability and affordability of prescription medications, the extensive regulatory system of the FDA, and the avenues of recovery still available to plaintiffs by claiming inadequate warning, mismanufacture,

improper marketing, or misrepresentation of information to the FDA, we conclude that a broad grant of immunity from strict liability claims based on design defects should be extended to FDA-approved prescription drugs in Utah.

Slip op. at 16.

On May 24, 1991, a hearing was held in the United States District Court to discuss the impact of this Court's holding on the trial of this action. The United States District Court Judge interpreted this Court's opinion, and denied Upjohn's motion for partial summary judgment on plaintiffs' design defect claim:

Court: . . . The motion for partial summary judgment as to the strict liability claim is denied. And the matters of mismarketing, failure to warn, misrepresentation to the FDA and defective design as it is indicated may be presented as a matter of evidence under that theory.

Proceedings of May 24, 1991, at 2, attached as Appendix A.

The United States District Court Judge explained further his interpretation of this Court's opinion:

Court: . . . I think we may need to talk about jury instructions and how they are going to be presented but within the discussion of the Supreme Court ruling, I consider that the broad discussion of defect would include design defect.

That is to say, if what the Supreme Court said about product defects, there is a mutually exclusive 3 part definition, and that includes the universe, manufacturing, design and inadequate warnings.

I do not intend to limit this case to inadequate warnings; it certainly is not going to include manufacturing flaws. It follows that it is within the purview of design defects.

And when the Supreme Court talks about the matter of defective or unreasonably dangerous product as related to the 4 or 5 matters that have been identified including mismarketing, misinformation to the FDA, inadequate warning and manufacturing flaws, that within that I think is the kind of design defect I'm talking about is embraced.

(emphasis added). Id., at 3-4.

II. RELIEF REQUESTED

Upjohn submits that when this Court expressly reached "the same conclusion as did the California Supreme Court in Brown" (Slip op. at 10), this Court held that plaintiffs in this prescription drug case should be allowed to proceed to trial for failure to adequately warn, under the standard enunciated by this Court in Barson v. E.R. Squibb & Sons, Inc., 682 P.2d 832 (Utah, 1984). The United States District Court, however, has interpreted this Court's opinion of May 14, 1991 to allow plaintiffs to proceed on a strict liability theory allowing for the admission of "design defect" evidence.

Upjohn respectfully submits that this Court's well-reasoned analysis of the public policy of the State of Utah regarding prescription drug manufacturer liability could not and should not have resulted in the interpretation given to this Court's opinion. The Upjohn Company respectfully requests the Court to clarify the holding in its opinion to make clear that liability against a prescription drug manufacturer focuses on the

manufacturer's failure to communicate information to prescribing physicians, not on some theory of design defect.

III. ARGUMENT

A. There is Seemingly an Ambiguity in this Court's Opinion

This Court's opinion holds that plaintiffs could proceed to trial on their failure to warn claims and that liability may be imposed according to the standard enunciated in Barson v. E.R. Squibb & Sons, Inc., 682 P.2d 832 (Utah 1984). Support for Upjohn's interpretation is found throughout the opinion. First, at page 2 of the slip opinion, the Court stated as follows:

Plaintiffs claim that Upjohn failed to adequately warn about certain adverse side effects of Halcion and that Halcion was defectively designed. The failure to warn claim is scheduled for trial. The strict liability claim based on design defect is the subject of Upjohn's pending summary judgment motion, the outcome of which depends on this Court's resolution of the certified question.

(emphasis added). Although plaintiffs had alleged both a failure to warn and a design defect claim, this Court clearly understood that its ruling would determine whether plaintiffs could proceed to trial on both theories. This Court went on to hold that plaintiffs could not proceed on a design defect theory. Slip op. at 10.

Further support for Upjohn's interpretation of this Court's holding is found at page 10 of the slip opinion. There, this Court stated:

We agree with the principle comment k embodies, that manufacturers of unavoidably dangerous products should not be liable for a claim of

design defect. We are persuaded that all prescription drugs should be classified as unavoidably dangerous in design because of their unique nature and value, the elaborate regulatory system overseen by the FDA, the difficulties of relying on individual lawsuits as a forum in which to review a prescription drug's design, and the significant public policy considerations noted in Brown. We, therefore, reach the same conclusion as did the Supreme Court in Brown, albeit pursuant to a slightly different rationale.

(emphasis added).

In Brown, the California Supreme Court addressed the very issues presented here, and stated:

While there is some disagreement as to its scope and meaning, there is a general consensus that, although it purports to explain the strict liability doctrine, in fact the principle it states is based on negligence. * * * That is, comment k would impose liability on a drug manufacturer only if it failed to warn of a defect of which it either knew or should have known. This concept focuses not on a deficiency in the product -- the hallmark of strict liability -- but on the fault of the producer in failing to warn of dangers inherent in the use of its product that were either known or knowable -- an idea which "rings of negligence,"
. . . .

751 P.2d at 476.

Notwithstanding the seemingly clear language of this Court's opinion, the United States District Court Judge interprets this Court's opinion to hold that if plaintiffs simply allege "mismarketing" or "misinformation to the FDA," plaintiffs may proceed on a strict liability theory, which includes "design defect." Upjohn respectfully suggests that this is not what this Court held or intended.

United States Magistrate Judge Ronald Boyce was recently apprised of the District Court Judge's interpretation of the May 14, 1991 opinion. His comments demonstrate that two federal jurists in Utah read this Court's holding differently:

Plaintiffs' counsel (reading to the Magistrate Judge the ruling of the District Court Judge): ". . . The motion for partial summary judgment as to strict liability claim is denied. And the matters of mismarketing, comma, failure to warn, comma, misrepresentation to the FDA, and defect in design, as it is indicated, may be presented as a matter of evidence under that theory." . . .

Magistrate Judge: I'll tell you what troubles me in that language is the term "misdesign." Is it --

Upjohn's Counsel: Defective design.

Magistrate Judge: Defective design. That as I read the Utah Supreme Court is just not Utah law.

Transcript of Proceedings, May 31, 1991, at 72-73, attached as Appendix B.

The United States District Court Judge's interpretation and the Magistrate Judge's comments make it clear that there is a need for clarification of the holding in this Court's opinion of May 14, 1991. This Court did not intend by its opinion of May 14, 1991 to allow plaintiffs to proceed on a strict liability theory which allows plaintiffs to present a case for design defect.

B. The Opinion Should Be Clarified to State
That Plaintiffs Can Proceed on Their
Failure to Warn Claim.

This Court acknowledged that trial courts are poorly suited to address the "polycentric" problem presented by a prescription drug design defect claim. Slip op. at 16. The benefits to society in promoting the development, availability, and reasonable price of drugs justify the approach of denying plaintiffs the theory of design defect. Id. This Court has so ruled.

Plaintiffs were scheduled for trial on their failure to warn claim. Upjohn anticipated that this Court's holding that plaintiffs had no design defect claim would result in the grant of summary judgment on that claim. Upjohn respectfully suggests that this Court too anticipated its ruling would have such affect. Slip op. at 2. At a minimum, clarification would facilitate further review of the District Court Judge's ruling in the Tenth Circuit Court of Appeals.

Accordingly, Upjohn requests that this Court's holding in the opinion of May 14, 1991 be clarified by the addition of the following paragraph:

Accordingly, there is no claim for design defect in a civil action for personal injuries involving FDA approved prescription drugs, and no evidence of design defect should be admitted in such a case involving an FDA approved prescription drug.

IV. CONCLUSION

WHEREFORE, for these reasons, The Upjohn Company respectfully requests that this Court grant rehearing for the limited purpose of clarifying its holding in the opinion of May 14, 1991 in accord with the particulars identified herein.

Dated this 11th day of June, 1991.

Respectfully submitted,

RAY, QUINNEY & NEBEKER

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CERTIFICATE OF COUNSEL

I certify that the foregoing Petitioner The Upjohn Company's Petition for Rehearing to Clarify Holding is filed in good faith and not for purpose of delay.

Thomas J. Kay

Attorney for Petitioner
The Upjohn Company

CERTIFICATE OF SERVICE

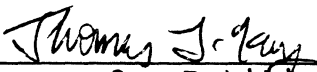
I hereby certify that on the 14th day of June, 1991, four true and correct copies of PETITIONER THE UPJOHN COMPANY'S PETITION FOR REHEARING TO CLARIFY HOLDING were mailed, postage prepaid, to the following:

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Atlanta, Georgia 30301

and one copy to:

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60 East South Temple
Salt Lake City, Utah 84111

Attorneys for Respondents



Attorney for Petitioner
The Upjohn Company

APPENDIX A

1 IN THE UNITED STATES DISTRICT COURT
2 IN AND FOR THE DISTRICT OF UTAH
3 CENTRAL DIVISION

4 -oOo-

4 ILO GRUNDBERG,) Case No. C89-274
5)
5 Plaintiff,) Salt Lake City, Utah
6) Date: May 24, 1991
6 vs.) Time: 9:30 a.m.
7)
7 THE UPJOHN COMPANY,)
8)
8 Defendant.)
9)

10 REPORTER'S TRANSCRIPT

11 BEFORE: THE HONORABLE J. THOMAS GREENE

12 APPEARANCES OF COUNSEL:

13 For the Plaintiff: NEAL POPE, ESQ.,
14 STEVEN SACCOCIA, ESQ. and
DANIEL SIGELMAN, ESQ.

15 For the Defendant: LANE BAUER, ESQ.,
16 THOMAS KAY, ESQ.,
STEPHEN SCHEVE, ESQ. and
17 ROB McCULLY, ESQ.

18 Court Reporter: REEVE M. BUTLER, RPR
19 Official Court Reporter
20 Rm. 224 Federal Bldg.
350 S. Main Street
Salt Lake City, Utah 84101

21 Tel. 328-0837
22
23
24
25

1 THE COURT: All right. With respect to this matter
2 I notice in the pleadings in this case on strict liability,
3 Count 2; there is incorporated in the previous pleading, which
4 specifically has to do with willful and fraudulent
5 misrepresentation of information to the Food and Drug
6 Administration.

7 There is also reference to defective condition,
8 unreasonably dangerous, defective packaging, false, misleading
9 advertising, defective warnings and instructions and
10 marketing.

11 The motion for partial summary judgment as to the
12 strict liability claim is denied. And the matters of
13 mismarketing, failure to warn, misrepresentation to the FDA
14 and defective design as it is indicated may be presented as a
15 matter of evidence under that theory.

16 Now it's 11:30. Would you like to take a quick
17 lunch now and come back?

18 MR. POPE: Let's do that, Your Honor.

19 MR. SCHEVE: Did you say evidence of defective
20 design, Your Honor, is admissible?

21 THE COURT: Yes. If you want to take a quick lunch
22 we can come back at 12:30 or we can go on for an hour now but
23 I suggest that we do that.

24 Let's take a break and I know that some of you would
25 like to get out soon. I've indicated we'll be through no

1 later than 4:30. We may need that much time. If we don't
2 we'll get out sooner but let's resume at quarter to one.

3 We're in recess until then.

4 (Recess was taken)

5 THE COURT: Mr. Bauer.

6 MR. BAUER: Your Honor, not being quite as sharp as
7 these young legal eagles, could I ask for clarification of
8 your ruling at the end of this morning if I could state it so
9 that I can understand it as to where we're going.

10 Your Honor, if I understood you correctly, you ruled
11 that evidence that can come into the case, mismarketing,
12 failure to warn, misleading the FDA - I'm paraphrasing these
13 concepts - and design defect, I understand that, but did Your
14 Honor rule or I understood you did not rule in effect that at
15 least at this time you will submit to the jury a separate
16 theory of design defect under either negligence or strict
17 liability. Am I correct in that assumption Your Honor?

18 THE COURT: Well I don't think I reached that exact
19 point. I think we may need to talk about jury instructions
20 and how they are going to be presented but within the
21 discussion of the Supreme Court ruling, I consider that the
22 broad discussion of defect would include design defect.

23 That is to say, if what the Supreme Court said about
24 product defects, there is a mutually exclusive 3 part
25 definition, and that includes the universe, manufacturing,

1 design and inadequate warnings.

2 I do not intend to limit this case to inadequate
3 warnings; it certainly is not going to include manufacturing
4 flaws. It follows that it is within the purview of design
5 defects.

6 And when the Supreme Court talks about the matter of
7 defective or unreasonably dangerous product as related to the
8 4 or 5 matters that have been identified including
9 mismarketing, misinformation to the FDA, inadequate warning
10 and manufacturing flaws, that within that I think is the kind
11 of design defect I'm talking about is embraced.

12 MR. BAUER: All right. Thank you.

13 (Excerpt concluded)

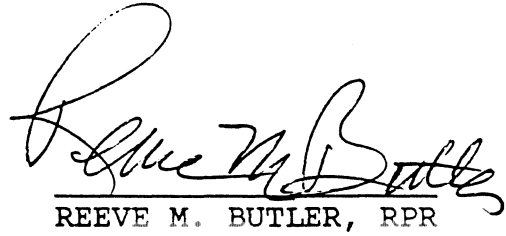
14 REPORTER'S CERTIFICATE

15 STATE OF UTAH)
16)
16 COUNTY OF SALT LAKE)

17 I, REEVE M. BUTLER, do hereby certify that I am
18 an Official Court Reporter for the United States District
19 Court for the District of Utah;

20 That as such Reporter I attended the hearing of
21 the foregoing matter on May 24, 1991, and thereat
22 reported in Stenotype all of the testimony and proceedings
23 had, and caused said notes to be transcribed into typewriting;
24 and the foregoing pages numbered from 2 to 4
25 constitute a full, true and correct report of the same.

1 DATED at Salt Lake City, Utah, this 30th day of
2 May, 1991.

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4 REEVE M. BUTLER, RPR

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APPENDIX B

IN THE UNITED STATES DISTRICT COURT
IN AND FOR THE DISTRICT OF UTAH, CENTRAL DIVISION

-o0o-

ILO MARIE GRUNDBERG,)	
individually, and JANICE GRAY,)	Civil No. C-89-274G
as personal representative of)	
the Estate of MILDRED LUCILLE)	
COATS, Deceased,)	
)	
Plaintiffs,)	
)	<u>TRANSCRIPT OF HEARING</u>
vs.)	
)	
THE UPJOHN COMPANY, a)	
corporation,)	
)	
Defendant.)	

-o0o-

BE IT REMEMBERED that on the 31st day of May, 1991,
the Hearing in the above-entitled action now pending before
the above-named Court, was heard by the Honorable Ronald N.
Boyce, United States Magistrate, commencing at the hour of
1:40 p.m. of said day, at the United States District
Courthouse, Second Floor, 350 South Main Street, Salt Lake
City, Utah.

**CERTIFIED
COPY**

SANDRA GARDINER
CSR NO. 298

**INDEPENDENT REPORTING
SERVICE**
Certified Shorthand Reporters

1200 Beneficial Life Tower
36 South State Street
Salt Lake City, Utah 84111
(801) 538-2333

1 necessarily especially in 1973, with any known hypothesis, but
2 what you're going to find with respect to unusual toxicity.
3 So if you find in a very high percentage of patients on the
4 drug, particularly compared with placebo, very untoward
5 effects, you have prospective experience, which is markedly
6 different from retrospective analysis with drug experience, of
7 course.

8 THE COURT: I think that, Mr. Sigelman, your argument
9 would make significantly greater impression if you still had
10 in this case a fraud on the FDA in obtaining approval. Then
11 the question of whether there had been a failure to adequately
12 control the experiment, failure to properly report data, or
13 withholding of information, all of that relevant to the
14 clinical trial would be significant. As I understand the
15 negligence issue that is before the Court now, it is not
16 negligence in the submissions to the FDA. That's foreclosed
17 by the Utah Supreme Court's decision and is the negligence in
18 the marketing, negligence in the information that's being
19 communicated concerning the use of the drug.

20 MR. SIGELMAN: Your Honor, if I may say so, that is not
21 the case.

22 THE COURT: Okay.

23 MR. SIGELMAN: First of all, on April 15, 1991, in
24 discussing defendant's objections to the plaintiff's claims in
25 the pretrial order, and this is in our response to their

1 submission to Your Honor, wherein plaintiffs requested
2 sanctions and we provided you a copy, Judge Greene held three
3 things with regard to plaintiff's fraudulent misrepresentation
4 theories. One, they come in under plaintiff's negligent
5 claims, in fact, which Mr. Scheve effectively admitted during
6 the two days of case management in mid-April.

7 THE COURT: But isn't it negligence with reference to
8 the marketing of the drug?

9 MR. SIGELMAN: No, it's negligent misrepresentations to
10 the Food and Drug Administration which involve mismarketing
11 and misinformation. Secondly, he ruled that we can bring in
12 the same kind of evidence in the same kinds of claims under
13 our punitive damages count. And then he ruled at that time
14 that we could bring it in under the exception to the
15 exception. Now Your Honor's referenced --

16 THE COURT: Now the exception to the exception is
17 essentially a fair marketing, fair notice claim.

18 MR. SIGELMAN: It was more than that, Your Honor. It
19 also involved misinformation to the FDA. It involved
20 misrepresentation to the FDA, as well as mismarketing. Judge
21 Greene found we could come in under all those things. And, in
22 fact, Your Honor, if you look at the Utah Supreme Court
23 opinion, where they talk about the exception under Comment K,
24 they have a whole line of different points of the opinion as
25 to what constitutes exceptions. And they're all divided by

1 commas. You have failure to word, comma, you have
2 misinformation, comma, you have mismarketing, comma. It's --

3 THE COURT: Now the information as I understand it, the
4 Utah Supreme Court, they did not know whether fraud upon the
5 FDA on misinformation to the FDA was a factor in the case.
6 And they just said, "We're not excluding this as a possible
7 claim." That would obviate the Unreasonably Unsafe Drug
8 Standard of 402(a). We're just saying this is something that
9 someone could claim. But they weren't saying that remained a
10 life issue in this case.

11 MR. SIGELMAN: Okay. Your Honor, if I may, Mr.
12 Tomlinson has handed me part of the transcript from our May
13 24, 1991 hearing before Judge Greene.

14 THE COURT: Okay.

15 MR. SIGELMAN: And the Court at -- in this part of the
16 transcript states, quote, "With respect to this matter, I
17 notice in the pleadings in this case in strict liability count
18 two, there is incorporated in the previous pleading, which
19 specifically has to do with willful and fraudulent
20 misrepresentation of information to the Food and Drug
21 Administration. There is also reference to a defective
22 condition, unreasonably dangerous defective packaging, false,
23 misleading advertising, defective warnings and instructions in
24 marketing. The motion for partial summary judgment as to
25 strict liability claim is denied. And the matters of

1 mismarketing, comma, failure to warn, comma, misrepresentation
2 to the FDA, and defective design, as it is indicated, may be
3 presented as a matter of evidence under that theory."

4 So, Your Honor, I would respectfully submit that Judge
5 Greene has ruled, as of the 16th or the 24th of May, that one
6 of the elements under which plaintiffs are permitted to
7 proceed at trial with evidence under the exception to the
8 exception, under Comment K, is with respect to
9 misrepresentation to the FDA.

10 THE COURT: I'll tell you what troubles me in that
11 language is the term "misdesign". Is it --

12 MR. KAY: Defective design.

13 THE COURT: Defective design. That as I read the Utah
14 Supreme Court is just not Utah law.

15 MR. SIGELMAN: Well, the Utah Supreme Court said that
16 if, in exchange for the immunity they were giving under
17 Comment K, a company provides misinformation to the FDA,
18 mismarkets a drug, etc., the product becomes defective. And
19 what Judge Greene held was that the universe of what can
20 happen is really a tripartite universe. And Judge Greene held
21 in this transcript, and I quote, "Well, I don't think I'd
22 reach that at that point. I think we may need to talk about
23 jury instructions and how they are going to be presented. But
24 within the discussion of the Supreme Court ruling, I
25 considered that the broad discussion of defect would exclude

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C E R T I F I C A T E

STATE OF UTAH)
)
COUNTY OF SALT LAKE)

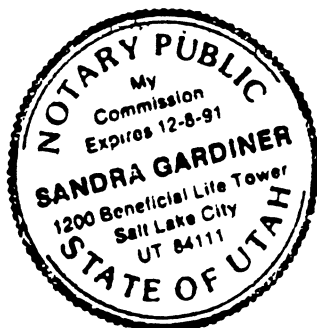
I, Sandra Gardiner, a Certified Shorthand Reporter and
Notary Public within and for the County of Salt Lake and
State of Utah, do hereby certify:

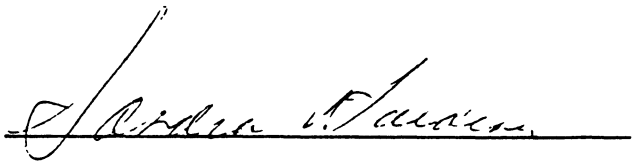
That the foregoing proceedings were taken before me at
the time and place herein set forth, and were taken down by
me in shorthand and thereafter transcribed into typewriting
under my direction and supervision:

That the foregoing 101 pages contain a true and correct
transcription of my shorthand notes so taken.

IN WITNESS WHEREOF, I have hereunto subscribed my name
and affixed my seal this 7th day of June, 1991.

My commission expires:
December 8, 1991




Sandra Gardiner, CSR License #298