

Complaint

71 F.T.C.

IN THE MATTER OF
GROVE LABORATORIES, INCORPORATED

ORDER, OPINION, ETC., IN REGARD TO THE ALLEGED VIOLATION OF
THE FEDERAL TRADE COMMISSION ACT

*Docket 8643. Complaint, Aug. 28, 1964—Decision, June 13, 1967 **

Order requiring a New York City manufacturing drug firm to cease misrepresenting the therapeutic effects of two of its hemorrhoid preparations and other drug products.

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act, and by virtue of the authority vested in it by said Act, the Federal Trade Commission having reason to believe that Grove Laboratories, Incorporated, a corporation, hereinafter referred to as respondent, has violated the provisions of said Act, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, hereby issues its complaint stating its charges in that respect as follows:

PARAGRAPH 1. Respondent Grove Laboratories, Incorporated is a corporation organized, existing and doing business under the laws of the State of Delaware, with its principal office and place of business located at 8877 Ladue Road in the city of St. Louis, State of Missouri.

PAR. 2. Respondent Grove Laboratories, Incorporated is now, and for some time last past has been, engaged in the sale and distribution of preparations offered for the treatment of piles or hemorrhoids and coming within the classification of drugs as the term "drug" is defined in the Federal Trade Commission Act.

The designations used by respondent Grove Laboratories, Incorporated, for said preparations, the formulas thereof and directions for use are as follows:

A. Designation: The PAZO Formula Ointment

Formula: Triolyte (Grove's brand of the combination of benzocaine and ephedrine sulphate), camphorated phenol, zinc oxide, eucalyptus oil in an emollient base.

Directions: Apply Stainless Pazo well up in rectum night and morning after each bowel movement. Repeat as often during the day as may be necessary to maintain comfort. Continue for one week after symptoms subside to help promote healing. When applicator is used, lubricate applicator first with Pazo. Insert slowly, then simply press tube.

*Modified by Commission's order of June 9, 1970, by allowing a manufacturing drug firm to state that its products would temporarily relieve pain and itching and help to reduce swelling associated with hemorrhoids in many cases.

B. Designation: The PAZO Formula Hemorrhoid Suppositories

Formula: Triolyte (Grove's brand of the combination of benzocaine and ephedrine sulphate), camphorated phenol, resorcinol monoacetate, zinc oxide and eucalyptus oil in an emollient base.

Directions: Remove foil and insert one Pazo suppository morning, evening and after each bowel movement * * * repeat as often during the day as may be necessary to maintain comfort. Continue for one week after symptoms subside to help promote healing.

PAR. 3. Respondent Grove Laboratories, Incorporated causes the said preparations, when sold, to be transported from its places of business located at 8877 Ladue Road, St. Louis, Missouri, 225 Market Avenue, Hillside, New Jersey, 95 Market Street, Oakland, California, and 3155 Leonis Boulevard, Vernon, California, to purchasers thereof located in various other States of the United States and in the District of Columbia. Respondent maintains, and at all times mentioned herein has maintained, a course of trade in said preparations in commerce, as "commerce" is defined in the Federal Trade Commission Act. The volume of business in such commerce has been and is substantial.

PAR. 4. In the course and conduct of their business, respondent has disseminated, and caused the dissemination of, certain advertisements concerning the said preparations by the United States mails and the various means in commerce, as "commerce" is defined in the Federal Trade Commission Act, including, but not limited to, advertisements inserted in newspapers, magazines and other advertising media for the purpose of inducing and which were likely to induce, directly or indirectly, the purchase of said preparations; and has disseminated, and caused the dissemination of, advertisements concerning said preparations by various means, including but not limited to the aforesaid media for the purpose of inducing and which were likely to induce, directly or indirectly, the purchase of said preparations in commerce, as "commerce" is defined in the Federal Trade Commission Act.

PAR. 5. Among and typical of the statements and representations contained in said advertisements disseminated as hereinabove set forth are the following:

Recent research reveals fast new way to shrink hemorrhoid tissues, stop pain and itching—all without surgery. It's a combination of seven modern medications in one complete formula: The Pazo Formula.

NEW, RELIABLE RELIEF. The Pazo Formula is the only leading formula with these seven active ingredients to shrink and soothe hemorrhoid tissues. Research shows this new, superior combination brings symptomatic relief even to long-time pile sufferers.

CLINICALLY TESTED BY DOCTORS. The Pazo Formula actually

proves to do more than just shrink hemorrhoids. It also relieves pain and itching promptly, fights infection, promotes healing, and lubricates membranes.

AVAILABLE NOW in stainless ointment and suppositories. Ask for * * * the PAZO Formula.

Why be hurt by hemorrhoids.

Research finds new fast way to shrink hemorrhoids without surgery.

PAR. 6. Through the use of said advertisements, and others similar thereto not specifically set out herein, respondent has represented and is now representing, directly and by implication that the use of The Pazo Formula Ointment and The Pazo Formula Hemorrhoid Suppositories, and each of them will:

1. Shrink hemorrhoids;
2. Avoid the need for surgery as a treatment for hemorrhoids;
3. Eliminate all itching due to or ascribed to hemorrhoids;
4. Relieve all pain attributed to or caused by hemorrhoids;
5. Heal or cure hemorrhoids.

PAR. 7. In truth and in fact the use of neither The Pazo Formula Ointment nor The Pazo Formula Hemorrhoid Suppositories, singly or in combination with each other:

1. Shrink hemorrhoids;
2. Avoid the need for surgery as a treatment for hemorrhoids;
3. Eliminate all itching due to or ascribed to hemorrhoids;
4. Relieve all pain attributed to or caused by hemorrhoids;
5. Heal or cure hemorrhoids;
6. Afford any relief or have any therapeutic effect upon the condition known as hemorrhoids or upon any of the symptoms or manifestations thereof in excess of affording temporary relief of minor pain or minor itching associated with hemorrhoids.

Therefore, the advertisements referred to in Paragraph Five were and are misleading in material respects and constituted, and now constitute, "false advertisements" as that term is defined in the Federal Trade Commission Act.

PAR. 8. The dissemination by the respondent of the false advertisements, as aforesaid, constituted, and now constitutes, unfair and deceptive acts and practices in commerce, in violation of Sections 5 and 12 of the Federal Trade Commission Act.

Mr. William E. McMahon, II, for the Commission.

Mr. Gilbert H. Weil, Weil and Lee, New York, N.Y., attorneys for respondent.

INITIAL DECISION BY WALTER R. JOHNSON, HEARING EXAMINER

OCTOBER 13, 1966

On August 28, 1964, the Federal Trade Commission issued a complaint charging the respondent with the violation of Sections 5 and 12 of the Federal Trade Commission Act in its advertising of The Pazo Formula Ointment and The Pazo Formula Hemorrhoid Suppositories for the treatment of hemorrhoids. An answer, which in general denied the material allegations of the complaint, was filed by the respondent.

On the same date the complaint was issued herein, the Commission initiated similar proceedings, involving like products, against four other firms, to wit: *Humphreys Medicine Company, Incorporated* (Docket No. 8640) [70 F.T.C. 1502]; *American Home Products Corporation* (Docket No. 8641) [70 F.T.C. 1524]; *E. C. DeWitt & Co., Inc.* (Docket No. 8642) [70 F.T.C. 1647]; and *The Mentholatum Company* (Docket No. 8644) [70 F.T.C. 1671]. All of the mentioned cases were assigned to this hearing examiner.

In due course, hearings were held in the *American Home Products Corporation* case, during which period the four companion cases were held in abeyance. Following the conclusion of extended hearings in *American Home Products*, on October 22, 1965, the hearing examiner issued his initial decision from which an appeal was taken by complaint counsel. Oral arguments were heard thereon before the Commission on April 20, 1966, where the matter remains pending.¹

At a hearing held on July 18, 1966, there was submitted a stipulation dated July 11, 1966, entered into between counsel for the parties hereto, which was approved by the hearing examiner and made a part of the record herein. The stipulation reads:

As a means of providing for the orderly and expeditious disposition of this proceeding, and for the purpose of providing a full record of facts upon which the Hearing Examiner may base his Initial Decision, it is, solely for the purposes of this proceeding, hereby stipulated and agreed by and between the parties to this proceeding as follows:

1. The record of hearings and exhibits in the Matter of American Home Products Corporation, Docket No. 8641, specifically excepting the Initial Decision, and also specifically excepting any and all testimony or other evidence denying the presence of a local anesthetic in the formulation, is incorporated by reference into and made a part of the record in this proceeding, just as

¹ During the months of May and June, 1966, the respondents in Dockets Nos. 8640, 8642, and 8644 have entered into stipulations which have been certified to the Commission for its consideration, whereby each such respondent has elected to be bound by the record in the *American Home Products Corporation* case.

though said record in Docket No. 8641, had been adduced herein, and no further evidence or testimony shall be introduced into the record of this proceeding.

2. The effect of the use of respondent Grove Laboratories' products, Pazo Formula Ointment and Pazo Formula Hemorrhoid Suppositories, is not significantly different from the effect of the use of American Home Products Corporation's products, Preparation H Ointment and Preparation H Suppositories.

3. The Pazo formulae have been changed from the form listed in the complaint by eliminating the ingredients resorcinol monoacetate and camphorated phenol.

It is further stipulated and agreed by and between the parties to this proceeding that each party specifically reserves the right to submit to the Hearing Examiner proposed findings of fact and conclusions of law together with a proposed form of order. And the parties hereto further reserve any rights of appeal or other procedural steps set forth in the Federal Trade Commission's Rules of Practice for Adjudicative Proceedings.

At the hearing, copies of five advertisements employed by the respondent in the sale of the preparations involved in this proceeding were received in evidence (CX 1, 2A-D).

Proposed findings were filed by respondent on September 13, 1966, and by complaint counsel on September 16, 1966. Replies were filed by both parties on September 30, 1966. The proposed findings of fact and conclusions not hereinafter specifically found or concluded are herewith rejected. Upon consideration of the entire record, the hearing examiner makes the following findings of fact and conclusions:²

Respondent, Grove Laboratories, Incorporated, was, until the end of 1963, a corporation organized, existing and doing business under the laws of the State of Delaware, with its principal office and place of business located at 8877 Ladue Road, in the city of St. Louis, State of Missouri; since 1963 it has been an unincorporated division of Bristol-Myers Company (a Delaware corporation with its principal office and place of business at 630 Fifth Avenue, city of New York, State of New York), with its principal office and place of business continuing at its previous location (C. and A.).

Respondent Grove Laboratories is now, and for some time last past has been, engaged in the sale and distribution of preparations offered for the treatment of piles or hemorrhoids and coming within the classification of drugs as the term "drug" is defined in the Federal Trade Commission Act (C. and A.).

² The following abbreviations have been used herein: "C." for Commission's Complaint; "A." for Respondent's Answer; "CX" for Commission's Exhibit; "T." for Transcript; and "Stip." for Stipulation dated July 11, 1966.

The designations used by respondent for the preparations referred to above and the formulae therefor are as follows:

A. Designation: The Pazo Formula Ointment

Formula: Triolyte (Grove's brand of the combination of benzocaine and ephedrine sulphate), zinc oxide, eucalyptus oil in an emollient base.

B. Designation: The Pazo Formula Hemorrhoid Suppositories

Formula: Triolyte (Grove's brand of the combination of benzocaine and ephedrine sulphate), zinc oxide and eucalyptus oil in an emollient base.

(C., A., and Stip.)

Partial directions for the use of The Pazo Formula Ointment and The Pazo Formula Hemorrhoid Suppositories are as follows:

The Pazo Formula Ointment

Apply Stainless Pazo well up in rectum night and morning and after each bowel movement. Repeat as often during the day as may be necessary to maintain comfort. Continue for one week after symptoms subside to help promote healing. When applicator is used, lubricate applicator first with Pazo. Insert slowly, then simply press tube.

The Pazo Formula Hemorrhoid Suppositories

Remove foil and insert one Pazo suppository morning, evening and after each bowel movement * * * repeat as often as necessary to maintain comfort. Continue for one week after symptoms subside to help promote healing.

(C. and A.)

Respondent Grove Laboratories causes the said preparations, The Pazo Formula Ointment and The Pazo Formula Hemorrhoid Suppositories, when sold, to be transported from its places of business located at 8877 Ladue Road, St. Louis, Missouri, 225 Market Avenue, Hillside, New Jersey, 95 Market Street, Oakland, California, and 3155 Leonis Boulevard, Vernon, California, to purchasers thereof located in various other States of the United States and in the District of Columbia. Respondent maintains, and at all times mentioned in the record of this proceeding has maintained, a course of trade in said preparations in commerce, as "commerce" is defined in the Federal Trade Commission Act. The volume of business in such commerce has been and is substantial (C. and A.).

In the course and conduct of its business, respondent has disseminated, and caused the dissemination of, certain advertisements concerning The Pazo Formula Ointment and The Pazo Formula Hemorrhoid Suppositories by the United States mails and the various means in commerce, as "commerce" is defined in the Federal Trade Commission Act, including, but not limited to, advertisements inserted in newspapers, magazines and other advertising media for the purpose of inducing and which were likely

to induce, directly or indirectly, the purchase of said preparations; and has disseminated, and caused the dissemination of, advertisements concerning said preparations by various means, including, but not limited to, the aforesaid media for the purpose of inducing and which were likely to induce, directly or indirectly, the purchase of said preparations in commerce, as "commerce" is defined in the Federal Trade Commission Act (C. and A.).

Typical advertisements disseminated as hereinabove mentioned contained one headline per advertisement from among the following:

- (a) RESEARCH FINDS NEW FAST WAY TO SHRINK HEMORRHOIDS WITHOUT SURGERY
- (b) WHY BE HURT BY HEMORRHOIDS
- (c) 7 MODERN MEDICATIONS FOR HEMORRHOID RELIEF
Now all in 1 formula
- (d) RELIEVE HEMORRHOID SWELLING AND PAIN, ENJOY LIFE AGAIN WITH PAZO FORMULA

followed by body copy reading:

Recent research reveals fast new way to shrink hemorrhoid tissues, stop pain and itching—all without surgery. It's a combination of *seven* modern medications in *one* complete formula: The Pazo Formula.

NEW, RELIABLE RELIEF. The Pazo Formula is the only *leading* formula with these seven active ingredients to shrink and soothe hemorrhoid tissues. Research shows this new, superior combination brings symptomatic relief even to long-time pile sufferers.

CLINICALLY TESTED BY DOCTORS. The Pazo Formula actually proves to do *more* than just shrink hemorrhoids. It also relieves pain and itching promptly, fights infection, promotes healing, and lubricates membranes.

AVAILABLE NOW in stainless ointment *and* suppositories, the easy to use form with an exact amount of medication for prompt relief. Ask for * * * The PAZO Formula.

(CX 1, 2A-D; T. 21-22.)

Through the use of said advertisements, the respondent has represented, directly and by implication, that the use of The Pazo Formula Ointment and The Pazo Formula Hemorrhoid Suppositories, and each of them, will:

1. Shrink hemorrhoids;
2. Avoid the need for surgery as a treatment for hemorrhoids;
3. Eliminate itching due to or ascribed to hemorrhoids;
4. Relieve pain attributed to or caused by hemorrhoids;
5. Promote the healing of hemorrhoids.

The findings of fact and conclusions of the hearing examiner in his initial decision *In the Matter of American Home Products*

Corporation, Docket No. 8641 [70 F.T.C. 1524], insofar as they are pertinent to this proceeding, are adopted and incorporated into and made a part hereof (Stip.).

The effect of the use of respondent's products, The Pazo Formula Ointment and The Pazo Formula Hemorrhoid Suppositories, is not significantly different from the effect of the use of American Home Products Corporation's products, Preparation H Ointment and Preparation H Suppositories (Stip.).

It is the opinion and finding of the hearing examiner that the evidence establishes that The Pazo Formula Ointment and The Pazo Formula Hemorrhoid Suppositories have a significant therapeutic effect in the treatment of hemorrhoids, and that, when used as directed, they will, in most cases, but not in all instances:

1. Shrink hemorrhoids;
2. Eliminate itching due to or ascribed to hemorrhoids;
3. Relieve pain attributed to or caused by hemorrhoids;
4. Promote the healing of hemorrhoids;

but they will not:

- (1) Avoid the need for surgery as a treatment for hemorrhoids where surgery is indicated.

ORDER

It is ordered, That respondent Grove Laboratories, Incorporated, and its officers, representatives, agents and employees, directly or through any corporate or other device, in connection with the offering for sale, sale or distribution of The Pazo Formula Ointment or The Pazo Formula Hemorrhoid Suppositories, or any other preparation of substantially similar composition or possessing substantially similar properties, do forthwith cease and desist from directly or indirectly:

1. Disseminating, or causing the dissemination of any advertisement by means of the United States mails or by any means in commerce, as "commerce" is defined in the Federal Trade Commission Act, which represents directly or by implication that the use of The Pazo Formula Ointment or The Pazo Formula Hemorrhoid Suppositories, will:

- (1) Shrink hemorrhoids in all cases;
- (2) Avoid the need for surgery as a treatment for hemorrhoids where surgery is indicated;
- (3) Eliminate itching due to or ascribed to hemorrhoids in all cases;
- (4) Relieve pain attributed to or caused by hemorrhoids in all cases;

(5) Promote the healing of hemorrhoids in all cases.

2. Disseminating or causing to be disseminated by any means for the purpose of inducing or which is likely to induce, directly or indirectly, the purchase in commerce, as "commerce" is defined in the Federal Trade Commission Act, of said preparation or preparations, any advertisement which contains any of the representations prohibited in Paragraph 1 hereof;

Provided, however, That nothing contained in this Order shall prevent nor be construed to prevent respondent, its officers, representatives, agents or employees from representing, or from disseminating or causing to be disseminated by any of the means or for any of the purposes referred to in Paragraphs 1 and 2 hereof any advertisements which represent, that the use of The Pazo Formula Ointment and The Pazo Formula Hemorrhoid Suppositories, or either of them, or any other preparation or preparations of substantially similar composition and intended use, will in most cases:

- (a) Be of significant therapeutic effect in the treatment of hemorrhoids;
- (b) Enable persons with hemorrhoids to avoid surgery except in unusually severe or persistent cases;
- (c) Shrink hemorrhoids;
- (d) Eliminate itching due to hemorrhoids;
- (e) Relieve pain due to hemorrhoids; or
- (f) Promote the healing of hemorrhoids.

OPINION OF THE COMMISSION

JUNE 13, 1967

BY JONES, *Commissioner*:

I

The complaint in this matter, issued on August 28, 1964, charged that respondent¹ violated Sections 5 and 12 of the Federal Trade Commission Act by making false representations in advertising its ointment and suppositories, sold under the name of The Pazo Formula Ointment and The Pazo Formula Hemorrhoid Suppositories,² for the treatment of hemorrhoids. The complaint al-

¹ Grove Laboratories, Incorporated, owned by Bristol-Myers Company since 1958, became an unincorporated division of Bristol-Myers in 1963 and thus has not in fact been a respondent herein, although it is named in the title of the proceedings. However, respondent and the examiner have used the terms "Grove," "Grove Laboratories" and "respondent" interchangeably to refer to both Grove and respondent Bristol-Myers.

² The terms "Pazo," "product(s)" and "preparation(s)" as used herein unless otherwise indicated each refer to The Pazo Formula Ointment and The Pazo Formula Hemorrhoid Suppositories.

leged, and respondent in its answer admitted, that in the sale of said preparations it was engaged in commerce within the meaning of the Federal Trade Commission Act.

Paragraph Five of the complaint charged that the following were typical of the statements made by respondent in its advertising:

Recent research reveals fast new way to shrink hemorrhoid tissues, stop pain and itching—all without surgery. It's a combination of seven modern medications in one complete formula: The Pazo Formula.

NEW, RELIABLE RELIEF. The Pazo Formula is the only leading formula with these seven active ingredients to shrink and soothe hemorrhoid tissues. Research shows this new, superior combination brings symptomatic relief even to long-time pile sufferers.

CLINICALLY TESTED BY DOCTORS. The Pazo Formula actually proves to do more than just shrink hemorrhoids. It also relieves pain and itching promptly, fights infection, promotes healing, and lubricates membranes.

AVAILABLE NOW in stainless ointment and suppositories. Ask for * * * The PAZO Formula.

Why be hurt by hemorrhoids.

Research finds new fast way to shrink hemorrhoids without surgery.

Respondent admitted in its answer that it had made these statements in its advertising but alleged that they had been taken out of context.

Paragraph Six of the complaint charged that through the use of these advertisements and others respondent had represented that use of The Pazo Formula Ointment and The Pazo Formula Hemorrhoid Suppositories, and each of them, will: (1) shrink hemorrhoids; (2) avoid the need for surgery as a treatment for hemorrhoids; (3) eliminate all itching due to or ascribed to hemorrhoids; (4) relieve all pain attributed to or caused by hemorrhoids; or (5) heal or cure hemorrhoids.

In Paragraph Seven the representations set forth in Paragraph Six were alleged to be false, and it was further alleged that Pazo would not "[a]fford any relief or have any therapeutic effect upon the condition known as piles or upon any of the symptoms or manifestations thereof in excess of affording temporary relief of minor pain or minor itching associated with piles."

Respondent denied the allegations in both Paragraphs Six and Seven of the complaint.

The complaint in this matter was issued simultaneously with four other complaints also charging misrepresentations in the advertising of hemorrhoidal preparations, one of which was

American Home Products Corporation, Docket No. 8641 [70 F.T.C. 1524]. Hearings in the *American Home Products* case took place in April and May 1965, and the initial decision in that case was rendered on October 22, 1965. Complaint counsel appealed. On January 12, 1966, before argument of his appeal, complaint counsel moved in each of the other four cases to suspend hearings pending the issuance of the Commission's decision in *American Home Products*. This motion was denied by the Commission on March 16, 1966, and the respondent in each of these four cases moved for reconsideration. On April 26, 1966, the Commission entered an order directing the examiner to proceed with the hearings in each of these cases unless the parties desired to enter into a stipulation providing essentially that their cases may be disposed of on the basis of the record and findings in the *American Home Products* case. Respondent herein advised complaint counsel and the examiner in a hearing on May 4, 1966, that it did not wish to take advantage of the Commission's offer of stipulation as stated in the order, principally for the reason that it did not wish to waive further proceedings before the examiner and before the Commission. As counsel stated:

We believe that there are certain issues inherent in the case which we would see in a somewhat different light than that which *American Home Products* has seen it and therefore we would like to present the case and argue the case in a somewhat different fashion (Transcript of hearing before examiner on May 4, 1966, at page 2).

On July 11, 1966, the parties entered into a stipulation, filed on July 18, 1966, incorporating into the record herein the record of hearings and exhibits in *American Home Products*³ except the Initial Decision and all evidence denying the presence of a local anesthetic in the formulation and providing further that the effect of the use of respondent's products is not significantly different from the use of *American Home Products Corporation's* products, Preparation H Ointment and Preparation H Suppositories. Complaint counsel introduced into evidence copies of five advertisements (CXs 1, 2A-D) dated 1961. These advertisements contain the statements set forth in Paragraph Five of the complaint as well as the following additional statements:

PAZO lets you be active in comfort;
7 modern medications for hemorrhoid relief
Now all in 1 formula; and

³ "Tr." will be used herein to refer to pages in the transcript of hearing before the examiner in *American Home Products Corporation*, Docket 8641; "F." will refer to Findings and "CX" to the Commission's exhibits in the present case.

Relieve hemorrhoid swelling and pain, enjoy life again with PAZO formula.

Respondent agreed that these advertisements "were typical of advertising done by the Respondent for the products at issue in this proceeding at that time in media of that kind [periodicals], and also in newspaper publications" (Transcript of hearing before examiner on July 18, 1966, at page 25). The stipulation provided that no further evidence or testimony would be introduced into the record of this proceeding.

Both parties submitted proposed findings of fact and on October 13, 1966, the examiner issued his initial decision, adopting and incorporating by reference the findings and conclusions in his initial decision in *American Home Products* "insofar as they are pertinent to this proceeding." He found that respondent had made the claims alleged in the complaint with respect to the use of Pazo to avoid surgery, which he found to be true in most instances. The examiner agreed with respondent that its advertisements did not make the representations alleged in the complaint that Pazo would eliminate "all" itching due to or ascribed to hemorrhoids, relieve "all" pain attributed to or caused by hemorrhoids or heal or cure hemorrhoids, and found that it had represented that its product will eliminate itching, relieve pain and promote the healing of hemorrhoids. He further found that each of these claims was true in most instances and that Pazo has a "significant therapeutic effect in the treatment of hemorrhoids."

Complaint counsel's appeal challenges the examiner's findings as to the meaning of the claims which respondent's advertising makes with respect to relief of itch and pain and healing or curing hemorrhoids and also his conclusions that "in most cases" Pazo will shrink hemorrhoids, eliminate itching, relieve pain and promote the healing of hemorrhoids and that it has a significant effect in the treatment of hemorrhoids. Both respondent and complaint counsel have raised questions as to the scope of the order which should be entered here and in addition respondent contends that the Commission erred in denying its motion for remand in order to hear evidence on the scope of the order.⁴ These are the issues which are before us on this appeal.

⁴ Neither party has appealed the examiner's findings and conclusions that respondent falsely claimed that Pazo will avoid the need for surgery as a treatment for hemorrhoids. Nor has either party appealed from the findings and conclusions that Pazo will not in all instances shrink hemorrhoids, eliminate itching, relieve pain or promote healing. Accordingly, we are entering our findings and conclusions on these issues without separate discussion in this opinion.

II

DISCUSSION OF ISSUES RAISED ON APPEAL

*A. Representations Made by Respondent In Its Advertising**1. Alleged representations respecting healing or curing*

The complaint alleged that respondent had represented that Pazo would "heal or cure hemorrhoids." The examiner, however, concluded that respondent's representations had been confined to claims that its product would "promote the healing of hemorrhoids." Respondent contends that its advertisements claim only symptomatic relief and do not represent that its product will "get rid of the varicosities" or cure hemorrhoids (Respondent's Brief on Appeal, p. 8).

Respondent admits that it claimed in its advertising that its preparation will shrink hemorrhoids and avoid the need for surgery. The obvious purpose and effect of the claim that Pazo will enable a user to avoid the need for surgery is to cause the reader to believe that Pazo will serve as a substitute for surgery as a means of healing or curing hemorrhoids. The claim that Pazo will shrink hemorrhoids will convey the same impression. It is within this context that its specific claim that Pazo will "promote healing" must be viewed. If it stood alone there would be no reason to assume that it meant anything beyond what it said. However, the claim does not stand alone. It appeared in a paragraph which started out "The Pazo Formula actually proves to do more than just shrink hemorrhoids." Immediately following appeared respondent's claim that "It also relieves pain and itching promptly, fights infection, promotes healing, and lubricates membranes." We doubt very much that a hemorrhoid sufferer will draw a very fine line in his own mind between a claim that a drug preparation will promote healing but will not heal. In the context of the entire advertising message, we are of the opinion that respondent's claim would cause a hemorrhoid sufferer to conclude that use of Pazo will within a reasonable period of time lead to the healing of hemorrhoids. We conclude, therefore, that the examiner was in error in his interpretation of respondent's claims respecting healing and that in fact readers of respondent's advertisement would conclude that Pazo will heal their hemorrhoids.

2. Alleged representations respecting relief of pain and itching

The complaint charged that respondent represented that Pazo

would "eliminate *all* itching due to or ascribed to hemorrhoids" and "relieve *all* pain attributed to or caused by hemorrhoids" (emphasis added). The examiner found that not "all" but only partial relief from these symptoms was promised. We cannot agree. Respondent's advertising states that Pazo will "*stop* pain and itching" (emphasis added). In our opinion this generalized and unlimited claim with respect to the relief of pain will be interpreted by the readers in its broadest sense. It would have been a simple matter for respondent to have stated in its advertising that the hemorrhoid sufferer will find some temporary relief from the symptoms of some types of pain or from some types of itch. It chose instead to make its claims in unequivocal terms. If claims of this nature, particularly those relating to health, are not designed to embrace the broadest interpretation reasonably attributable to them, then they must be specifically limited by express qualifying language. We will not imply such qualifying language in our interpretation of such claims, nor indeed do we think the ordinary reader would do so. In this instance the totality of the relief claimed for respondent's product is underscored by the balance of its advertising message which claims that use of respondent's product will shrink hemorrhoids and avoid the need for surgery. Respondent admits making these latter claims. They clearly imply that the hemorrhoidal condition itself including pain, itch and other symptoms will be eliminated. Accordingly, we reject the examiner's conclusions with respect to pain and itch and find that respondent represented in its advertising that relief from *all* pain and itching attributable to or associated with hemorrhoids would be afforded by use of its medication.

B. Efficacy of Pazo

The parties have stipulated that the effect of the use of The Pazo Formula Ointment and The Pazo Formula Hemorrhoid Suppositories is not significantly different from the effect of the use of American Home Products Corporation's products, Preparation H Ointment and Suppositories (Stip., ¶2). Accordingly, the findings of fact and conclusions reached in *American Home Products* with respect to the efficacy of Preparation H, drawn from the record and Findings of Fact in that case, are equally applicable to Pazo. It is in the light of these findings and conclusions, therefore, that the allegations in Paragraph Seven must be analyzed. In reaching our conclusions we have disregarded all evidence in *American Home Products* denying the presence of a local anesthetic in Preparation H.

The issues to be considered herein with respect to the efficacy of respondent's product are: (1) the ability of Pazo to shrink hemorrhoids; (2) the effect of this product on pain; (3) its effect on itching; (4) its ability to heal or cure hemorrhoids and (5) other therapeutic effects of Pazo.

1. The ability of Pazo to shrink hemorrhoids

The examiner found that Pazo will shrink hemorrhoids "in most cases." In reaching this conclusion, the examiner apparently concurred with respondent's contention that hemorrhoids as a condition must be considered not only in terms of the underlying vein but also the surrounding tissue and that since Preparation H will reduce the swelling in the surrounding tissue it will thereby shrink hemorrhoids.

Respondent's advertising, as we have noted, assures that Pazo will "shrink hemorrhoids without surgery." This claim is not confined to superficial swelling but extends implicitly to the underlying hemorrhoidal vein as well. Hemorrhoids are by definition veins located underneath the mucous membrane of the rectum and the skin of the anal canal (F. 16). The evidence of record is that hemorrhoidal preparations such as Pazo may have some effect upon edema or swelling in the tissue overlying hemorrhoids (F. 31(c), 32), but that it cannot reduce the size of the hemorrhoidal veins (F. 31(b), 32). The record also demonstrates that this product will not reduce swelling even in the surrounding tissue when the swelling is due to thrombosis (F. 31(c), 32). Thus, even if we were to assume that some reduction of swelling is effected by respondent's preparation, not all types of swelling will be affected in this way.

In sum, we are confronted here with a flat, unequivocal representation by respondent that its product will shrink hemorrhoids. This claim is clearly false because Pazo cannot shrink hemorrhoids themselves and, while it may possibly have some effect on certain types of swelling in the surrounding tissue, it cannot reduce swelling in all cases. Accordingly, we find that respondent's representations with respect to shrinkage of hemorrhoids are in all respects false and misleading.

2. Effect of Pazo on pain

The hearing examiner concluded that Pazo will relieve pain in most cases. Respondent accepts this finding as well as the provision of the order proposed by the examiner to cover representa-

tions respecting pain. Complaint counsel argues that this finding is in error.

Complaint counsel's medical witnesses in the hearing in *American Home Products*⁵ testified either that Preparation H will have no effect on pain or that it will afford only temporary relief of minor pain associated with hemorrhoids (Tr. 131, 207, 279, 372-373, 439-440, 503, 562, 632-633, 747). The consensus of these experts was that pain is a symptom associated almost entirely with external hemorrhoids and that even with this type of hemorrhoid if the pain is caused by thrombosis, a principal cause of pain in such hemorrhoids, it cannot be affected by the application of any external treatment such as ointment and suppositories. Where pain in external hemorrhoids results from ulceration, inflammation or swelling, some of these witnesses testified that pain might be relieved to a minor degree by the lubricants contained in Preparation H, although other of complaint counsel's witnesses were of the opinion that Preparation H would not even alleviate pain when attributable to these causes (Tr. 129, 648, 742-743). Finally, it appears from the testimony of complaint counsel's witnesses in *American Home Products* that in the unusual case of internal hemorrhoids where pain results from spasm or strangulation, Preparation H will rarely be of benefit (see Tr. 631-632).

In general respondent's witnesses in *American Home Products* did not seriously controvert much of the testimony of complaint counsel's witnesses respecting the effect of Preparation H or of suppositories and ointments in general to relieve pain. At best their testimony supported the conclusion that Preparation H may afford some relief for pain in some instances when used as part of a general conservative course of treatment.⁶ We noted in our opinion in *American Home Products* that notwithstanding the testimony of its witnesses that they prescribed Preparation H only as part of a general conservative course of treatment, the respondent therein nowhere indicated that its product should be

⁵ A brief description of the qualifications of each of the experts testifying for complaint counsel in *American Home Products* is set forth in Finding 10 of our Findings of Fact entered herein.

⁶ A brief description of the qualifications of each of the experts testifying for respondent in *American Home Products* is set forth in Finding 11 of our Findings of Fact entered herein. The testimony of these witnesses is discussed more fully at pages 13-19 [70 F.T.C. 1524, 1613-1616] of our opinion in *American Home Products*. The consumer witnesses appearing for respondent testified that the use of Preparation H had relieved pain, discomfort or soreness resulting from hemorrhoids. However, it is impossible to determine whether the reduction in pain which they claim had been achieved came as the result of the product used or merely by the passage of time. Therefore, we believe that the medical testimony on this issue is entitled to greater weight in our determination.

used in connection with other conservative measures such as diet, sitz baths and the like. Similarly, in respondent's advertisements of Pazo there are no references to other conservative measures; therefore, even if we were to agree with respondent's witnesses that Pazo may provide some relief when used as part of a general conservative course of treatment, these advertisements would still be deceptive.

Finally, the evidence is clear that pain is normally associated only with external hemorrhoids and is not a symptom common to all hemorrhoids. Yet the overall purpose of respondent's advertisements is to imply that pain is a usual symptom of all types of hemorrhoids. Thus, many hemorrhoid sufferers may be misled by respondent's advertisements and take Pazo as a precautionary measure even though they do not have any pain and in most circumstances may never experience pain.

We therefore conclude not only that respondent's representations that Pazo will relieve all pain is false and misleading but also that the examiner's finding that this product will relieve pain "in most cases" was not supported by the evidence. Accordingly, we reject this finding and hold that at best respondent's product may afford some temporary relief against some types of pain associated with certain types of hemorrhoids.

3. *Effect of Pazo on itching*

Complaint counsel appeals from the examiner's finding that Pazo will "in most instances" eliminate itching due to or ascribed to hemorrhoids.

According to the testimony of complaint counsel's expert witnesses in the hearing in *American Home Products*, itching is only in rare cases a symptom of hemorrhoids and is almost always caused by some other condition such as fungus infection or by unknown factors (F. 23). The testimony of some of these witnesses indicated that whether or not itching in the anal and rectal area is connected with a hemorrhoidal condition, it would not be palliated by Preparation H. Dr. Manheim pointed out that "[t]here is nothing in this formula that could possibly be considered as * * * [a]n anti-itch agent" (Tr. 278). Dr. Smith was of the opinion that Preparation H "doesn't relieve the itch * * * [since] there is nothing in this prescription itself which would reduce itching or relieve itching" (Tr. 741). Dr. Pope stated that he "would not agree that even with * * * minor irritation that it gives any particular relief, and it certainly doesn't in the symptoms that are more severe * * *" (Tr. 633).

Other of complaint counsel's medical experts felt, however, that Preparation H may provide some temporary relief for minor itching due or attributed to hemorrhoids (Tr. 131, 215, 372-373, 439-440, 503-505, 566). The only explanation given by any of these doctors for its effect on minor itching was that it acts as a lubricant and may thereby possibly relieve dryness and soothe surface irritation. (See, e.g., Dr. Sarner's testimony at Tr. 440.)

At best the testimony of respondent's witnesses warranted the finding that Preparation H may in certain cases temporarily relieve some of the itching due or ascribed to hemorrhoids.⁷

We have therefore concluded that while Pazo, like Preparation H, may, through the lubricants which it contains, relieve dryness and surface irritation and thereby provide some temporary relief from some types of itching associated with hemorrhoids, it will not provide any further relief from itching caused by hemorrhoids. Thus it will neither stop all itching due to or ascribed to hemorrhoids as implicitly promised by respondent in its advertising nor eliminate itching in most cases as found by the examiner.

4. Ability of Pazo to heal or cure hemorrhoids

Paragraph Seven (5) of the complaint charged that Pazo will not "heal or cure hemorrhoids." Since the examiner found that respondent had not represented that Pazo will heal or cure hemorrhoids—but rather that it had merely claimed that this product would promote the healing of hemorrhoids—he did not reach the specific question as to whether or not it would heal or cure hemorrhoids. However, he adopted all of the pertinent findings and conclusions in his decision in *American Home Products*, including, it would appear, the finding that Preparation H (and therefore Pazo) will not "heal, cure, or remove hemorrhoids, or cause hemorrhoids to cease to be a problem" (*American Home Products* Initial Decision, p. 1602). Moreover, respondent appears to concede that Pazo cannot heal or cure hemorrhoids; the entire thrust of its argument is that its product does not even claim to provide more than symptomatic relief, thus in effect conceding that correction of the underlying pathology—healing or curing—will not be afforded.

⁷ The testimony of American Home Products' witnesses is discussed more fully at pages 22-24 [70 F.T.C. 1524, 1618-1620] of our opinion in that case. Four of respondent's seven consumer witnesses stated that they had had itching associated with their hemorrhoids and that this itching had been relieved by Preparation H (Tr. 1835, 1859, 1873-1874, 1899-1900). However, this testimony is of dubious probative value in view of the fact that the cause of these witnesses' itching was not disclosed. For example, some itch is caused by the process of healing of the tissues (F. 23). If this was the case with these witnesses, there would be no way of determining whether their itch had been stopped by Preparation H or by the healing of their hemorrhoidal tissues.

It is clear from the record that Pazo cannot in fact heal or cure hemorrhoids. It was demonstrated that surgical removal is the only means by which hemorrhoids can be permanently cured (F. 28) and that although certain symptoms may be ameliorated by conservative measures (F. 29, 30) or may disappear spontaneously (F. 27), the patient will be subject to recurring episodes of symptoms unless the underlying vascular condition is remedied (F. 27). Since Pazo cannot affect the underlying dilated veins it cannot heal or cure hemorrhoids (F. 31(a), 32).

We also reject the examiner's conclusion that Pazo will "in most cases * * * promote healing." Since, as we have concluded, this product can only provide temporary palliation of some of the symptoms of hemorrhoids and that only surgery can permanently heal this condition, it is obvious not only that healing cannot be effected through use of Pazo but also that application of this preparation will not "promote" healing.

5. *Other therapeutic effects of Pazo*

In addition to the allegations that respondent's affirmative representations with respect to its products were false, the complaint also charged that Pazo would not "[a]fford any relief or have any therapeutic effect upon the condition known as hemorrhoids or upon any of the symptoms or manifestations thereof in excess of affording temporary relief of minor pain or minor itching associated with hemorrhoids" (Complaint, Paragraph Seven (6)).

As we have noted, it is clear from the record that Pazo cannot shrink hemorrhoids, avoid the need for surgery as a treatment for hemorrhoids, heal or cure hemorrhoids or provide any relief from pain or itching other than the temporary relief in some cases. The record also demonstrates that this product can have no other therapeutic effect upon hemorrhoids (F. 31(f), 32).

The hearing examiner found that Pazo will "have a significant therapeutic effect in the treatment of hemorrhoids." The examiner failed, either in his decision herein or in his decision in *American Home Products*, to set forth the basis or explain the meaning of this conclusion. There would appear to be two interpretations of his finding: first that the specific effects which he found which Pazo would have, namely, shrinking hemorrhoids, eliminating itching, relieving pain and promoting healing in most cases, were "significant," and second that the product has other significant therapeutic effects. Neither of these conclusions is supported by the record. As we have pointed out, the evidence demonstrates that Pazo will not have the specific effects found

by the examiner on swelling, itching and pain and in promoting healing, but can only have some temporary effect on some types of pain and itching. This limited effect can hardly be considered significant, in view of our finding that the symptoms of hemorrhoids will persist and re-occur unless corrected by surgical means. Nor, as we have further found, can Pazo have any additional effect on hemorrhoids—significant or otherwise. Therefore, we conclude that the examiner's finding that Pazo has a significant therapeutic effect in the treatment of hemorrhoids must be rejected.

III

THE ORDER

In view of our rejection of the examiner's findings and conclusions discussed above, we are entering our own order in this matter.

In determining what order is necessary to ensure that respondent's misrepresentations respecting the efficacy of its drug preparation will not occur again, it is of primary importance to consider the segment of the public which is most likely to be particularly affected by these misrepresentations. Advertising claims with respect to drugs are directed to those in distress, frequently the aged and infirm, who are especially vulnerable to inflated promises as to the curative powers of drugs. With Medicare now a reality, it is possible for a growing number of persons to consult directly with doctors and hence many persons will become aware for the first time that aches and pains, which in the past they have taken for granted, may be symptoms of illnesses and ailments which they had never heard of before or never before associated with their own distress. Thus claims made in advertising as to the efficacy of drugs for a variety of ailments and diseases will be more meaningful and of concern to an increasing number of people. Accordingly, it becomes of even greater importance today to make sure that representations respecting health claims and relief of distress are absolutely accurate and do not contain promises, impressions, or even highly veiled suggestions of efficacy which are in any sense false and misleading. It is with these basic principles in mind that we must fashion the type of prohibitive provisions which in our judgment are necessary in order to protect the public from deception.

A. Product Application of the Order

The order entered by us applies to representations made by

respondent with respect to both Pazo and to any medication sold by respondent in the future for the treatment of hemorrhoids.⁸ Respondent's counsel stated on oral argument that this portion of the order is acceptable and is not being opposed by respondent (Tr. O.A. 25).⁹ It is therefore unnecessary to go into any extended discussion of this portion of the order other than to note that in our judgment the provision of the order as originally proposed by complaint counsel, conditioning its applicability to Pazo or to any hemorrhoid preparation containing "substantially similar ingredients" or possessing "substantially similar properties," is ambiguous, difficult of enforcement, and could be too easily circumvented. Accordingly, the order we are entering provides that it shall be applicable to all products offered for sale for the treatment or relief of hemorrhoids or hemorrhoidal symptoms.

The order being entered by us applies additionally in part to respondent's advertising of any drug products which it offers for sale. Respondent vigorously opposes the application of the order to drug products other than hemorrhoid preparations.¹⁰ Respondent contends that an order applicable to products other than hemorrhoid preparations would be too broad and would deprive respondent of its right to have any issues as to the falsity of its advertisements determined in the first instance by the Commission rather than in a *de novo* proceeding before a court on a civil penalty action. Respondent also argues that if the order is to be so expanded, the Commission should have granted its motion to remand the proceeding to enable it to offer evidence on its good faith (Tr. O.A. 26 and 30).

The law is clear that the Commission is empowered to enter an order of sufficient breadth to ensure that respondent will not engage in violations of the law in the future.¹¹ The Courts have stated that they will not interfere with the Commission's choice

⁸ This is an expansion of the order proposed by complaint counsel which applied the order to Pazo "or any other preparation of substantially similar composition or possessing substantially similar properties."

⁹ "Tr. O.A." will be used herein to refer to pages in the Transcript on Oral Argument, March 14, 1967.

¹⁰ Respondent's counsel stated on oral argument of the appeal in this case that it had had no opportunity to brief the scope of the order point (Tr. O.A. 4). We do not understand the purport of this remark since the Commission's order of January 26, 1967, denying respondent's motion to remand the case for purposes of taking evidence on the issue as to the scope of the order, expressly stated that the denial did not preclude respondent from making any argument it wished with regard to the scope of the order. Counsel did not request leave to file a supplemental brief on this point but apparently elected instead to state its position on this matter in the course of its oral argument on this appeal.

¹¹ *Jacob Siegel v. Federal Trade Commission*, 327 U.S. 608, 611 (1946); *Federal Trade Commission v. Ruberoid Co.*, 343 U.S. 470, 473 (1952); *Federal Trade Commission v. National Lead Co.*, 352 U.S. 419, 428-430 (1957).

of remedy if the prohibitions in the order bear a reasonable relationship to, or as the Second Circuit phrased it recently, are "persuasively * * * related to,"¹² the unlawful practices found to exist and if the prohibitions are sufficiently specific so that the respondent and the courts can be "definitely informed as to the extent of the prohibited area."¹³

The frequency and duration of the violations, whether they have been flagrant and extensive,¹⁴ and whether the respondent had been engaged in past violations,¹⁵ as well as the likelihood of whether the respondent knew or should have known that its conduct was unlawful are material factors which the courts have said the Commission may take into account in fashioning an appropriate remedy in a given case.¹⁶ As the Supreme Court has said on two occasions, respondents "must remember that those caught violating the Act must expect some fencing in."¹⁷

In its recent decision involving the proper scope of Commission orders (*Federal Trade Commission v. Colgate-Palmolive*, *supra*, 380 U.S. at 393-395), the Supreme Court sustained a Commission order prohibiting the misleading use of mock ups in television advertising and expressly rejected respondents' contention that the order was improper because it was made applicable to all products advertised by the respondent whereas the original violation had occurred with respect to the advertising of a single product, "Rapid Shave." The Supreme Court pointed out that the order was "as specific as the circumstances will permit" and that the

¹² *Wm. H. Rorer, Inc. v. Federal Trade Commission*, 1967 Trade Cases ¶72,042 (2nd Cir. 1967) citing *N.L.R.B. v. Express Publishing Co.*, 312 U.S. 426, 433 (1941); *Jacob Siegel Co. v. Federal Trade Commission*, *supra*, 327 U.S. at 613; *Federal Trade Commission v. Ruberoid Co.*, *supra*, 343 U.S. at 473; *Federal Trade Commission v. National Lead Co.*, *supra*, 352 U.S. at 429; *Swanee Paper Corporation v. Federal Trade Commission*, 291 F.2d 833, 837 (2nd Cir. 1961).

¹³ *Asheville Tobacco Board of Trade, Inc. v. Federal Trade Commission*, 294 F.2d 619, 628 (4th Cir. 1961); *Federal Trade Commission v. Henry Broch & Co.*, 368 U.S. 360, 366-368 (1962) (dicta); *Swanee Paper Corporation v. Federal Trade Commission*, *supra*, 291 F.2d at 838; *Wm. H. Rorer, Inc. v. Federal Trade Commission*, *supra*.

¹⁴ *Maryland Baking Co. v. Federal Trade Commission*, 243 F.2d 716, 718 (4th Cir. 1957); *Wm. H. Rorer v. Federal Trade Commission*, *supra*, 1967 Trade Cases at 83,707; *Joseph A. Kaplan & Sons, Inc. v. Federal Trade Commission*, 347 F.2d 785, 789 (D.C. Cir. 1965); *Federal Trade Commission v. National Lead Co.*, *supra*, 352 U.S. at 429. Cf. *Grand Union Company v. Federal Trade Commission*, 300 F.2d 92, 100 (2nd Cir. 1962) (single violation involving novel issue of law does not justify broad order) and to the same effect *R. H. Macy & Co. v. Federal Trade Commission*, 326 F.2d 445, 450 (2nd Cir. 1964) and *Swanee Paper Corporation v. Federal Trade Commission*, *supra*, 291 F.2d at 837-838.

¹⁵ *Carter Products, Inc. v. Federal Trade Commission*, 323 F.2d 523, 532-533 (5th Cir. 1963); *Joseph A. Kaplan & Sons, Inc. v. Federal Trade Commission*, *supra*, 347 F.2d at 789.

¹⁶ *Joseph A. Kaplan & Sons, Inc. v. Federal Trade Commission*, *supra*, 347 F.2d at 789; *Federal Trade Commission v. National Lead Co.*, *supra*, 352 U.S. at 429; *Wm. H. Rorer v. Federal Trade Commission*, *supra*, 1967 Trade Cases at 83,707.

¹⁷ *Federal Trade Commission v. National Lead Co.*, *supra*, 352 U.S. at 431; *Federal Trade Commission v. Colgate-Palmolive*, 380 U.S. 374, 395 (1965).

respondents "will have no difficulty applying the Commission's order to the vast majority of their contemplated future commercials" and can seek the Commission's advice on borderline questions. The Court also noted that the respondents had produced three different commercials that employed "the same deceptive practices" and that this factor was a sufficient basis for a belief that the respondents would be inclined to use similar devices in future commercials.¹⁸

Contrary to what the respondent appeared to contend on oral argument (Tr. O.A. 19-25), we find no principle from the case law which supports the argument that an order is improper if it contains prohibitions which in the event of their violation would require the District Court in an enforcement proceeding to make *de novo* findings of fact on issues normally regarded as within the Commission's expertise.¹⁹

In virtually every order entered by the Commission, whether it involves issues of price discrimination or of false and deceptive claims, the District Court in a civil penalty action brought in the event of violation, will have to make findings and conclusions *de*

¹⁸ Other cases sustaining the application of Commission orders to the full line of a respondent's products even though the violation had occurred with respect to a single product include the following: *Fred Meyer, Inc. v. Federal Trade Commission*, 359 F.2d 351 (9th Cir. 1966) (order against schemes to induce discriminatory prices applicable to all products); *United Biscuit Company v. Federal Trade Commission*, 350 F.2d 615 (7th Cir. 1965) (price discrimination order applicable to all products); *Carter Products, Inc. v. Federal Trade Commission*, *supra*, 323 F.2d 523 (prohibition against the use of deceptive demonstrations applicable to all products); *Mueller v. Federal Trade Commission*, 323 F.2d 44 (7th Cir. 1963) (price discrimination order applicable to all of respondents' products); *Lane v. Federal Trade Commission*, 130 F.2d 48 (9th Cir. 1942) (prohibition of making claims found to have been false in connection with advertising of all of respondent's publications); *Niresk Industries, Inc. v. Federal Trade Commission*, 278 F.2d 337 (7th Cir. 1960), *cert. den.*, 364 U.S. 883 (1960) (misrepresentations prohibited applied to all products sold by respondent); *Consumer Sales Corp. v. Federal Trade Commission*, 198 F.2d 404 (2nd Cir. 1952) (misrepresentations prohibited applied to all merchandise sold by respondent); *Benrus Watch Co. v. Federal Trade Commission*, 352 F.2d 313 (8th Cir. 1965), *cert. den.*, 384 U.S. 939 (1966) (fictitious pricing, misleading guarantees and preticketing misrepresentations found with respect to watches also prohibited in connection with the sale of all Benrus products whether or not related to the watch industry).

¹⁹ There are numerous issues involved in the application of the Clayton and Federal Trade Commission Acts which the courts regard as particularly within the Commission's expertise. Nevertheless, many of these issues must often be resolved *de novo* by the District Courts in enforcement proceedings. For example, the Supreme Court has made it clear that the complicated factual determinations of the meeting competition defense in a case involving the Robinson-Patman Act "are for the Commission, not the courts." [*Federal Trade Commission v. A. E. Staley Mfg. Co.*, 324 U.S. 746, 760 (1945).] However, the Supreme Court has made it equally clear that all price discrimination orders implicitly contain this statutory defense. [*Federal Trade Commission v. Ruberoid*, *supra*, 343 U.S. at 476.] We do not read *Federal Trade Commission v. Morton Salt*, 334 U.S. 37 (1948) and *Swanee Paper Corp. v. Federal Trade Commission*, *supra*, 291 F.2d 833, as laying down any different rule for determining the reasonableness and propriety of Commission orders. Even though both Courts referred in the course of their opinions to the problem of District Courts in enforcement decisions being compelled to make *de novo* findings on matters ordinarily regarded as within the Commission's expertise, the Courts' decisions turned on their concern with the ambiguity and lack of specificity of the proposed Commission orders.

One final point should be noted here. Respondents are not required to act at their peril in complying with Commission orders. The Commission's Rules of Practice²⁴ expressly provide that a respondent subject to an order can request advice from the Commission as to whether a proposed course of action would be in compliance with the order and further provide that the Commission will so advise the respondent. Indeed the availability of this procedure was expressly noted and relied upon by the Supreme Court in sustaining the Commission's broad product order in the *Colgate-Palmolive* case.²⁵

In the instant case, a careful determination of the circumstances surrounding respondent's conduct here convinces us that it is essential that the order not be limited to hemorrhoidal preparations and that it apply additionally to all drug products which respondent offers for sale in the future.

Respondent's advertising of its hemorrhoid preparation, Pazo, was long and continuous and the deceptions found here go to the essence of its advertising message (F. 8, 9, and 31). Moreover, the very efficacy claims about stopping pain and itching which we have found in this proceeding to be false and misleading were made previously by this same respondent with respect to an earlier hemorrhoid preparation (also called Pazo but apparently containing different ingredients) which were also found by this Commission to have been false and misleading.²⁶

Moreover, respondent (Grove and its present owner Bristol-Myers) has a long history of involvement with the Commission on its advertising of other products as to which respondent's claims of efficacy were challenged and were either thereupon withdrawn by respondent or were found to have been false. Thus Grove and Bristol-Myers have been the object of no less than six formal Commission proceedings involving misrepresentations of the therapeutic value of preparations for the relief and treatment of hemorrhoids; the common cold; mouth, tooth or gum disease; and various skin diseases, including dandruff, baldness, and other scalp disorders. Four of these cases proceeded to final order and two

²⁴ Section 3.26(b), Federal Trade Commission Rules of Practice, August, 1963.

²⁵ *Federal Trade Commission v. Colgate-Palmolive Co.*, *supra*, 380 U.S. at 394.

²⁶ *Grove Laboratories, Inc.*, 31 F.T.C. 342 (Dkt. 3445, 1940). See the claims set forth in Paragraph 4 of the Complaint (p. 344) and the Findings (p. 348) of that earlier proceeding—"Effective treatment today for Piles"; "It stops pain and itching"; "It assures comfort, day and night"; "Pazo almost instantly stops the pain and itching"; "Pazo will give you relief, too!"

were terminated by stipulations of discontinuance.²⁷ The challenged claims were alleged or found to be objectionable either because the product provided *no* effective treatment of the disorder,²⁸ or because the product was claimed to "cure" the disorder when in fact it would only help relieve some of the symptoms.²⁹ In several cases the immediacy of the promised relief was greatly exaggerated;³⁰ and in one case a portion of the objectionable claims involved the alleged value of separate ingredients in the product.³¹

In addition to these formal proceedings, in 1937 and 1938 Bristol-Myers signed six additional stipulations as a result of Commission investigations of its advertising of six different products all of which involved allegedly false and misleading therapeutic claims.³² While these stipulations go back in history some thirty years, it is significant that two of the Commission's subsequent actions against respondent involved many of the same representations for the identical products which respondent had agreed not to make only a few years before.³³

Accordingly, we are convinced that we would be derelict in our responsibilities if we were to limit the prohibitions of the order against false representations solely to hemorrhoidal preparations

²⁷ Final orders were issued against either Grove or Bristol-Myers as follows:

Grove Laboratories, Inc., 27 F.T.C. 1180 (Dkt. 2771, 1938) (order prohibited misrepresentations as to the therapeutic effect of a laxative preparation).

Grove Laboratories, Inc., 31 F.T.C. 342 (Dkt. 3445, 1940) (order prohibited misrepresentations as to efficacy of Pazo and also deceptive claims as to benefits of a scalp preparation).

Bristol-Myers Company, 36 F.T.C. 707 (Dkt. 3645, 1943) (order prohibited misrepresentations as to the therapeutic effect of a laxative preparation).

Bristol-Myers Company, 46 F.T.C. 162 (Dkt. 4861, 1949), *aff'd.*, 185 F.2d 58 (4th Cir. 1950) (order prohibited claiming therapeutic value for *Ipana* toothpaste in treatment of mouth, tooth or gum diseases).

Stipulations of Discontinuance were agreed to as follows:

Grove Laboratories, Inc., 47 F.T.C. 1458 (Dkt. 5772, 1950) (agreed to discontinue claims that a cold preparation would cure, prevent, or shorten the duration of the common cold).

Bristol-Myers Company, 47 F.T.C. 1441 (Dkt. 5752, 1950) (agreed to discontinue claims that a cold preparation would cure, prevent, or shorten the duration of the common-cold).

²⁸ 31 F.T.C. 342, 36 F.T.C. 707, 46 F.T.C. 162.

²⁹ 27 F.T.C. 1180, 31 F.T.C. 342, 36 F.T.C. 707, 47 F.T.C. 1458, 47 F.T.C. 1441.

³⁰ 27 F.T.C. 1180, 47 F.T.C. 1458, 47 F.T.C. 1441.

³¹ 27 F.T.C. 1180.

³² Stip. No. 01700, 24 F.T.C. 1546 (1937) involving health claims for "Vitalis" hair preparation; Stip. No. 01714, 24 F.T.C. 1554 (1937) involving claims that "Ipana" toothpaste, *inter alia*, is an effective treatment for tooth and gum disease; Stip. No. 01720, 24 F.T.C. 1558 (1937) involving claims that "Sal Hepatica" would, *inter alia*, cure the common cold, rid the body of poisonous wastes, be effective in the treatment of arthritis and rheumatism, and help regulate the balance of body fluids; Stip. No. 01864, 25 F.T.C. 1626 (1937) involving claims for "Minit Rub" cold remedy; Stip. No. 02191, 27 F.T.C. 1602 (1938) involving health claims for "Ingram's Milkweed Cream"; and Stip. No. 02204, 27 F.T.C. 1609 (1938) involving healing claims for "Ingram's Shaving Cream."

³³ Cf. Stip. No. 01720, 24 F.T.C. 1558 (1937) with 36 F.T.C. 707 (1943) (involving efficacy claims for Sal Hepatica for the common cold) and Stip. No. 01714, 24 F.T.C. 1554 (1937) with 46 F.T.C. 162 (1949), *aff'd.* 185 F.2d 58 (4th Cir. 1950) (involving efficacy of Ipana toothpaste for tooth and gum disease).

having the same or similar ingredients. The ease with which such orders can be avoided has been amply demonstrated by the Commission's experience with this respondent alone. We are equally convinced that it is essential that this order also "fence this respondent in" in connection with all of its future advertising of drug preparations. It is our judgment that in the circumstances of this case and of this respondent, it is essential that the order which we are entering cover all drug products sold by respondent.

B. Respondent's Representations Respecting the Efficacy of Pazo

The order entered by us prohibits respondent from continuing to represent, directly or by implication, that its product will shrink hemorrhoids; avoid the need for surgery as a treatment for hemorrhoids; cure hemorrhoids; afford any relief from pain or itching in excess of providing some temporary relief in some cases of pain or itching; or have any other effect on hemorrhoids or its symptoms.

Respondent argued on appeal that these substantive prohibitions respecting the type of claims which could be made for their product were too broad. Respondent's contention was that if a product in some situations and for some types of hemorrhoids might relieve pain for *some* people then it was proper to make such a claim across the board without limitation since the public had only to purchase the product to find out if the claim was true in his case (Tr. O.A. 12). Respondent conceded that no case had ever sustained such a proposition. We find no basis in reason or in logic, nor any support in the legislative history of this act, to warrant such an interpretation of this legislation. Congress quite clearly was concerned with ensuring that advertising was to be truthful. As we have discussed above, in our view an advertisement which claims without qualification that a product will "stop pain and itching" is not truthful if in fact it will not relieve all pain in all cases but will only relieve some pain in some cases. Accordingly, we conclude that the order must prohibit respondent from making any absolute claims as to efficacy where in fact, as here, the record is clear that such absolute claims are not true.

We have furthermore prohibited respondent from continuing to represent that Pazo will "shrink hemorrhoid tissue." The record demonstrates that it is the hemorrhoid itself and not just the tissue that frequently causes the pain and itching. The evidence is also clear that the product will *not* shrink the hemorrhoid itself and will only shrink the tissue under certain circumstances. In our view any member of the public who reads a representation that a

product will shrink hemorrhoidal tissue will be unlikely to distinguish between this representation and the claim that the product will shrink hemorrhoids. We believe, therefore, that respondent's use of the representation about shrinking tissue is likely to mislead and must therefore be enjoined.

On the same grounds we have forbidden respondent's use of the phrase "promotes healing." An individual suffering from hemorrhoids would undoubtedly assume that if Pazo promoted healing, use of this medication would within a reasonable period of time lead to the healing of hemorrhoids. Since such a result cannot be achieved by the use of respondent's medication, the representation that healing will be promoted is false and misleading.

Respondent's 1961 advertising, which is the only advertising which is before us in this proceeding, stresses that Pazo "is a combination of *seven* modern medications in *one* complete formula" and "is the *only* leading formula with these seven active ingredients to shrink and soothe hemorrhoid tissue." The record does not indicate whether at that time Pazo in fact did contain seven active ingredients or whether it was the "only leading formula" to do so. In any event, as respondent's own proposed findings disclosed (Respondent's Proposed Findings, ¶2) respondent's preparation today contains only three or perhaps four active ingredients in a base. Consequently it would clearly be deceptive if respondent were to continue making its prior claims as to the number of ingredients in Pazo. However, even if respondent were to amend its advertising to conform the number of ingredients specified to the number actually in the product, it would in our opinion still be deceptive for respondent to emphasize any ingredient, any number of ingredients, or the uniqueness of any one or more of its ingredients, since each of such claims would convey the false impression that such ingredients are of special importance in the treatment of hemorrhoids and will afford relief not provided by other hemorrhoid preparations. The indication that Pazo contains ingredients which render it superior to other leading hemorrhoid preparations, which would include Preparation H, contradicts respondent's stipulation that the effect of the use of its product is not significantly different from the effect of the use of Preparation H. We have therefore prohibited respondent from referring either generally or specifically to any of its ingredients, unless each ingredient referred to is effective in the treatment of hemorrhoids and unless the specific effect thereof is expressly and truthfully set forth. On the same grounds we have forbidden respondent from claiming or implying

that its product is significantly more effective in the treatment or relief of hemorrhoids or its symptoms than other hemorrhoid preparations. In so ruling we are by no means suggesting that a bona fide comparison of the quality or efficacy of a product with that of competitive merchandise is in any way improper. To the contrary, we believe that the freedom to make such comparisons where supported by valid data and concerned with significant qualities or properties of the product is an essential part of the process of competition and serves the beneficial purposes of assisting the consumer in the selection of goods. But where, as here, it has been conceded that the effect of the use of a product is not significantly different from the effect of the use of the product sold by its leading competitor, a claim to the opposite effect would necessarily be false and deceptive.

C. Respondent's Efficacy Claims Made In Connection With Its Sales of All of Its Drug Products

As noted above, we have included in the order prohibitions against misrepresenting not only the efficacy of respondent's hemorrhoidal preparations but also the efficacy of the other drug products which respondent offers for sale.

We believe that respondent's history of engaging in a variety of unfounded claims of efficacy necessitates such a provision in this order.

These prohibitions in our order do no more than place on respondent an obligation to advertise precisely what benefits the product can in fact be expected to achieve and not, as respondent's counsel argued it should be permitted to do, leave it to the user to determine from his own experience the exact efficacy of the drugs for his particular condition (Tr. O.A. 11). The circumstances of this case make it imperative in our judgment that respondent be placed under this type of prohibition relating to other drug products in order to ensure that the public will not in the future be misled by respondent's advertising as it has been so frequently misled in the past.

If respondent has any doubt as to what constitutes a misrepresentation of a product's efficacy, respondent has its right to secure advance Commission advice for any of its advertising claims through our compliance procedures. Moreover, we are constrained to note in this connection that respondents have a broad range of experience with efficacy claims which the Commission has challenged in the past. Both the instant proceeding as well as the

previous proceedings involving this respondent³⁴ have involved claims that a product will cure a disease when in fact it will not; claims that a product is effective in the treatment of a disease when in fact it only has an effect upon some of the symptoms of that disease; claims that a product will offer the same degree of benefit to everyone who uses the product when in fact it will not; singling out specific ingredients as having special significance in the treatment of a disease or its symptoms when such ingredients have no significant therapeutic effect; and exaggerations of the immediacy of the promised relief. We believe that the order which we are entering here with respect to other drug preparations is essential if the public interest in the accuracy of therapeutic claims is to be ensured under the circumstances of this case, and that respondent can easily determine what its obligations under the order are and if not that it can secure such a determination from the Commission.

The Remand Issue

Respondent argued that the Commission committed error in refusing to remand this case for the taking of additional evidence on the good faith of respondent.³⁵ Specifically, respondent's counsel stated on oral argument that it desired an opportunity to offer evidence on the percentage relationship of the advertising which had ever been challenged by the Commission to the totality of respondent's advertising (Tr. O.A. 20 and 28). Respondent contended that the remand was necessary because it had not anticipated that the Commission might consider entry of an order applicable to all of its products.

We do not believe that the denial of respondent's motion was in error. As we pointed out in our opinion denying respondent's motion to reopen the proceeding, the scope of the order is always in issue in every proceeding before the Commission. The application of an order to a respondent's full product line is hardly a novel question. (See cases cited *supra* note 18.) Thus respondent cannot seriously contend that the Commission's anticipated action in applying the order in this case to respondent's full product line raised any new issue of law or fact which it could not reasonably

³⁴ See notes 26-32 *supra*.

³⁵ Respondent's original motion to remand requested that hearings be reopened for the purpose of presenting "evidence relevant to the issue of including in the final cease and desist order" prohibitions relative to its advertising of non-hemorrhoid drug preparations. However, on the oral argument of the appeal in this case respondent's counsel stated that basically the issue as to the scope of the order was one of "good faith" and that this was the issue on which it desired to offer evidence (Tr. O.A. 20 and 28).

have been expected to anticipate in preparing its case for hearing. Respondent could well have anticipated that the order entered by the Commission might be expanded to cover all of its drug products.³⁶

In any event, its failure to offer evidence on this point during the hearing does not warrant a remand of this action now.

Moreover, we cannot find that respondent could in any way be said to have been prejudiced by denial of its motion to remand since we find the scope of the order is wholly justified by the facts of this record.

The compelling reasons we have found for the necessity of an order which applies to respondent's other drug products could not possibly be outweighed by any additional facts which respondent could now offer on the issue of its good faith. Even if we assume that the prior advertising of Grove and Bristol-Myers which has been challenged by the Commission in the past constitutes only a small percentage of these companies' total advertising, and assume further that respondent would have offered evidence to show that it has a firm policy of compliance with the law and that each of its advertising messages subsequently found to have been deceptive had been prayerfully considered by respondent beforehand with a view to determining whether it might be challenged by the Commission, such evidence would in no way alter the facts of respondent's prior advertising record. However, our order is not simply predicated on the existence of their prior advertising record nor need it be. As the Second Circuit recently observed in *Wm. H. Rorer v. F.T.C.*, *supra*, 1967 Trade Cases at 83,707, *even the complete absence of previous violations* is "relevant but hardly controlling." We are convinced that respondent is not entitled to a remand of this proceeding and that even if remanded and the proffered evidence admitted, it would not have changed our views as to the need for the broad type of order which we are entering here.

Throughout this opinion we have explained the reasons why, and the extent to which, we disagree with the hearing examiner

³⁶Obviously, the form of order which accompanies the complaint is very tentative indeed since it is drafted before there has been any hearing on the allegations in the complaint and before the views of counsel have been heard. In fact, even the order proposed by the hearing examiner after the hearings have been concluded is still tentative, as reflected in § 3.24 of the Commission's Rules of Practice (August, 1963):

"(a) Upon appeal from or review of an initial decision, the Commission * * * will, to the extent necessary or desirable, exercise all the powers which it could have exercised if it had made the initial decision.

"(b) In rendering its decision, the Commission will adopt, modify, or set aside the findings, conclusions and order contained in the initial decision, * * *" (emphasis added).

concerning what the respondent's advertising represents, what relief in fact is offered by the respondent's products, and the appropriate order necessary to avoid future violations of the type found herein. Accordingly, we have set aside the initial decision and proposed order of the examiner and have entered our own Findings of Fact, Conclusions and Order consistent with this opinion.

FINDINGS OF FACT, CONCLUSIONS AND ORDER

FINDINGS OF FACT

A. Respondent and the Products Considered in This Proceeding

1. Grove Laboratories, Incorporated, owned by Bristol-Myers since 1958, was, until the end of 1963, a corporation organized, existing and doing business under the laws of the State of Delaware, with its principal office and place of business located at 8877 Ladue Road, in the city of St. Louis, State of Missouri; since 1963 it has been an unincorporated division of Bristol-Myers Company, a Delaware corporation with its principal office and place of business at 630 Fifth Avenue, City of New York, State of New York (C., ¶1; A., ¶1; RPF, ¶1; I.D., p. 826).¹ Thus Grove Laboratories, Incorporated, which appears in the title of these proceedings, has never been the respondent herein. However, respondent and the examiner have used the terms "Grove," "Grove Laboratories" and "respondent" interchangeably to refer to both Grove and respondent.

2. Respondent Bristol-Myers Company is now, and for some time last past has been, engaged in the sale and distribution of preparations offered for the treatment of piles or hemorrhoids and coming within the classification of drugs as the term "drug" is defined in the Federal Trade Commission Act (C., ¶2; A., ¶2; RPF, ¶2; I.D., p. 826).

3. The designations used by respondent for the preparations referred to above and the formulae therefore are as follows:

A. Designation: The Pazo Formula Ointment

Formula: Triolyte (Grove's brand of the combination of benzocaine

¹ The following abbreviations have been used herein: "C" for Commission's Complaint; "A" for Respondent's Answer; "CPF" for Complaint Counsel's Proposed Findings; "RPF" for Respondent's Proposed Findings; "CX" for Commission's Exhibit; "A.H.P. CX" for Commission's Exhibit in *American Home Products Corporation*, Docket 8641; "A.H.P. RX" for Respondent's Exhibit in *American Home Products*; "A.H.P. F." for paragraphs of Findings of Fact entered by the Commission in *American Home Products*; "A.H.P. Tr." for transcript page number of hearing before examiner in *American Home Products*; "Stip." for Stipulation entered into by the parties hereto dated July 11, 1966, filed July 18, 1966; "I.D." for Initial Decision.

and ephedrine sulphate), zinc oxide, eucalyptus oil in an emollient base.
B. Designation: The Pazo Formula Hemorrhoid Suppositories

Formula: Triolyte (Grove's brand of the combination of benzocaine and ephedrine sulphate), zinc oxide and eucalyptus oil in an emollient base.

(C., ¶2; A., ¶2; Stip., ¶3; I.D., p. 827.)

4. Partial directions for the use of The Pazo Formula Ointment and The Pazo Formula Hemorrhoid Suppositories are as follows:

The Pazo Formula Ointment

Apply Stainless Pazo well up in rectum night and morning and after each bowel movement. Repeat as often during the day as may be necessary to maintain comfort. Continue for one week after symptoms subside to help promote healing. When applicator is used, lubricate applicator first with Pazo. Insert slowly, then simply press tube.

The Pazo Formula Hemorrhoid Suppositories

Remove foil and insert one Pazo suppository morning, evening and after each bowel movement * * * repeat as often as necessary to maintain comfort. Continue for one week after symptoms subside to help promote healing.

(C., ¶2; A., ¶2; CPF, ¶4; I.D., p. 827.)

5. Respondent causes the said preparations, The Pazo Formula Ointment and The Pazo Formula Hemorrhoid Suppositories, when sold, to be transported from its places of business located at 8877 Ladue Road, St. Louis, Missouri; 225 Market Avenue, Hillside, New Jersey; 95 Market Street, Oakland, California; and 3155 Leonis Boulevard, Vernon, California, to purchasers thereof located in various other States of the United States and in the District of Columbia. Respondent maintains, and at all times mentioned in the record of this proceeding has maintained, a course of trade in said preparations in commerce, as "commerce" is defined in the Federal Trade Commission Act. The volume of business in such commerce has been and is substantial (C., ¶3; A., ¶3; I.D., p. 827).

6. In the course and conduct of its business, respondent has disseminated, and caused the dissemination of, certain advertisements concerning The Pazo Formula Ointment and The Pazo Formula Suppositories by the United States mails and the various means in commerce, as "commerce" is defined in the Federal Trade Commission Act, including, but not limited to, advertisements inserted in newspapers, magazines and other advertising media for the purpose of inducing and which were likely to induce, directly or indirectly, the purchase of said preparations; and has disseminated, and caused the dissemination of, advertisements concerning said preparations by various means, including, but not

limited to, the aforesaid media for the purpose of inducing and which were likely to induce, directly or indirectly, the purchase of said preparations in commerce, as "commerce" is defined in the Federal Trade Commission Act (C., ¶4; A., ¶4; I.D., pp. 827-28).

B. Stipulation Entered Into By Parties

7. The parties hereto entered into a Stipulation, dated July 11, 1966, and filed on July 18, 1966, providing as follows:

As a means of providing for the orderly and expeditious disposition of this proceeding, and for the purpose of providing a full record of facts upon which the Hearing Examiner may base his Initial Decision, it is, solely for the purposes of this proceeding, hereby stipulated and agreed by and between the parties to this proceeding as follows:

1. The record of hearings and exhibits in the Matter of American Home Products Corporation, Docket No. 8641, specifically excepting the Initial Decision, and also specifically excepting any and all testimony or other evidence denying the presence of a local anesthetic in the formulation, is part of the record in this proceeding, just as though said record in Docket No. 8641, had been adduced herein, and no further evidence or testimony shall be introduced into the record of this proceeding.

2. The effect of the use of respondent Grove Laboratories' products, Pazo Formula Ointment and Pazo Formula Hemorrhoid Suppositories, is not significantly different from the effect of the use of American Home Products Corporation's products, Preparation H Ointment and Preparation H Suppositories.

3. The Pazo formulae have been changed from the form listed in the complaint by eliminating the ingredients resorcinol monoacetate and camphorated phenol.

It is further stipulated and agreed by and between the parties to this proceeding that each party specifically reserves the right to submit to the Hearing Examiner proposed findings of fact and conclusions of law together with a proposed form of order. And the parties hereto further reserve any rights of appeal or other procedural steps set forth in the Federal Trade Commission's Rules of Practice for Adjudicative Proceedings.

C. Representations Made by Respondent

8. Typical advertisements disseminated as hereinabove mentioned contained one headline per advertisement from among the following:

- a) RESEARCH FINDS NEW FAST WAY TO SHRINK HEMORRHOIDS WITHOUT SURGERY
- b) WHY BE HURT BY HEMORRHOIDS
- c) 7 MODERN MEDICATIONS FOR HEMORRHOID RELIEF

Now all in 1 formula

- d) RELIEVE HEMORRHOID SWELLING AND PAIN, ENJOY LIFE AGAIN WITH PAZO FORMULA

followed by body copy reading:

Findings

71 F.T.C.

Recent research reveals fast new way to shrink hemorrhoid tissues, stop pain and itching—all without surgery. It's a combination of *seven* modern medications in *one* complete formula: The Pazo Formula.

NEW, RELIABLE RELIEF. The Pazo Formula is the *only* leading formula with these seven active ingredients to shrink and soothe hemorrhoid tissues. Research shows this new, superior combination brings symptomatic relief even to long-time pile sufferers.

CLINICALLY TESTED BY DOCTORS. The Pazo Formula actually proves to do *more* than just shrink hemorrhoids. It also relieves pain and itching promptly, fights infection, promotes healing, and lubricates membranes.

AVAILABLE NOW in stainless ointment *and* suppositories, the easy to use form with an exact amount of medication for prompt relief. Ask for * * * The PAZO Formula.

(C., ¶5; CX 1, 2 A-D; RPF ¶5; I.D., pp. 827-828.)

9. Through the use of said advertisements, the respondent has represented, directly and by implication, that the use of The Pazo Formula Ointment and The Pazo Formula Hemorrhoid Suppositories, and each of them, will:

- (a) Shrink hemorrhoids;
- (b) Avoid the need for surgery as a treatment for hemorrhoids;
- (c) Eliminate all itching due to or ascribed to hemorrhoids;
- (d) Relieve all pain attributed to or caused by hemorrhoids;
- (e) Heal or cure hemorrhoids.

D. Evidence Pertaining to Truthfulness of Claims Made

10. The following medical experts, all of whom were proctologists, or specialists in diseases affecting the anus, rectum and lower colon, including hemorrhoids (A.H.P. Tr. 102, 185-186, 248, 336, 409-410, 478, 536-537, 601, 695), testified on the basis of their experiences in their practices with the treatment of hemorrhoids and on the basis of their general knowledge in the field of their specialty:

(a) *Dr. Richard Hopping*: formerly Chief of Proctology, Bethesda Naval Hospital and presently President of the Medical Board and Chief of Proctologic Services, Saint Barnabas Medical Center, Newark, New Jersey; author of a number of articles on disorders of the anus, rectum and lower colon (A.H.P. CX 28).

(b) *Dr. Sylvan Manheim*: formerly Chief of the Rectal Clinic, Mount Sinai Hospital, New York, New York and Clinical Professor of Surgery for Rectal Diseases, New York Medical College; presently, Consulting Proctologist, Mount Sinai Hospital. Author of the book "Proctology," published by Oxford University Press in 1943; co-author of a number of articles in the field (A.H.P. CX 29).

(c) *Dr. W. Martin Marino*: Chief, Department of Surgery, Division of General Surgery, Division of Proctology, The Brooklyn-Cumberland Medical Center (A.H.P. CX 30).

(d) *Dr. Samuel W. Eisenberg*: Clinical Professor of Proctology, Temple University Medical Center (A.H.P. CX 31).

(e) *Dr. Joseph B. Sarnet*: Senior Attending Proctologist, Einstein Medical Center, Philadelphia; instructor in proctology at Graduate School of Medicine, University of Pennsylvania (A.H.P. CX 32).

(f) *Dr. Andrew J. McAdams*: Chief of Department of Proctology, Division of Surgery, Western Pennsylvania Hospital (A.H.P. CX 33).

(g) *Dr. Karl Zimmerman*: formerly President of the American Proctologic Society, author of over 30 articles and papers in the field (A.H.P. CX 34).

(h) *Dr. Charles Evans Pope*: Head of the Proctologic Department, St. Francis Hospital, Evanston, Illinois; author of 30 papers and articles in the field (A.H.P. CX 35).

(i) *Dr. Durand Smith*: Chief of the Surgical Rectal-Proctoscopy Clinic at Northwestern University Medical School (A.H.P. CX 37).

11. The following medical experts testified for respondent with respect to clinical studies which they had conducted of Preparation H and on the basis of their experiences in their medical practices with Preparation H, other ointments and suppositories and other methods of treating hemorrhoids:

(a) *Dr. Robert E. S. Young*: General surgeon; instructor in surgery at Ohio State University; director of the Institute of Medical Research, Inc., of Columbus, Ohio (A.H.P. RX 79).

(b) *Dr. Olin Burt*: Obstetrician and gynecologist; Fellow of the American College of Obstetricians and Gynecologists (A.H.P. Tr. 1514-1517).

(c) *Dr. Jerome Epstein*: Specialist in internal medicine and gastroenterology; Assistant Clinical Professor of Medicine at George Washington University School of Medicine; formerly a "New Drug officer" with the Federal Food and Drug Administration (A.H.P. Tr. 1540-1541; A.H.P. RX 80).

(d) *Dr. Norman H. Isaacson*: Surgeon, who, according to his testimony, had a "special interest in Proctology"; Clinical Instructor at George Washington University Medical School (A.H.P. Tr. 1653; A.H.P. RX 81).

(e) *Dr. Donald Berkowitz*: Specialist in gastroenterology; Associate Professor of Medicine at Hahnemann Medical College; attending in Gastroenterology at the Albert Einstein and Sidney

Hillman Medical Centers in Philadelphia; holder of Master of Science and Master of Arts degrees in biochemistry; author of numerous articles on a variety of medical subjects (A.H.P. Tr. 1075-1080; A.H.P. RX 76).

(f) *Dr. William Lieberman*: Proctologist; Director of Department of Proctology, Unity Hospital, Brooklyn, New York; Fellow and President Elect of International Academy of Proctology; author of numerous articles in the field of proctology (A.H.P. Tr. 1219-1224; A.H.P. RX 77).

(g) *Dr. Harold S. Feldman*: General practitioner, with emphasis on internal medicine and psychosomatic medicine; holder of Doctorate in Philosophy on Medical Sciences with Major in Pharmacology; Clinical Instructor of New York Medical College and instructor in Psychopharmacology at Seton Hall Medical School (A.H.P. RX 72; A.H.P. Tr. 887-891).

(h) *Dr. Fred J. Phillips*: General practitioner; associate with two other general practitioners and a surgeon at Quakertown, Pa. (A.H.P. Tr. 835-843).

(i) *Dr. Frederick Steigman*: Specialist in internal medicine and gastroenterology; Associate Clinical Professor of Medicine at University of Illinois College of Medicine and Professor of Gastroenterology of Cook County Graduate School of Medicine (A.H.P. RX 71; A.H.P. Tr. 808-813).

The following medical expert testified for respondent on the basis of his knowledge as a pharmacologist:

Dr. Arthur Grollman: Professor of Medicine and Chairman of the Department of Experimental Medicine at Southwestern Medical School of the University of Texas; author of "Pharmacology and Therapeutics" (6th Ed. 1965 [A.H.P. Tr. 1769]), a leading text, and numerous other books and publications (A.H.P. RX 83).

12. Evidence was submitted by respondent pertaining to three clinical studies, each of which had been conducted at the request of respondent:

(a) Dr. Robert Young, who, assisted by Dr. Olin Burt, conducted a clinical study of Preparation H with 127 patients during 1958 and 1959.

(b) Dr. Jerome Epstein and Dr. Norman Isaacson, who, working independently of each other, each conducted a clinical study of Preparation H with 119 of their hemorrhoid patients during 1961-62.

(c) Dr. Donald Berkowitz and Dr. William Lieberman who conducted separate clinical studies during 1963-64 on 196 patients,

approximately half of whom used "Anusol," an ethical hemorrhoidal preparation, as a control.

These clinical studies are described in Findings 13, 14 and 15.

13. *Young-Burt Study.*

Of the 127 patients in the study, 19 were pregnant women who were treated in whole or in part by Dr. Burt, and the balance were treated by Dr. Young. Each patient participating in the study was told by Dr. Young or Dr. Burt that it was a clinical investigation and that he did not know whether the product would be of value or not. The patients were not told what the product was although the doctors did know that they were testing Preparation H (A.H.P. Tr. 1456). The patients were instructed to use the medication after each bowel movement and at night when they went to bed. They were also instructed not to use any other type of medication or treatment. After the initial visit, the patient was seen again in three or four days and at intervals thereafter until there was no further need for observation. The report forms were broken down into various items: "Chief Complaint," "Diagnosis," "Follow Up," "Reactions" or "Sensitivity" and "Comments." No information was recorded respecting the patients' medical histories, previous medication used, the types of examinations performed or the size or state of the patient's hemorrhoids. No control was used. Of the patients who participated, 13 did not have hemorrhoids but had some other anal or rectal disorder (A.H.P. RX 5C, 5P, 5V, 5Z8, 5Z10, 5Z13, 5Z18, 5Z28, 5Z31, 5Z33, 5Z35, 5Z57 and 5Z74). The study could not be completed on 13 cases due to failure to contact or death (A.H.P. RX 5L, 5Z12, 5Z15, 5Z17, 5Z25, 5Z32, 5Z36, 5Z37, 5Z38, 5Z41, 5Z42, 5Z63, 5Z69). Twenty-nine of the patients were examined by other doctors (A.H.P. Tr. 1489).

14. *Epstein-Isaacson Studies.*

Dr. Epstein's study involved 33 subjects who were patients in his private practice. Each patient was told that the doctor was evaluating some hemorrhoidal preparations which were completely safe, but were not informed as to the name of the drug; he was put on the doctor's usual, conservative program and was instructed by the doctor to use the preparation morning, evening, and following each bowel movement. The records show that each patient made either two or three visits after the initial examination, usually about a week apart (A.H.P. RX 6A-6Z7). No control was used in the study. Dr. Epstein reported that of the 33 cases, 1 was referred for surgery (A.H.P. RX 6N); 6 did not have hemor-

rhoids (A.H.P. RX 6J, 6K, 6L, 6M, 6Z2, 6Z3); 7 were free from symptoms on the fourth visit (A.H.P. RX 6A, 6C, 6-O, 6X, 6Z, 6Z1, 6Z5); 12 still had symptoms on the fourth visit (A.H.P. RX 6B, 6D, 6G, 6H, 6I, 6P, 6Q, 6R, 6S, 6V, 6Z4, 6Z6); 5 did not complete the test (A.H.P. RX 6F, 6T, 6U, 6X, 6Z7); 2 others with hemorrhoids did not complete the test since they claimed they were cured (A.H.P. RX 6E, 6W).

Dr. Isaacson's study consisted of 86 cases. The patient was not told the name of the ointment or suppositories which he was given but was advised that the medication was "reported to be pretty good" (A.H.P. Tr. 1661). The patient was instructed to apply the medication morning, evening, and after each bowel movement (A.H.P. Tr. 1662); Dr. Isaacson also prescribed a diet and bowel softener (A.H.P. Tr. 1675). The records show that each subject was treated two to four times following the initial visit, such visits usually being spaced three to seven days apart (A.H.P. RX 6Z8-RX 6Z93). No control was used in the study. Of the 86 cases Dr. Isaacson found that 26 (A.H.P. RX 6Z8, 6Z10, 6Z13, 6Z18, 6Z19, 6Z21, 6Z23, 6Z24, 6Z29, 6Z35, 6Z41, 6Z42, 6Z43, 6Z45, 6Z46, 6Z49, 6Z55, 6Z58, 6Z60, 6Z62, 6Z64, 6Z66, 6Z69, 6Z71, 6Z78, 6Z80) required surgery. In addition, 4 patients reported "no improvement" in their symptoms (A.H.P. RX 6Z9, 6Z16, 6Z20, 6Z28) and 5 others still had some symptoms at the end of the study (A.H.P. RX 6Z31, 6Z36, 6Z37, 6Z40, 6Z47).

15. *Berkowitz-Lieberman Studies.*

Dr. Berkowitz and Dr. Lieberman were requested by respondent and paid a fee of \$7,500 each to conduct a test comparing Preparation H ointments and suppositories with "Anusol," another preparation for hemorrhoids. The study was said to be "double blind," in that the doctors were not told which of the applications were Preparation H and which were Anusol and the patients were not given any information as to the identity of the items. The products, however, differed in color (A.H.P. Tr. 1105-1106). In Dr. Berkowitz's study 54 patients were treated with Preparation H, and 42 treated with Anusol. In Dr. Lieberman's study 48 were treated with Preparation H and 52 were treated with Anusol. Dr. Berkowitz also prescribed "other therapeutic measures, such as hygiene, diet, sitz baths, stool softeners" (A.H.P. Tr. 1107). Dr. Lieberman told each patient to continue with whatever course of treatment he had previously been giving himself.

Each of the doctors was requested to observe the patients during 3 visits. In Dr. Berkowitz's study the visits generally covered a

14-day period. In Dr. Lieberman's study the span of the study generally exceeded this period; the total period was in every case except one less than 30 days, although one case spanned 4 months.

Of the 48 patients in Dr. Lieberman's group who used Preparation H, 9 received surgical treatment (A.H.P. RX 80, 8Z75, 8Z81, 8Z95, 8Z101, 8Z107, 8Z123, 8Z145, 8Z149), and 3 more needed it but did not receive it (A.H.P. RX 8Z66, 8Z133, 8Z143), and all but 5 (A.H.P. RX 85, 8Z31, 8Z35, 8Z73 and 8Z93) still had some symptoms at the end of the study.

E. General Medical Facts Pertaining to Hemorrhoids and Their Treatment

16. "Hemorrhoids" are masses of dilated weak-walled veins located underneath the mucous membrane of the lower portions of the rectum and under the skin on the anal canal and the peri-anal area (A.H.P. Tr. 193, 255, 340, 413-414, 478, 543, 606, 709, 817, 838, 867, 892).

17. The terms "hemorrhoids" and "piles" are synonymous (A.H.P. Tr. 117, 193, 255, 340, 414, 478-479, 543, 607 and 709).

18. "Internal hemorrhoids" are hemorrhoids occurring above the pectinate line and are covered by mucosa. "External hemorrhoids" are hemorrhoids occurring below the pectinate line and are covered by skin (A.H.P. Tr. 193, 199, 232, 236, 255-257, 262, 342, 420, 421, 486, 548, 549, 608, 609, 817, 838, 867 and 892).

19. An "external thrombotic hemorrhoid" is a blood clot under the surface of the skin located in the immediate vicinity of the anal opening (A.H.P. Tr. 117). It is also referred to as an "anal hematoma" (A.H.P. Tr. 719) or a "perianal thrombosis" (A.H.P. Tr. 549).

20. A "prolapse" or "prolapsing hemorrhoid" is an internal hemorrhoid which, due to laxity of the rectum is enabled to fall outside the anal canal and protrudes to the surface (A.H.P. Tr. 199).

21. Hemorrhoids develop in a human being largely because of the fact that he stands in an upright position. In such a position a column of blood is formed from the splenic to the superior hemorrhoidal vein. The hemorrhoidal veins do not have valves to support the weight of this column of blood. The resulting pressure causes the hemorrhoidal veins to dilate (A.H.P. Tr. 594, 231). Hemorrhoids tend to be hereditary (A.H.P. Tr. 144, 231). Other factors leading to the development of hemorrhoids are abnormally long periods of standing, straining, difficulty with bowel move-

ment, impacted stool, pregnancy and cirrhosis of the liver (A.H.P. Tr. 231-232, 144).

22. The most common symptom of internal hemorrhoids is bleeding (A.H.P. Tr. 256, 393, 479). The other principal symptom of internal hemorrhoids is prolapse (A.H.P. Tr. 256). Pain rarely occurs in internal hemorrhoids since the sympathetic nervous system which services the region above the pectinate line where hemorrhoids are located does not contain sensory nerve fibers (A.H.P. Tr. 266, 294, 342-343). Pain, however, may occur in infrequent cases of severe complicated internal hemorrhoids as the result of spasm or strangulation caused by prolapse or as the result of the involvement of tissues beyond the pectinate line (A.H.P. Tr. 342, 415, 631-632, 723).

23. The most common symptoms of external hemorrhoids are pain and swelling (A.H.P. Tr. 256, 742). Pain in external hemorrhoids is frequently caused by an external thrombotic hemorrhoid (A.H.P. Tr. 503). Other causes of pain in external hemorrhoids are inflammation, swelling and ulceration (A.H.P. Tr. 174, 267, 358, 519). Pain may also result from infection. However, this cause of pain is a relatively infrequent occurrence since the rectal and anal area is relatively highly resistant to infection (A.H.P. Tr. 520) and thus infection occurs very rarely as a symptom of hemorrhoids (A.H.P. Tr. 315).

24. Swelling, as distinguished from the dilation of the hemorrhoidal veins, may be a symptom of hemorrhoids as well as a possible cause of pain in external hemorrhoids. Swelling usually results either from a blood clot or thrombosis, which causes distension in the tissue overlying the hemorrhoid, or from edema, which is the accumulation of serous fluid in the interfibrillar spaces in such tissue (A.H.P. Tr. 144, 550).

25. Itching is not a common symptom of internal or external hemorrhoids (A.H.P. Tr. 129, 265, 618-619, 727). The itching thought to be caused by hemorrhoids is usually the result of some other condition such as fungus infection or idiopathic pruritis (A.H.P. Tr. 326, 502, 504, 347, 618-619, 727). The itching which is caused by hemorrhoids is usually the result of discharge from a prolapsed internal hemorrhoid (A.H.P. Tr. 318, 425, 618-619), or healing of an external hemorrhoid (A.H.P. Tr. 265, 502).

26. The symptoms of hemorrhoids can be confused with other conditions such as fissure, fistula, peri-anal or peri-rectal abscess, hypertrophic papillae, papillitis, cryptitis, polyps, proctitis, ulcerative colitis, pruritis ani and carcinoma (cancer). Any of these conditions can co-exist with hemorrhoids and it is not uncommon

to find such a situation (A.H.P. Tr. 114-115, 196-197, 205, 259-260, 347-349, 483-484, 545-546, 612-613, 714-715).

27. The symptoms of hemorrhoids often disappear spontaneously within short periods of time, which may range from several days to two weeks (A.H.P. Tr. 119, 264, 324, 355, 361, 424, 875, 1613). However, the underlying pathology, namely, the vascular dilation, will persist unless corrected and will be subject to recurring episodes of symptoms (A.H.P. Tr. 516, 214).

28. Surgical removal is the only means by which hemorrhoids can be permanently cured (A.H.P. Tr. 118-119, 195, 200-202, 262-263, 352, 422, 487, 550, 554, 623, 719-723, 830). However, surgery does not effect a complete cure in every case (A.H.P. Tr. 150). Surgery may not be advisable or necessary in every case. Surgery may be contra-indicated in cases in which the patient's general medical condition is such that the danger of anesthesia and surgery outweigh the possible benefits to be derived (A.H.P. Tr. 226). Surgery is also not advisable for a simple, uncomplicated hemorrhoid (A.H.P. Tr. 169). Although hemorrhoids may be uncomfortable they are rarely a very serious medical problem, so that a patient, if he chooses to avoid surgery or should avoid it for medical reasons, can go through life without having his hemorrhoids removed (A.H.P. Tr. 135).

29. The symptoms of simple, uncomplicated, internal hemorrhoids of small size can frequently be ameliorated by injectional therapy. This consists of the injection of a sclerosing solution into the hemorrhoid itself which causes scar tissue to form which cuts off the blood vessel feeding the hemorrhoid (A.H.P. Tr. 145, 200, 262-263, 353). A further treatment which has been used within the last several years is the baron ligation method whereby a ligature of rubber is placed around internal hemorrhoids as another means of cutting off blood circulation to the hemorrhoid (A.H.P. Tr. 200-201, 488).

30. In cases on which surgery, injectional therapy or the baron ligation method are not used, a so-called "conservative" course of treatment may be prescribed. The measures used in such a course of treatment include cleanliness, altering of the diet to eliminate irritative foodstuffs, control of the bowels to ensure a smooth, soft stool, warm baths, witch hazel, boric acid, local anesthetic, ointments, suppositories, avoidance of standing and manual reinsertion of prolapse (A.H.P. Tr. 120, 202, 306, 356-357, 684-686). Ointments and suppositories contain lubricants which may protect the anal and rectal canal against the passage of hard, dry stool. Such lubricants may also serve to relieve dryness and

soften the skin as well as provide a psychological advantage; many people derive mental relief from the fact that some sort of treatment is applied (A.H.P. Tr. 203-204, 279, 313, 355, 358, 362-363, 525, 555, 557).

F. Conclusions re Effect of Pazo

31. In *American Home Products* we reached the following conclusions with respect to the effect of Preparation H Ointment and Suppositories on hemorrhoids and its symptoms based on the citations set forth below:

(a) Preparation H will not avoid the need for surgery where it is indicated, or heal, cure or remove hemorrhoids, or cause hemorrhoids to cease to be a problem (A.H.P. Tr. 25, 26, 28, 29) (A.H.P. F. 31).

(b) Preparation H cannot reduce the size of hemorrhoidal veins (A.H.P. Tr. 128-129, 173-174, 212-213, 276, 369-370, 436-437, 500, 563-564, 629-630, 740, 1497, 1668) (A.H.P. F. 32).

(c) Preparation H may possibly, through the lubricants which it contains, temporarily protect inflamed surface areas from the passage of hard, dry stool and thereby have some effect upon edema or swelling in the tissue overlying hemorrhoids (A.H.P. Tr. 202, 1471, 1570, 1668. But *cf.* Tr. 128-129, 463, 684, 742-743). However, where swelling is due to thrombosis (A.H.P. Tr. 264), it will have no beneficial effect (A.H.P. Tr. 503) (A.H.P. F. 33).

(d) Preparation H may in some cases afford some temporary relief against some types of pain associated with hemorrhoids (A.H.P. Tr. 131, 207, 279, 372-373, 439-440, 503, 566, 632-633, 744). Through the lubricants which it contains, this medication may protect inflamed surface areas against the passage of hard, dry stool and thereby temporarily relieve some pain caused by ulceration or from edema or swelling resulting from such inflammation (A.H.P. Tr. 174, 212-213, 358, 493, 525. But *cf.* Tr. 128-129, 463, 684, 742-743). Preparation H can, however, have no effect upon pain due to thrombosis (A.H.P. Tr. 295, 358, 503) or due to spasm or strangulation caused by prolapsing internal hemorrhoids (A.H.P. Tr. 631-632) (A.H.P. F. 34).

(e) Through the lubricants which it contains, Preparation H may possibly relieve dryness and surface irritation and thereby provide some temporary relief from some types of itching associated with hemorrhoids (A.H.P. Tr. 131, 215, 279-280, 373-374, 439-440, 503-504, 566, 633-634, 741) (A.H.P. F. 35).

(f) Except for the effects set forth in A.H.P. F. 33, 34, 35, as well as possible psychological effects (see A.H.P. F. 28), Prepara-

tion H will not have any beneficial effect in the treatment or relief of hemorrhoids or any of its symptoms (A.H.P. Tr. 131, 215, 279, 315-316, 372-373, 424, 439-440, 503-504, 566, 632-633, 682-683, 744) (A.H.P. F. 36).

32. We hereby enter findings with respect to the effect of The Pazo Formula Ointment and The Pazo Formula Hemorrhoid Suppositories on hemorrhoids and its symptoms and manifestations identical to the findings with respect to Preparation H set forth in paragraph 31 hereof (Stip., ¶2).

CONCLUSIONS RE ALLEGATIONS IN COMPLAINT

1. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of respondent.

2. Through the use of the advertisements set forth in paragraph 8 hereof and others similar thereto not specifically set out therein, we conclude that Grove Laboratories, Inc., now Bristol-Myers Company, has represented and is now representing, directly and by implication, that the use of The Pazo Formula Ointment and The Pazo Formula Hemorrhoid Suppositories will:

- (a) Shrink hemorrhoids;
- (b) Avoid the need for surgery as a treatment for hemorrhoids;
- (c) Eliminate all itching due to or ascribed to hemorrhoids;
- (d) Relieve all pain attributed to or caused by hemorrhoids;
- (e) Heal or cure hemorrhoids.

3. The Pazo Formula Ointment and The Pazo Formula Hemorrhoid Suppositories will not:

- (a) Shrink hemorrhoids;
- (b) Avoid the need for surgery as a treatment for hemorrhoids;
- (c) Eliminate all itching due to or ascribed to hemorrhoids;
- (d) Relieve all pain attributed to or caused by hemorrhoids;
- (e) Heal or cure hemorrhoids; or
- (f) Afford any relief or have any therapeutic effect upon hemorrhoids or upon any of the symptoms or manifestations thereof, in excess of affording some temporary relief in some cases of pain and itching associated with some types of hemorrhoids.

4. Therefore, the advertisements referred to in paragraph 8 hereof were and are misleading in material respects and constituted and now constitute "false advertisements" as that term is defined in the Federal Trade Commission Act; and the dissemination of said false advertisements constituted, and now constitutes, unfair and deceptive practices in commerce, in violation of Sections 5 and 12 of the Federal Trade Commission Act.

Order

71 F.T.C.

ORDER

I. *It is ordered*, That respondent Bristol-Myers Company, a corporation, and its officers, representatives, agents and employees, directly or through any corporate or other device, do forthwith cease and desist from disseminating or causing the dissemination of any advertisement by means of the United States mails or by any means in commerce, as "commerce" is defined in the Federal Trade Commission Act:

A. In connection with the offering for sale, sale or distribution of The Pazo Formula Ointment and The Pazo Formula Hemorrhoid Suppositories, or any other product offered for sale for the treatment or relief of hemorrhoids or piles or any of its symptoms, which:

1. Represents directly or by implication that the use of such product will:

(a) Reduce or shrink hemorrhoids or hemorrhoidal tissue or membranes or reduce or shrink swelling associated with hemorrhoids;

(b) Avoid the need for surgery as a treatment for hemorrhoids or hemorrhoidal symptoms;

(c) Heal or cure hemorrhoids or promote the healing or curing of hemorrhoids;

(d) Afford any relief from pain or itching attributed to or caused by hemorrhoids in excess of affording some temporary relief in some cases of pain and itching associated with some types of hemorrhoids; or

(e) Afford any other type of relief or have any other therapeutic effect upon the condition known as hemorrhoids or upon any of the symptoms or manifestations thereof.

2. Contains any reference (a) to any word or words which implies or imply that said product will shrink-hemorrhoids or (b) to any word or words which implies or imply that said product will provide any relief from pain or itching associated with hemorrhoids in excess of affording some temporary relief in some cases of pain and itching associated with some types of hemorrhoids;

3. Contains any general or specific reference to any ingredient either singly or in combination unless each such ingredient referred to is effective in the treatment of relief of hemorrhoids or any of its symptoms and unless the specific effect thereof is expressly and truthfully set forth; or

4. Makes any statement claiming or implying that said product

is more effective in the treatment or relief of hemorrhoids than other preparations sold for the treatment or relief of hemorrhoids.

B. In connection with the offering for sale, sale or distribution of any "drug" within the meaning of the Federal Trade Commission Act, including without limitation, any product referred to in Paragraph I(A) hereof, which misrepresents directly or by implication the efficacy of such drug.

II. *It is further ordered*, That respondent do forthwith cease and desist from disseminating or causing to be disseminated, by any means, for the purpose of inducing, or which is likely to induce, directly or indirectly, the purchase of respondent's drugs in commerce, as "commerce" is defined in the Federal Trade Commission Act, any advertisement which contains any of the representations prohibited in Paragraphs I(A) and I(B) hereof.

III. In the event that respondent at any time in the future markets any preparation for the treatment or relief of hemorrhoids or any of its symptoms for which it desires to make any of the representations now prohibited under Paragraph I(A) of this order, it may petition the Commission for a modification of the order. Such petition shall be accompanied by a showing that the representation is not false or misleading within the meaning of the Federal Trade Commission Act, and if such has been the case, that the specific representation has been approved by the Secretary of the Department of Health, Education and Welfare under the provisions of the Federal Food, Drug and Cosmetic Act as it is presently constituted or as it may hereafter be amended.

It is further ordered, That respondent shall, within sixty (60) days after service upon it of this order, file with the Commission a report, in writing, setting forth in detail the manner and form in which it has complied with this order to cease and desist.

FINAL ORDER

This matter having been heard by the Commission on appeal by counsel supporting the complaint from the initial decision of the hearing examiner, and upon briefs and argument in support thereof and in opposition thereto; and

The Commission having rendered its decision and issued its Opinion herein determining that the appeal should be granted, that the initial decision of the examiner should be set aside and

that the Commission should issue its Findings of Fact, Conclusions and Order consistent with said Opinion.

Now therefore, it is hereby ordered, That the initial decision and proposed order of the hearing examiner be and they hereby