
IN THE MATTER OF
AMERICAN HOME PRODUCTS CORPORATION

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

*Docket 8641. Complaint, Aug. 28, 1964—Decision, July 15, 1969 **

Order modifying pursuant to a decision of the Court of Appeals, Sixth Circuit, 402 F. 2d 232, an earlier order dated December 16, 1966, 70 F.T.C. 1524, which inhibited certain misrepresentations about the efficacy of "Preparation H" for treatment of hemorrhoids by prohibiting any claims that the product afforded any relief from pain or itching in excess of temporary relief, and restricting the order to non-prescription drug preparations.

OPINION OF THE COMMISSION

JULY 15, 1969

BY JONES, *Commissioner*:

On October 18, 1968, the United States Court of Appeals for the Sixth Circuit affirmed in major part the Commission's decision and order in the above-captioned matter holding respondent liable under Section 5 of the Federal Trade Commission Act for

* Modified by Commission's order of June 9, 1970, by modifying paragraph I.A.(4).

having made misrepresentations in its advertising of Preparation H.¹

The Circuit Court stated that it found " * * * in the record substantial evidence to support most but not all of the provisions of the Commission's order, * * * " directed the Commission to modify its order to reflect its views, and remanded the case " * * * for proceedings consistent with this opinion." ²

Neither party petitioned the Supreme Court for a writ of certiorari to review the Sixth Circuit Court's opinion, and the Commission subsequently submitted a proposed modified order to respondent and to complaint counsel and solicited their comments.³

After hearing oral argument on the form of the order to be entered herein, the Commission notified counsel that it would defer issuing its own order pending an exploration by the parties of the submission of an agreed-upon order. Such an order was submitted to the Commission by the parties on May 16, 1969.

The two order provisions concerning hemorrhoid products which the Circuit Court found to be too broad were those prohibiting " * * * representations that Preparation H will relieve pain and itching and reduce swelling associated with hemorrhoids." ⁴ The Court held that the prohibitions in the order must be formulated in the light of a definition of hemorrhoids which includes " * * * not only the varicose vein itself but also the tissue contiguous to the vein." ⁵ Thus, although the Court acknowledged that Preparation H will have no effect on the hemorrhoidal vein, it held that the evidence, when viewed in the light of a broad definition of hemorrhoids, would not support the Commission's finding that Preparation H " * * * will not help to reduce swelling as-

¹ *American Home Products Corp. v. F.T.C.*, 402 F. 2d 232 (6th Cir. 1968).

² 402 F. 2d at 237-8.

³ The Commission sent a proposed modified order to respondent on December 23, 1968. Respondent subsequently had informal discussions with the Commission staff and on January 29, 1969, submitted a counter-proposal to the Commission. At this point the Commission requested an oral argument on the appropriate order to be entered, and invited respondent and complaint counsel to submit comments on the Commission's proposed modified order and on respondent's proposal. Each party filed a brief, and oral argument was heard on April 10, 1969.

⁴ 402 F. 2d at 236. The Commission's order would have prohibited any representation that the product will:

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

⁵ 402 F. 2d at 236.

sociated with hemorrhoids and caused by edema, infection, or inflammation, except to the extent that such swelling is of the hemorrhoidal vein itself.”⁶ On pain and itching, the Court held—again in the light of its broader definition of hemorrhoids—that the evidence in the record did not support the Commission’s findings that Preparation H “ * * * will not afford in many cases temporary relief from the pain and itching associated with this malady.”⁷

Thus the Court remanded this order to the Commission for revision in light of a definition of “hemorrhoids” that includes both the hemorrhoidal *vein* and hemorrhoidal *tissue*. The proposed order which has now been jointly submitted by respondent and counsel supporting the complaint still fails to heed the specific injunction by the Circuit Court that the order must reflect this broad definition of hemorrhoids. The provisions which define the claims which would be permitted with respect to shrinking and pain and itch, speak solely in terms of “hemorrhoids” and thus suffer from the same infirmity—in their excessive permissiveness—as the Court found inhered in the Commission’s order in its excessive prohibitiveness.⁸ In addition, respondent’s provisions ignore the careful delineation of the Circuit Court as to the types of swelling affected by the product (*i.e.*, only swelling caused by edema, infection, or inflammation).

The jointly proposed order therefore fails to conform either to the opinion of the Sixth Circuit or to the record evidence. Nor do we believe that it adequately protects the consumer from the misrepresentations which have been found to have been made in the advertising of Preparation H. We are accordingly entering our own modified order which departs in some respects from the order agreed to by the parties.

The Commission’s task is to fashion an order which reflects the Court’s view of the evidence and which will clearly state what features of respondent’s advertising are false and misleading so that respondent will have reasonably defined guidelines to follow and so that consumers will no longer be misled or deceived as to what Preparation H can and cannot do for them.

⁶ *Id.* at 237.

⁷ *Id.* at 237.

⁸ The jointly proposed order would prohibit shrink claims respecting the hemorrhoidal *vein* and then provide that the respondent is specifically permitted to claim that the use of such product will:

“Help shrink hemorrhoids.”

“Afford temporary relief from pain of hemorrhoids.”

“Afford temporary relief from itching of hemorrhoids.”

The only way consumers can know what Preparation H will and will not do for them is for respondent's advertising to be reasonably precise about its effect on swelling of tissue. To say that the product helps shrink hemorrhoids is just as false as its original claim that it will shrink hemorrhoids. It will not. The Court's opinion made this quite clear. The Court specifically found that the Commission's original order prohibition was overly broad because it would have prohibited *any* claim of reducing swelling, even with respect to the hemorrhoidal tissue. The Court held that there was evidence in the record that certain types of swelling might be helped, *i.e.*, swelling of hemorrhoidal tissue caused by edema, infection, or inflammation.⁹ It is obvious that this finding by the Court cannot be translated into an order provision *permitting* respondent to assert that Preparation H will "help shrink hemorrhoids." The order prohibition must reflect what Preparation H can and cannot do. It cannot shrink hemorrhoidal veins. It can, according to the Circuit Court, help reduce certain types of swelling of the hemorrhoidal tissue.

The modification to the Commission's order required by the Court's opinion must prohibit not only claims that the product will shrink the hemorrhoidal vein, but also any other claims about shrinking except claims that the product will help reduce swelling of hemorrhoidal tissue due to edema, infection, or inflammation. Or, alternatively, respondent could state that Preparation H helps reduce swelling of the hemorrhoidal tissue by lubricating the affected area. This alternative claim in effect is another—and shorter—way of communicating truthfully to consumers the way in which the evidence indicates the preparation works on swelling due to edema, infection, or inflammation.

We have accordingly modified our original order to reflect these principles with respect to claims involving swelling.

With regard to pain and itching, the jointly proposed order simply would permit respondent to advertise that Preparation H affords temporary relief from pain and itching of hemorrhoids.

The Court did not find that the product would stop *all* pain and itch. Nor did it recognize any pain-relieving qualities in the prod-

⁹ 402 F. 2d at 237. The Court did not disturb—and indeed apparently relied upon—the Commission's Finding 33 to the effect that "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. * * * However, where swelling is due to thrombosis (Tr. 264), it will have no beneficial effect (Tr. 503)."

The Court also agreed with the Commission's conclusion (Finding 32) that Preparation H would have no effect on the hemorrhoidal vein. [402 F. 2d at 236-7.]

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uct except as a lubricant. It determined simply that the evidence would not support the Commission's finding that Preparation H "will not afford *in many cases* temporary relief from the pain and itching associated with this malady." [402 F. 2d at 237, emphasis added.] Indeed, it left undisturbed the Commission's finding that the product has *no* effect upon pain "due to thrombosis * * * or due to spasm or strangulation * * *." [Finding 34]

The fact that evidence is lacking to support the proposition that temporary relief from pain is not available "in many cases" does not justify a conclusion that the evidence supports an affirmative claim that temporary relief will always be afforded in *all* cases by the product. Moreover, here again the use of the term "hemorrhoids" ignores the Court's careful definition of hemorrhoids as embracing in the consumer's mind hemorrhoidal veins, hemorrhoidal tissue, and hemorrhoidal symptoms.

We conclude that the Commission's order relating to pain and itching must be modified so that it prohibits representations that the use of the product will:

"Afford any relief from pain or itching associated with hemorrhoids in excess of affording temporary relief of many types of pain and itching of hemorrhoidal tissue."

Finally, we have completed our modification of the original order in accordance with the Court's opinion by restricting the entire order to non-prescription drug preparations which are offered for sale for the treatment or relief of hemorrhoids or any of the symptoms thereof.

FINAL ORDER

The Commission having issued its original order to cease and desist in this matter on December 16, 1966, and the respondent having appealed from the Commission's decision; and

The matter having been remanded to the Commission for further proceedings by the United States Court of Appeals for the Sixth Circuit by its opinion and order issued October 18, 1968; and

The time for filing a petition for certiorari having expired without any such petition having been filed; and

The Commission having considered order modifications suggested by counsel supporting the complaint and modifications suggested by respondent, and having heard oral argument from both parties on the issues involved herein,

Final Order

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It is ordered, That the previously issued cease and desist order of the Commission be, and it hereby is, modified to read as follows:

ORDER

I. *It is ordered*, That respondent American Home Products Corporation, 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, in connection with the offering for sale, sale or distribution of Preparation H Ointment or Suppositories, or any other non-prescription drug product offered for sale for the treatment or relief of hemorrhoids or piles or any of its symptoms, which:

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

(1) Reduce, shrink, or afford any relief of hemorrhoidal veins themselves: *Provided, however*, That nothing contained herein shall be construed to prohibit the dissemination of any advertisement which represents that the use of such products will help reduce swelling of hemorrhoidal tissue caused by edema, infection or inflammation, or that the use of such product will help reduce swelling of hemorrhoidal tissue by lubricating the affected area;

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

(3) Heal, cure, or remove hemorrhoids, or eliminate the problem of hemorrhoids;

(4) Afford any relief from pain or itching associated with hemorrhoids in excess of affording temporary relief of many types of pain and itching of hemorrhoidal tissue;

(5) Afford any other type of relief, or have any other effect on, hemorrhoids or hemorrhoidal symptoms.

B. Contains any reference to the word "Bio-Dyne"; or contains any reference to any other ingredient either singly or in combination unless each such ingredient is effective in the treatment or relief of hemorrhoids or any of its symp-

toms and unless the specific effect thereof is expressly and truthfully set forth.

II. *It is further ordered*, That respondent and its officers, representatives, agents and employees, directly or through any corporate or other device, 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 Preparation H Ointment or Suppositories, or any other non-prescription drug product offered for sale for the treatment or relief of hemorrhoids or any of its symptoms, in commerce, as "commerce" is defined in the Federal Trade Commission Act, any advertisement which contains any of the representations prohibited in Paragraph I hereof.

III. In the event that respondent at any time in the future markets any non-prescription drug 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 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 accepted as part of the labeling for such product 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.
