

IN THE MATTER OF
STERLING DRUG, INC., ET AL.

Docket 8919. Interlocutory Order, Opinion, Oct. 14, 1983

OPINION OF THE COMMISSION

BY CLANTON, *Commissioner*:

Respondent Sterling Drug Inc. ("Sterling") has filed a Petition for Reconsideration seeking to delete Paragraphs II, III and V of the order that we entered against it on July 5, 1983. [102 F.T.C. 395] For the reasons stated below, the Petition is denied in its entirety.

Paragraph II of the order prohibits Sterling from representing that the superior freshness, purity, stability or speed of disintegration of a nonprescription analgesic has been established unless Sterling possesses a reasonable basis for such a claim. In petitioning for reconsideration, Sterling contends that its advertising did not make superior freshness, purity, stability or speed of disintegration claims; that we misinterpreted test results for two other aspirin brands, and improperly disregarded factors other than test results relating to physical integrity of the tablets; and that the record does not demonstrate a propensity to make future claims regarding specific pharmaceutical attributes.

We reject Sterling's assertion that its advertising made no superior freshness, purity, stability, or speed of disintegration claims. Sterling, having had adequate opportunity to argue the meaning of its advertisements in its appeal from the administrative [2] law judge's initial decision, cannot challenge our interpretation of the advertisements in petitioning for reconsideration of our final order. *See* 16 C.F.R. 3.55.

With respect to the substantiation for these claims, Sterling contends (1) that the Parke-Davis test results should be disregarded because they included an inadequate number of samples; (2) that the test results of the Safeway and Safeway S Brands should be grouped together and that when so combined, the results demonstrate Bayer's superiority; (3) that we considered an improper mix of test results in determining that Bayer was not fresher, purer, or more stable; and (4) that we should have considered factors other than the actual speed of disintegration in determining whether Bayer was quicker to disintegrate.

Each of these contentions is without merit. First, the test result may be inconclusive, because of the limited sample size, to demonstrate the Parke-Davis brand's superiority. Sterling was charged however, with falsely representing that tests established Bayer's su

periority over other tested brands. *See* Slip op. at 14. [102 F.T.C. at 755] That representation was clearly false. Secondly, we decline Sterling's belated invitation to combine the test results. Sterling's own tests treat the Safeway and Safeway Super S brands separately. *See* Ex. 430. Thirdly, we see no reason to reverse the position that we took in our opinion concerning which tests were relevant to Sterling's claims that Bayer was fresher, purer, and more stable. In order to determine which mix was appropriate, we relied on the testimony of Dr. Rhodes, an expert in drug formulation and evaluation, and of Sterling's own chemist. *See* Slip op. 33-35. [102 F.T.C. at 773-775] Sterling, on the other hand, has not cited anything in the record to support its claim that the mix of test results was improper. Lastly, Sterling's contention that the Commission erred in failing to consider that disintegration time can easily be shortened by taking steps that will cause more breakage and deterioration fails to take into account the actual representations that were made.

The advertisements claimed simply that Bayer was quicker to disintegrate than other leading brands (Slip op. at 14). [102 F.T.C. at 755] Sterling made no attempt to qualify those claims or to explain that this representation must be considered in light of other factors. Furthermore, in determining whether a particular aspirin brand disintegrates rapidly enough to be marketed, the United States Pharmacopoeia examines the actual speed of disintegration, not the other factors mentioned by Sterling.

Sterling next objects that Paragraph II is inappropriate because the Commission has no reason to anticipate that it will make future claims regarding specific pharmaceutical attributes. Abandonment of a practice does not, however, preclude entry of an order provision prohibiting the practice. Paragraph II is carefully tailored to prohibit precisely the types of violations that Sterling has committed. [3]

Finally, none of Sterling's arguments regarding order Paragraph II is properly raised for the first time in a petition for reconsideration. *See* 16 C.F.R. 3.55. Sterling had ample opportunity on appeal to contest the finding that its advertisements represented Bayer's superiority with respect to certain attributes. Indeed, the administrative law judge reached this finding (F. 329) and it is discussed in Sterling's Brief on Appeal (pp. 43, 85-86). Furthermore, Sterling took advantage of its opportunity on appeal to raise arguments regarding whether the 223 Study showed Bayer to be fresher, purer, more stable and quicker to disintegrate. (In fact, in its appeal brief Sterling argued, in contrast to the position it now takes, that the results of the 223 Study should not be used to draw conclusions regarding any specific pharmaceutical attribute (p. 43).)

Paragraph III

Paragraph III of our order prohibits Sterling from making any therapeutic performance claims regarding a nonprescription internal analgesic unless it possesses a reasonable basis for that claim. Well-controlled clinical tests supporting a claim are deemed to be a reasonable basis. This provision is similar to Paragraph II of the order that we entered against Bristol-Myers and Sterling's objections are similar to those asserted by Bristol-Myers in its Petition for Reconsideration (Petition for Reconsideration pp. 2-6). For the reasons set forth below, we reject each of Sterling's arguments regarding Paragraph III and decline to modify it.

First, Sterling contends that Paragraph III is vague and imprecise, noting that these reasons were cited by the Third Circuit when it set aside a similar provision in the order that we entered against its competitor, American Home Products Corporation ("AHP"). [98 F.T.C. 136 (1981)] However, as we explained in our response to Bristol-Myers' Petition for Reconsideration, there are important differences in the cases that are reflected in the challenged provisions. Paragraph III applies only to nonprescription analgesics and our opinion in this case contains an extensive discussion of analgesic testing. On the other hand, Paragraph II(D) in the AHP order applied to all drugs even though our opinion in that case contained no discussion of the criteria for testing any product other than analgesics. Moreover, Paragraph III sets forth a level of evidence (well-controlled clinical tests) that will constitute a reasonable basis. Paragraph II(D) contained no such standard.

Even more important, Paragraph II(D) was based only upon AHP's tension-relief claims for Anacin. On the other hand, as discussed in our opinion in this case, we found numerous instances in which Sterling had represented that Cope and Midol could relieve tension (Slip op. pp. 39-40). [102 F.T.C. at 778-779] We also found that Sterling lacked a reasonable basis for these claims and for its comparative superiority claims regarding Bayer (Slip. op. [4] p. 38). [102 F.T.C. at 777] Finally, we found that Sterling made numerous other nonestablishment claims which should be judged under a reasonable basis standard (*see, e.g.*, slip op. pp. 16-19). [102 F.T.C. at 757-759] Thus we found that Sterling lacked a reasonable basis for claims regarding three of its analgesics. Since it appears that Paragraph III would only apply to a total of five analgesics (slip op. p. 56) [102 F.T.C. at 794], the order in this case is much narrower and more carefully tailored to the violation than the order provision rejected by the Third Circuit.

Sterling contends that the order does not give it adequate direction as to what constitutes a reasonable basis. It also contends that Com-

mission advisory opinions are not an adequate means of curing this imprecision (Petition for Reconsideration pp. 3-4). We reject these arguments for the same reasons that we rejected identical arguments raised by Bristol-Myers.

Paragraph V

Paragraph V of our order prohibits Sterling from falsely representing that the analgesic ingredient in an aspirin-containing product is different from aspirin. This provision was based upon advertisements placed by Sterling regarding Midol. In its Petition for Reconsideration, Sterling contends that our interpretation of the Midol advertisements was inconsistent with our interpretation of advertisements disseminated by Bristol-Myers for Excedrin P.M. Sterling argues that its analgesic was different from aspirin (Petition for Reconsideration pp. 10-15).

Sterling misunderstands the portion of the Bristol-Myers decision that addressed the Excedrin P.M. advertisements. What we held in that decision was that Bristol-Myers did not represent that the sleep-inducing ingredient in Excedrin P.M. was *unique*. The complaint in that case did not allege that Bristol-Myers had represented that the sleep-inducing ingredient was different from another ingredient. In fact, advertisements for Excedrin P.M. do not contrast the sleep-inducing ingredient with the sleep-inducing ingredient in any other product.

The advertising for Midol is different. We did not find that the Midol advertisements represent that Midol's pain relieving ingredient is unique. Indeed, the Complaint contains no such allegation. Thus our interpretation of the Midol and Excedrin P.M. ads is consistent. However, we did find that advertisements for Midol represent that its pain-relieving ingredient is different from the pain-relieving ingredient in "ordinary pain relievers." Sterling contends that this finding is also inconsistent with our Bristol-Myers opinion. It argues that in *Bristol-Myers* we found that Bufferin and Excedrin ads falsely represented that the product did not contain aspirin by stressing the aspirin content of competing products and failing to disclose the aspirin content of Bufferin and Excedrin. Sterling seems to be arguing that since its Midol advertisements did not take the exact same approach as the Bristol-Myers [5] advertisements the Commission could not find that the advertisements falsely differentiated the product's analgesic ingredient from aspirin.

We reject this argument. It is true that the approach taken in the Midol advertisements is not exactly the same as in those for Bufferin and Excedrin. Nonetheless, using a slightly different approach, Sterling created the impression that Midol's analgesic ingredient is other

than aspirin. Since we discuss the Midol advertising in great detail in the opinion on pages 45-48 [102 F.T.C. at 783-787], there is no reason to repeat it here.

We reject Sterling's arguments regarding paragraph V for the reasons stated above and for the additional reason that the arguments are not timely. Petitioner would appear to argue that it had no opportunity to raise these arguments regarding paragraph V on appeal because it had not yet seen our decision in *Bristol-Myers*. However, although Sterling does mention the *Bristol-Myers* decision, in fact all of its arguments could have been raised in its appeal brief. Sterling chose to devote only one page of a 90 page appeal brief (p. 89) to the Midol advertising. It is not entitled to a second opportunity to raise those arguments now.

CONCLUSION

For each of the foregoing reasons, we deny Sterling Drug's Petition for Reconsideration in its entirety.

ORDER DENYING RESPONDENT STERLING DRUG'S PETITION FOR RECONSIDERATION

An opinion and final order in this matter were issued on July 5, 1983. [102 F.T.C. 395] Respondent Sterling Drug was served with the opinion and order and petitioned for reconsideration thereof on August 8, 1983. The Commission, for the reasons stated in the accompanying opinion, has determined to deny Sterling Drug's Petition for Reconsideration. Therefore,

It is ordered, That Respondent Sterling Drug's Petition for Reconsideration be, and hereby is, dismissed.

Modifying Order

102 F.T.C.

IN THE MATTER OF
DAMON CORPORATION

MODIFYING ORDER IN REGARD TO ALLEGED VIOLATION OF SEC. 5 OF THE
FEDERAL TRADE COMMISSION ACT AND SEC. 7 OF THE CLAYTON ACT

Docket C-2916. Consent Order, Feb. 23, 1978—Modifying Order, Oct. 14, 1983

The Federal Trade Commission has modified Part II of the order issued against Damon Corporation on Feb. 23, 1978 (91 F.T.C. 301). The addition of Paragraph E exempts from the prior approval requirements of Paragraphs A-C of Part II, acquisitions of any independent laboratory whose net sales of tests and services during the 4 most recent fiscal quarters preceding the acquisition was less than \$2 million.

MODIFIED ORDER TO CEASE AND DESIST

The Commission having considered respondent Damon Corporation's Petition of June 1, 1982, for reopening and modification of the Commission's Order, entered February 23, 1978, in Docket No. C-2916; and the Commission having denied the said Petition and, instead, having issued, on March 29, 1983, an Order to Show Cause Why Order Requiring Commission Approval For Certain Acquisitions Should Not Be Modified; and the Commission, having considered responses to its Order to Show Cause, now enters the following order:

It is hereby ordered, That pursuant to 15 U.S.C. 45, and Section 3.72 of the Commission's Rules of Practice, 16 C.F.R. 3.72 (1983), Part II, Paragraph E of the aforesaid order to cease and desist be, and it hereby is, modified to read:

E. Acquisitions consummated after [the date at which this modification becomes effective], of any independent laboratory which, during the four most recent fiscal quarters preceding the acquisition, has had less than \$2 million in Net Sales of Medical Laboratory Tests and Test Services performed on all specimens (from wherever originating) are exempt from the provisions of Paragraphs A through C of this Part II.

Commissioner Pertschuk dissents for the reasons stated in his Dissenting Statement on the Order to Show Cause.*

* Copies of the Commission's Order to Show Cause and Commissioner Pertschuk's Dissenting Statement are available from the Public Reference Branch, Room 130, Federal Trade Commission, 6th St. and Pa. Ave., N.W., Washington, D.C. 20580.