

IN THE MATTER OF

BRISTOL-MEYERS COMPANY, ET AL.

Docket 8917. Interlocutory Order, Opinion, Oct. 14, 1983

OPINION OF THE COMMISSION

BY CLANTON, *Commissioner*:

Respondent, Bristol-Myers Company ("Bristol") has filed a petition for reconsideration asking that the Commission delete two paragraphs of the order entered against it on July 5, 1983 [102 F.T.C. 21]. Bristol asserts that Paragraph II of the order places the company at a competitive disadvantage and is excessively vague and not reasonably related to the violations giving rise to it. Bristol contends Paragraph III-A should be deleted because our order dismissed all the claims on which it was premised. In addition, Bristol asserts that marketplace changes have eliminated entirely the need for the kind of relief ordered in the two provisions. For the reasons stated below, the petition is denied in its entirety.

Paragraph II

Paragraph II of our order reads in pertinent part:

*It is * * * ordered,* That respondent Bristol-Myers * * * do forthwith cease and desist from making any therapeutic performance or freedom from side effects claim for ["Bufferin", "Excedrin", or any other nonprescription internal analgesic] unless respondent possesses a reasonable basis for making that [2] claim. A reasonable basis for such a claim shall consist of competent and reliable scientific evidence supporting that claim. Well-controlled clinical tests conducted in accordance with the criteria set forth in Order Paragraph I shall be deemed to constitute a reasonable basis for a claim.

Bristol contends that Paragraph II places it at an unwarranted competitive disadvantage vis-a-vis its competitor, American Home Products Corporation ("AHP"), because a "virtually identical" provision in the order we entered against AHP (Paragraph II(D)) was deleted by the Third Circuit on AHP's petition for review. *See American Home Products Corp. v. FTC (AHP)*, 695 F.2d 681, 710-711 (3d Cir. 1982).

Preliminarily, we disagree that the two provisions are "virtually identical". The provision deleted on AHP's petition for review was directed to noncomparative representations of effectiveness or freedom from side effects of all over-the-counter drugs. By contrast, Paragraph II of the order in this case applies only to claims concerning the company's internal analgesics. It was this greater breadth of the AHP order that constituted one of the Third Circuit's objections to it.

Even more important is the fact that the only violation of the sort prohibited by Paragraph II(D) that AHP actually committed was covered by another provision in its order. Moreover, the AHP order contains provisions not found in the Bristol order, and taken as a whole, provides protection against deceptive advertising at least as great. To delete the corresponding provision in this case would mean that the numerous nonestablishment performance and freedom from side effects claims made by Bristol (*see slip op. at 7-17*) [102 F.T.C. at 321-330] would not be covered by any other provision in our order, and Bristol would be free to engage in deceptive advertising now foreclosed by order to its competitors.

Bristol next argues that Paragraph II is impermissibly vague because it does not specify the amount and kinds of evidence that are necessary to constitute a reasonable basis for future claims.

We believe that Bristol will have no difficulty in applying the requirements of Paragraph II to its contemplated future advertising. In its opinion the Commission construed the "reasonable basis" requirement of Paragraph II to mean "competent and reliable scientific evidence." We also specified a type of scientific evidence that will always satisfy that standard—*i.e.*, two well-controlled clinical trials¹ (*Slip op. at 71*). [102 F.T.C. at 375] [3] However, because we were unable to determine on the basis of the record whether some lesser standard might ever constitute a reasonable basis, we fashioned an order that allows Bristol to show in a given case that a lesser amount of support is adequate. Indeed, it is the advertiser who best knows the product and is best situated to verify the accuracy of claims made for it, *Sears Roebuck & Co. v. FTC*, 676 F.2d 385, 400 (1982). Should a situation arise in which Bristol is genuinely unable to determine whether two well-controlled clinical trials are required, it can, by complying with Rule 2.41(d) of the Commission's Rules of Practice and Procedure, obtain definitive advice as to whether its proffered substantiation would satisfy the order. *See, e.g., FTC v. Colgate-Palmolive Co.*, 380 U.S. 374, 392 (1965); *Jay Norris, Inc. v. FTC*, 598 F.2d 1244, 1251 (2d Cir. 1979).

Bristol's final objection to Paragraph II is that it is premised on too slender a basis—*i.e.*, the tension relief claims for Bufferin and Excedrin. In support of this argument it relies on the portions of the Third Circuit's opinion in *AHP* that explain why the one noncomparative tension-relief claim for Anacin did not justify imposing a reasonable basis requirement on all efficacy and freedom-from-side effects claims for all over-the-counter drugs.

¹ Thus this case differs from *Standard Oil Co. v. FTC*, 577 F.2d 653 (9th Cir. 1978). There, the court of appeals rejected the Commission's suggestion that any vagueness could be cured by an advisory opinion because various paragraphs of the Commission's order simply restated general principles of fair advertising. 577 F.2d at 661.

Paragraph II, however, is more solidly based and more narrowly drawn. The only advertising claim made by AHP in the category proscribed by Paragraph II(D) of our order was the one noncomparative tension-relief claim for Anacin. Bristol, on the other hand, disseminated at least 20 inadequately substantiated tension-relief claims for Bufferin and Excedrin (slip op. at 44-48) [102 F.T.C. at 353-356] and also claimed without a reasonable basis that Bufferin would cause no stomach upset (slip op. at 30-31) [102 F.T.C. at 341-342]. Finally, in contrast to the provision that we entered against AHP, Paragraph II is narrowly limited to internal analgesics—the specific product category for which the offending claims were made. Thus, there is no conflict with the Third Circuit's decision in *AHP*, which, as noted before, sustained a Commission order that taken as a whole was at least as extensive as that here.

Paragraph III-A

Paragraph III-A of our order prohibits Bristol from representing that any nonprescription drug product contains an "unusual" or "special" ingredient when in fact the ingredient is commonly used in other nonprescription drug products that are intended for the same use. Bristol objects that the provision is inappropriate in view of our decision to dismiss the allegations of the complaint that charged the company with falsely [4] representing the uniqueness of the ingredients in Excedrin P.M. *See* slip op. at 56-57. [102 F.T.C. at 362-363]

Paragraph III-A is not, however, premised on the advertisements for Excedrin P.M. *See* slip op. at 73. [102 F.T.C. at 377] Rather, it was based on the advertisements for Bufferin and Excedrin that falsely claimed that the analgesic ingredient was something other than aspirin (the violation specifically prohibited by Paragraph IV) and that also implied that those ingredients were special and unusual. *See* slip op. at 50-52. [102 F.T.C. at 358-359]

Marketplace Changes

Finally, Bristol contends that Paragraphs II and III-A should be deleted because it faces the growing market dominance of McNeilab's Tylenol and a significant increase in private enforcement under the Lanham Act, similar state statutes, and through the advertising industry's self-regulatory mechanism.

Under Section 3.55 of the Commission's Rules of Practice the scope of petitions for reconsideration is limited to "new questions raised by the decision or final order upon which the petitioner had no opportunity to argue before the Commission. Bristol, having had adequate opportunity to raise these contentions before the administrative law judge and again on its appeal from the law judge's decision, cannot

now assert them for the first time in a petition for reconsideration of our final order.

CONCLUSION

For all the foregoing reasons, the petition for reconsideration is denied in its entirety.

ORDER DENYING RESPONDENT BRISTOL-MYERS' PETITION FOR RECONSIDERATION

An opinion and final order in this matter were issued on July 5, 1983. [102 F.T.C. 21] Respondent Bristol-Myers was served with the opinion and order and petitioned for reconsideration thereof on August 8, 1983. The Commission, for reasons stated in the accompanying opinion, has determined to deny Bristol-Myers' Petition for Reconsideration. Therefore,

It is ordered, That Respondent Bristol-Myers' Petition for Reconsideration be, and hereby is, dismissed.

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