

IN THE MATTER OF

REMOVATRON INTERNATIONAL CORPORATION, ET AL.

MODIFYING ORDER IN REGARD TO ALLEGED VIOLATION OF
SECS. 5 AND 12 OF THE FEDERAL TRADE COMMISSION ACT

Docket 9200. Final Order, Nov. 4, 1988—Modifying Order, Nov. 20, 1991

This order reopens the proceeding and modifies the Commission's 1988 final order [111 FTC 206]—requiring respondents to cease making certain claims about their hair-removal device—by setting aside a provision requiring an affirmative disclosure in conjunction with certain efficacy claims. However, the respondents are still prohibited by the order from making unsubstantiated hair-removal claims.

ORDER REOPENING THE PROCEEDING AND
MODIFYING CEASE AND DESIST ORDER

On July 23, 1991, Removatron International Corporation and Frederick E. Goodman (Petitioners) filed a petition pursuant to Section 5(b) of the Federal Trade Commission Act, 15 U.S.C. 45(b), and Rules 2.51 and 3.72 of the Commission's Rules of Practice, 16 CFR 2.51 and 3.72, to reopen the proceeding and modify the final cease and desist order issued against them by the Commission on November 4, 1988, in Docket No. 9200 (111 FTC 206), and upheld by the United States Court of Appeals for the First Circuit on September 11, 1989, in *Removatron International Corp. v. FTC*, 884 F.2d 1489 (1st Cir. 1989).

The final order in this matter was the product of litigation concerning unsubstantiated claims of permanent or long-term (as opposed to temporary) hair removal for the Removatron radio frequency energy (RFE) tweezer-type epilation device. Part I.A of the order prohibits Petitioners from making permanent or long-term hair removal representations with respect to their RFE epilator unless they possess and rely upon competent and reliable scientific evidence that substantiates such representation. The order defines competent and reliable scientific evidence as adequate and well-controlled, double-blind clinical testing conforming to acceptable designs and protocols and conducted by a person or persons qualified by training and experience to conduct such testing. Part I.B of the order prohibits Petitioners, for a period of five (5) years, from representing that their

RFE epilator is intended to or is able to remove hair unless the following disclosure is also made:

IMPORTANT: There is no reliable evidence that [name of device treatments] provides anything more than *temporary* hair removal.

The request to reopen the proceeding to set aside Part I.B of the order was filed on July 23, 1991. The request was placed on the public record for thirty days for the purpose of receiving public comment on July 29, 1991. No comments were received during the comment period.

STANDARD FOR REOPENING A FINAL ORDER OF THE COMMISSION

Section 5(b) of the Federal Trade Commission Act, 15 U.S.C. 45(b), provides that the Commission shall reopen an order to consider whether it should be altered, modified, or set aside if the respondent "makes a satisfactory showing that changed conditions of law or fact" so require.¹ A satisfactory showing sufficient to require reopening is made when a request to reopen identifies significant changes in circumstances and shows that the changes eliminate the need for the order or make continued application of the order inequitable or harmful to competition. *Louisiana Pacific Corp.*, Docket No. C-2956, Letter to John C. Hart (June 5, 1986) at 4. *See*, S. Rep. No. 96-500, 96th Cong., 2d Sess. 9 (1979) (significant change or changes causing unfair disadvantage); *see Phillips Petroleum Co.*, Docket No. C-1088, 78 FTC 1573, 1575 (1971) (modification not required for changes reasonably foreseeable at time of consent negotiations); *Pay Less Drugstores Northwest, Inc.*, Docket No. C-3039, Letter to H.B. Hummelt (Jan. 22, 1982) (changed condition must be unforeseeable, create severe competitive hardship and eliminate dangers order sought to remedy) (unpublished); *see also United States v. Swift & Co.*, 286 U.S. 106, 119 (1932) ("clear showing" of changes that eliminate reasons for order or such that order causes unanticipated hardship).

¹ Section 5(b) provides, in part:

[T]he Commission shall reopen any such order to consider whether such order (including any affirmative relief provision contained in such order) should be altered, modified, or set aside, in whole or in part, if the person, partnership, or corporation involved files a request with the Commission which makes a satisfactory showing that changed conditions of law or fact require such order to be altered, modified, or set aside, in whole or in part.

The 1980 amendment to Section 5(b) did not change the standard for order reopening and modification, but "codified[d] existing Commission procedures by requiring the Commission to reopen an order if the specified showing is made," S. Rep. No. 96-500, 96th Cong., 2d Sess. 9-10 (1979), and added the requirement that the Commission act on petitions to reopen within 120 days of filing.

The language of Section 5(b) plainly anticipates that the burden is on the requester to make "a satisfactory showing" of changed conditions to obtain reopening of the order. *See also Gautreaux v. Pierce*, 535 F. Supp. 423, 426 (N.D. Ill. 1982) (requester must show "exceptional circumstances, new, changed or unforeseen at the time the decree was entered"). The legislative history also makes clear that the requester has the burden of showing, by means other than conclusory statements, why an order should be modified.² If the Commission determines that the requester has made the necessary showing, the Commission must reopen the order to determine whether the modification is required and, if so, the nature and extent of the modification. The Commission is not required to reopen the order, however, if the requester fails to meet its burden of making the satisfactory showing of changed conditions required by the statute. The requester's burden is not a light one in view of the public interest in repose and finality of Commission orders. *See Federated Department Stores, Inc. v. Moitie*, 425 U.S. 394 (1981) (strong public interest considerations support repose and finality); *Bowman Transportation, Inc. v. Arkansas-Best Freight System, Inc.*, 419 U.S. 281, 296 (1974) ("sound basis for . . . [not reopening] except in the most extraordinary circumstances"); *RSR Corp. v. FTC*, 656 F.2d 718, 721-22 (D.C. Cir. 1981) (applying *Bowman Transportation* standard to FTC order).

CHANGED CONDITIONS OF FACT WARRANT REOPENING THE ORDER

Petitioners have requested that the Commission reopen and modify the order because changed conditions of fact and the public interest require such action. For the reasons described below, changes of fact warrant reopening and modifying the order against Petitioners. Having reopened and modified the order on the basis of changes of fact, the Commission does not reach the issue of whether the public interest warrants reopening.

Petitioners rely on a clinical study entitled "Evaluation of the Effect of Radio-Frequency Energy Delivered by the Removatron Hair Removal Device on Hair Regrowth" to support their request that Part

² The legislative history of amended Section 5(b), S. Rep. No. 96-500, 96th Cong., 2d Sess. 9-10 (1979), states:

Unmeritorious, time-consuming and dilatory requests are not to be condoned. A mere facial demonstration of changed facts or circumstances is not sufficient . . . The Commission, to reemphasize may properly decline to reopen an order if a request is merely conclusory or otherwise fails to set forth specific facts demonstrating in detail the nature of the changed conditions and the reasons why these changed conditions require the requested modification of the order.

I.B of the order be set aside. The study was conducted by Nellie Konnikov, M.D., Assistant Professor of Dermatology, Tufts University School of Medicine; Chief, Dermatology Section, Boston VA Hospital; and Director, Dermatology Residency Program, Tufts-New England Medical Center. Dr. Konnikov concluded that Removatron's RFE device "appears to provide a safe, painless, and effective approach to the troublesome problem of unwanted hair." Dr. Konnikov bases this conclusion on her observation that contrary to the hair regrowth on the control sites, 46% of the facial hairs treated with the Removatron device could be considered with reasonable medical certainty to have been permanently removed.

Petitioners have also submitted the qualified opinion of a Medical Officer of the Food and Drug Administration's (FDA) Center for Devices and Radiological Health that the Konnikov study provides reasonable assurance of the efficacy of the Removatron RFE device. The Medical Officer, in a reference to the Standards for the Treatment of Permanent Hair Removal of the International Guild of Professional Electrologists, found that the range of effectiveness was in the minimum bracket of 40-50%—and the number of hairs studied per person was low. Consequently, he recommended that a statistical analysis of the study be conducted before the study could be pronounced an unqualified final determination that there is adequate evidence of safety and effectiveness of the Removatron device.³

Petitioners also had Dr. Eugene Van Scott, a dermatologist who testified as an expert on behalf of complaint counsel at the trial of this matter, review the Konnikov study. Dr. Van Scott stated that overall the study reported was designed quite well and the results appeared to be valid. However, he questioned whether the papilla was destroyed, the generally accepted definition of permanent hair removal.

Based on the foregoing, Petitioners argue that they have sufficient evidence on which to base representations of efficacy, *i.e.*, that Removatron's RFE device permanently removes hair. We do not agree. Arguably, the Konnikov study provides some evidence of permanent hair removal but it is by no means dispositive of this key issue. Supporting opinions are qualified, indicating that additional evidence will be required to substantiate permanent removal claims.

Dr. Van Scott's review of the Konnikov study is especially instructive. First, Dr. Scott proposes three possible effects of RFE on

³ The FDA, to our knowledge, has never conducted this statistical study. The FDA did compare the Konnikov study to the Standards of the International Guild of Professional Electrologists and determined there was not substantial equivalence between the RFE device and electrolysis.

the hair follicles' ability to grow hair, only one of which suggests the irreparable destruction of the papilla, the accepted definition of permanent removal. A second hypothesis is that the Removatron device merely extends the resting phase of the hair's growth period, the hair taking longer to grow back. A third hypothesis is that the Removatron device damages but does not destroy the papilla, causing the hair to grow back finer and shorter, so that it is no longer conspicuous but resembles the hair normally found in the affected region. The Konnikov study does not support the conclusion that permanent hair removal is the correct hypothesis among these three. Therefore, more study is needed.

Nevertheless, Dr. Van Scott has stated that he is convinced that RFE does something more than temporary hair removal. In his letter to the Petitioner Goodman, Dr. Van Scott wrote:

In my judgment this study does a great deal to satisfy the earlier criticisms and reservations regarding the effects of RFE on hair. In this regard consideration should be given however to positioning the claims for RFE, that is, "permanent removal" versus "diminishment of hirsutism" or some such statement to indicate that conspicuous hairs are eradicated, or conspicuous hairs fail to regrow. To insist on "permanent removal" invites the controversy over permanent destruction. In fact, if RFE can restore follicles to a state of normalcy (for the skin region involved) that is, convert follicles from producing coarse, long hairs to follicles producing short, fine hairs—which is suggested by the study of Dr. Konnikov—this would be cosmetically more desirable than trying to achieve baldness for the region. The result would be to normalize hair for that region.

Dr. Van Scott believes the study is evidence that something more profound than temporary hair removal is occurring.

PART I.B OF THE ORDER SHOULD BE SET ASIDE

Although the evidence presented is insufficient to substantiate a permanent removal representation, Part I.B does not require the same level of evidence to demonstrate a changed condition of fact. Since the evidence now demonstrates that Removatron's RFE epilation device achieves something more than temporary hair removal, Petitioners have shown that there is no need now for Part I.B of the order and that its continued application would be inequitable or harmful to competition.

It is therefore ordered, That the proceeding is hereby reopened and that Part I.B of the final order effective November 10, 1989, in Docket No. 9200 is hereby set aside.

IN THE MATTER OF

HOECHST CELANESE CORPORATION, ET AL.

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

Docket 9216. Complaint, Nov. 17, 1988—Decision, Nov. 26, 1991

This consent order prohibits, among other things, a German company and its U.S. subsidiaries, for a period of ten years, from entering into any agreement, with any producer of acetal products, to allocate, divide or restrict competition in markets for acetal products. In addition, the consent order prohibits the respondents from using certain restrictions to limit competition from Daicel Chemical Industries and Polyplastics Company of Japan, their partners in a joint venture.

Appearances

For the Commission: *Rhett R. Krulla.*

For the respondents: *James T. Halverson, Shearman & Sterling,*
New York, N.Y.

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act, and of the Clayton Act, and by virtue of the authority vested in it by said Acts, the Federal Trade Commission, having reason to believe that Hoechst Aktiengesellschaft, a corporation, Hoechst Corporation, a corporation, and Hoechst Celanese Corporation, a corporation, hereinafter sometimes referred to as respondents, have violated said Acts, and it appearing to the Commission that a proceeding in respect thereof would be in the public interest, hereby issues its complaint stating its charges in that respect as follows:

DEFINITION

PARAGRAPH 1. For purposes of this complaint, "acetal" means the crystalline engineering thermoplastic polymer resin known as acetal, polyacetal or polyoxymethylene (POM), and includes both acetal homopolymers, manufactured from formaldehyde and consisting of repeating oxymethylene units with esterified terminal hydroxy