

IN THE MATTER OF
ELI LILLY AND COMPANY

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

Docket C-3594. Consent Order, July 28, 1995—Set Aside Order, May 13, 1999

This order reopens and sets aside a 1995 consent order that, among other things, required Eli Lilly and Company to ensure that the acquired company, PCS Health Systems, maintains an open formulary.

Participants

For the Commission: *Pamela Gill and Roberta Baruch.*

For the respondent: *Jack Kaufman, Dewey Ballantine, New York*

ORDER REOPENING AND SETTING ASIDE ORDER

On February 5, 1999, respondent Eli Lilly and Company ("Lilly") filed a Petition to Reopen and Set Aside July 28, 1995 Decision and Order ("Petition"), pursuant to Section 5(b) of the Federal Trade Commission Act, 15 U.S.C. 45(b), and Section 2.51 of the Commission's Rules of Practice and Procedure, 16 CFR 2.51. In its Petition, Lilly requests that the Commission reopen the order in Docket No. C-3594 ("Order") to relieve Lilly of its compliance obligations under the Order.¹ The Petition was placed on the public record for thirty days pursuant to Section 2.51(c) of the Commission's Rules of Practice and Procedure. The Order requires that Lilly, a pharmaceuticals manufacturer, take measures to ensure that its drugs are not given unwarranted preference over those of its competitors in the "Pharmacy Benefits Management Services" ("PBM Services") that Lilly would provide after PCS Health Systems, Inc. ("PCS"), a subsidiary of McKesson Corporation ("McKesson"), became Lilly's subsidiary. Specifically, the Order requires Lilly to cause PCS to maintain an "Open Formulary."² The Open Formulary must include any drug approved by an independent "Pharmacy and Therapeutics Committee," as prescribed by the Order. In addition, Lilly is required to cause PCS to accept all discounts, rebates or other concessions

¹ 120 FTC 243 (1995). Paragraphs II.B.-II.E., and III-X are the only remaining operative paragraphs of the Order. See Order ¶¶ II.B.-II.E., III-X.

² A formulary is a list of drugs used as a guide in prescribing and dispensing pharmaceuticals to health plan beneficiaries.

offered by Lilly's competitors for drugs on the Open Formulary and to accurately reflect such discounts in ranking the drugs on the formulary. Another provision of the Order prohibits PCS and Lilly from sharing proprietary or other "Non-Public Information," such as price data, that PCS may obtain from competitors of Lilly whose drugs may be placed on a PCS formulary, or from PBM competitors of PCS that must deal with Lilly to complete their formularies. Lilly is also required to obtain the prior approval of the Commission for any exclusive distribution agreement with McKesson. The other provisions of the Order require Lilly to file annual reports respecting its compliance with the Order and provide that the Commission shall have access to specified records and officers and personnel of Lilly. The Order expires, pursuant to Paragraph X, on August 18, 2005.

On January 22, 1999, Rite Aid Corporation ("Rite Aid") acquired from Lilly 100% of the stock of PCS Holdings Corporation, which in turn owns 100% of the stock of PCS. According to Lilly, with this change, the Order no longer serves any useful purpose.³

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 modified if the respondent "makes a satisfactory showing that changed conditions of law or fact" so require.⁴ 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 it inequitable or harmful to competition.⁵

The language of Section 5(b) plainly places the burden on the petitioner to make a "satisfactory showing" of changed conditions to obtain reopening of the order. The legislative history also makes clear that the petitioner has the burden of showing, other than by

³ Petition at 2; Kauffman Affidavit at ¶ 6.

⁴ Section 5(b) also provides that the Commission may modify an order when, although changed circumstances would not require reopening, the Commission determines that the public interest so requires. Respondents are therefore invited in petitions to reopen to show how the public interest warrants the requested modification. Lilly has based its request upon changed conditions of fact and not the public interest standard for reopening and modifying orders.

⁵ S. Rep. No. 96-500, 96th Cong., 1st Sess. 9 (1979) (significant changes or changes causing unfair disadvantage); *Louisiana-Pacific Corp.*, Docket No. C-2956, Letter to John C. Hart (June 5, 1986), at 4 (unpublished) ("Hart Letter"). See also *United States v. Louisiana-Pacific Corp.*, 967 F.2d 1372, 1376-77 (9th Cir. 1992) ("A decision to reopen does not necessarily entail a decision to modify the order. Reopening may occur even where the petition itself does not plead facts requiring modification").

conclusory statements, why an order should be modified. The Commission "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."⁶ If the Commission determines that the petitioner has made the necessary showing, the Commission must reopen the order to consider whether 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 petitioner fails to meet its burden of making the satisfactory showing required by the statute. The petitioner's burden is not a light one in view of the public interest in repose and the finality of Commission orders.⁷ However, if the Commission denies relief, it must provide a sufficient explanation of its reasons for the denial.⁸

Upon consideration of Lilly's request and other information, the Commission finds, pursuant to Section 2.51 of the Commission's Rules of Practice and Procedure, that changed conditions of fact warrant reopening and setting aside the Order. Lilly has shown that there is no need for the Order by presenting evidence of the sale by Lilly of PCS to Rite Aid and that Lilly is not in a position to control PCS. As a result of the sale, Lilly is no longer engaged in the PBM Services business which gave rise to the Order, and the Commission has no reason to believe that Lilly has any present intent to re-enter that business in the future. The Order addresses competitive concerns that arose through the vertical integration between Lilly, a pharmaceuticals manufacturer, and PCS, a PBM Services provider. Rite Aid, unlike Lilly, is not a pharmaceuticals manufacturer. Therefore, the competitive problems that prompted issuance of the Order no longer exist. Since there are no competitive concerns that would justify the need to maintain the Order, the Order should be set aside.

Accordingly, *It is ordered*, That this matter be, and it hereby is, reopened and that the Commission's Order issued on July 28, 1995, be and it hereby is, set aside as of the effective date of this Order.

⁶ S. Rep. No. 96-500, 96th Cong., 1st Sess. 9-10 (1979); *see also* Rule 2.51(b) (requiring affidavits in support of petitions to reopen and modify).

⁷ *See Federated Department Stores, Inc. v. Moitie*, 425 U.S. 394 (1981) (strong public interest considerations support repose and finality).

⁸ *United States v. Louisiana-Pacific Corp.*, 754 F.2d 1445 (9th Cir. 1985).

IN THE MATTER OF
NOVARTIS CORPORATION, ET AL.

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

Docket 9279. Complaint, June 21, 1996—Final Order, May 13, 1999

This final order, among other things, prohibits Novartis Corporation and Novartis Consumer Health, Inc., successors-in-interest to Ciba-Geigy Corporation and Ciba Self Medication, Inc., and the marketers of Doan's Pills, from representing that any over-the-counter analgesic drug is more effective than other over-the-counter analgesic drugs unless they possess and rely upon competent and reliable scientific evidence that substantiates their claims. In addition, the order requires the respondents to include a corrective notice in certain of Doan's advertisements, and to possess and rely upon competent and reliable scientific evidence as substantiation for any claims regarding the efficacy, safety, benefits or performance of any over-the-counter analgesic they market.

Participants

For the Commission: *Theodore Hoppock, Michael Ostheimer, Kevin Bank, Lynne Colbert, C. Lee Peeler, and Susan Braman.*

For the respondents: *Michael Denger, Boyd Johnson and Phillip Rudolph, Gibson, Dunn & Crutcher, Washington, D.C.*

COMPLAINT

The Federal Trade Commission, having reason to believe that Ciba-Geigy Corporation, and CIBA Self-Medication, Inc., corporations ("respondents"), have violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, alleges:

PARAGRAPH 1. Respondent Ciba-Geigy Corporation ("Ciba-Geigy") is a New York corporation with its principal office or place of business at 444 Saw Mill River Road, Ardsley, New York.

Respondent CIBA Self-Medication, Inc. ("CIBA Self-Medication"), is a Delaware corporation with its principal office or place of business at 581 Main Street, Woodbridge, New Jersey. CIBA Self-Medication is a wholly-owned subsidiary of Ciba-Geigy.

PAR. 2. Respondents have manufactured, labeled, advertised, offered for sale, sold, and distributed drug products, including Doan's analgesic products, to the public. Doan's analgesic products are