UNITED STATES DISTRICT COURT

DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA, Plaintiff, v. CIBA Corporation, and CPC International, Inc. Defendants.	)	Civil Action No. 792-69 (Judge Meanor)

Filed: MAR 8 1978

COMPETITIVE IMPACT STATEMENT

Pursuant to Section 2(b) of the Antitrust Procedures and Penalties Act (15 U.S.C. § 16(b)), the United States of America hereby submits this Competitive Impact Statement relating to the proposed consent judgment submitted for entry in this civil antitrust proceeding.

I. NATURE OF THE PROCEEDING

The government filed this civil action on July 9, 1969, alleging that the defendants, CIBA Corporation (which is now named CIBA-GEIGY Corp., and which, together with its predecessors in interest are referred to hereafter as "CIBA") and CPC International, Inc. (referred to hereafter as "CPC"), violated § 1 of the Sherman Act by restraining the distribution and sale of the tranquilizer and antihypertensive drug known by the generic name deserpidine. The complaint also alleged that CIBA's patent on deserpidine is invalid, since deserpidine is merely a purified product of nature.

The prayer for relief sought: (1) an adjudication and decree that the defendants have entered into contracts and agreements that unlawfully restrain trade and commerce in deserpidine in violation of § 1 of the Sherman Act; (2) an injunction against each of the defendants agreeing to restrict any persons from selling any drug product in bulk form or under a name other than a specified tradename; (3)

a declaration that CIBA's deserpidine patent is invalid, or an order that CIBA dedicate the patent to the public; and (4) an injunction against each of the defendants agreeing not to challenge the validity of a United States patent. The prayer also sought such other relief as the Court may deem just and proper, and the cost of the suit.

II. DESCRIPTION OF THE PRACTICES INVOLVED IN THE ALLEGED VIOLATION

In 1959, CIBA Pharmaceutical Products, Inc. (a predecessor to CIBA-GEIGY), and S.B. Penick & Co. (which merged with CPC in 1968, and is referred to hereafter as "Penick") agreed to settle a pending Patent Office interference proceeding concerning their respective applications for a patent on deserpidine. On May 2, 1961, United States Patent No. 2,982,769 issued covering the product deserpidine, and was assigned to CIBA. Pursuant to the 1959 agreement, CIBA granted to Penick an exclusive license under the deserpidine patent to make and/or sell deserpidine in bulk form only, subject to CIBA's right to make, use, and sell deserpidine. Neither Penick nor CIBA had the right to sublicense others. The agreement also provided that the parties would cooperate with each other to eliminate infringement of the deserpidine patent by others, and that neither party would contest the validity of the deserpidine patent.

Penick's only customer for deserpidine was Abbott Laboratories ("Abbott"), which made the bulk deserpidine into dosage form. Prior to the patent's issuance, however, Abbott bought bulk deserpidine at a cheaper price from a third party that imported bulk deserpidine from France. Abbott wanted to continue buying from the third party after

the patent issued, and sought a license from CIBA to permit Abbott to buy from that firm. Since Penick wanted to be Abbott's sole source of bulk deserpidine in the United States, Penick invoked the cooperation against infringement clause in the 1959 CIBA-Penick agreement, and sent an infringement notice to the third party in January 1962. Penick persisted in this posture until October 1962 when Penick offered to consider a sublicense to Abbott. CIBA would agree to allow Penick to sublicense Abbott if CIBA received the royalty it wanted. In December 1962, CIBA and Penick amended their 1959 agreement to authorize Penick to grant Abbott "a license to use, manufacture or have manufactured, and sell Deserpidine in package dosage form under Abbott's label only." The "under Abbott's label only" language was proposed by Penick. Penick did not want Abbott offering bulk deserpidine (or its equivalent) generally to the drug industry. Although Abbott objected to the "under Abbott's label only" language in the draft sublicense Penick offered, and to a clause in that draft prohibiting Abbott from contesting the validity of the deserpidine patent even beyond the term of the sublicense, Abbott finally agreed to these provisions. On May 15, 1963, Penick granted Abbott a non-exclusive sublicense under the deserpidine patent "to make or have made, to import or have imported and to use Deserpidine, and to sell Deserpidine in Package Dosage Form under ABBOTT's label."

III. EXPLANATION OF THE PROPOSED CONSENT DECREE AND ITS ANTICIPATED EFFECT ON COMPETITION

The United States and the defendants have stipulated that the proposed consent judgment, in the form negotiated by the parties, may be entered by the Court at any time after compliance with the Antitrust Procedures and Penalties

Act. The proposed judgment provides that there has been no admission by any party with respect to any issue of fact or law. Under the provisions of Section 2(e) of the Antitrust Procedures and Penalties Act, entry of the proposed judgment is conditioned upon a determination by the Court that the proposed judgment is in the public interest.

The proposed judgment would eliminate the basis for the challenged restrictions, the deserpidine patent. Thus, Article IV would require CIBA to disclaim the remaining term of the deserpidine patent, voiding the effect of the patent after the date of entry of the judgment. Article IV also would prohibit CPC (Penick's successor under the deserpidine patent license agreements) from enforcing any rights under the deserpidine patent.

In order for Abbott to obtain a license to use bulk deserpidine, Abbott had to meet not only the terms of CIBA, which had the right to use bulk deserpidine, but also the terms of Penick, an exclusive licensee only as to the manufacture and sale (but not use) of bulk deserpidine. To prohibit practices such as this, Article IV also would bar each defendant from an agreement pursuant to which the grant by the licensor of a license under a United States patent claiming the manufacture, use, or sale of deserpidine would require the prior approval of a third party (other than the prospective licensee).

These provisions in the judgment would allow, after the entry of the judgment, anyone in the United States to make, use, or sell deserpidine in bulk or other form without infringement of CIBA's deserpidine patent or payment of any royalties to CIBA or CPC. This would allow others freely to enter the market for deserpidine products.

IV. REMEDIES AVAILABLE TO POTENTIAL PRIVATE PLAINTIFFS

Any potential private plaintiffs who might have been damaged by the alleged violations will retain the same right to sue for monetary damages, and any other legal or equitable relief to which they would have been entitled, as if the proposed judgment were not entered. This judgment may not be used as prima facie evidence in private litigation, however, pursuant to Section 5(a) of the Clayton Act, 15 U.S.C. § 16(a).

V. ALTERNATIVES TO THE PROPOSED JUDGMENT CONSIDERED BY THE UNITED STATES

A full trial on the merits was considered as an alternative to settlement. Because the relief in the proposed judgment would be substantially equivalent to that sought in the complaint, and because the relief would become effective upon entry of the judgment, the alternative of a trial on the merits was rejected.

In addition to considering provisions substantially similar to those contained in the proposed judgment, proposals considered by the government and then rejected included the following:

(a) A substantial issue during negotiations was broader product scope (e.g., all Rauwolfia plant derivatives, not just deserpidine). Government counsel concluded, however, that it is unlikely that the defendants would enter into the prohibited practices with other products, because the defendants would know that the government would challenge the practices again if the defendants subsequently adopted them. Thus, the government considers the limitation of the proposed judgment to deserpidine to be adequate.

(b) A substantial issue during negotiations also was a provision prohibiting the grant of a license under a patent claiming the manufacture, use, or sale of deserpidine unless at least one party to the license agreement has a unilateral right to grant either further licenses or sub-licenses. Because the proposed judgment would prohibit a third party from having a veto power over a licensor's grant of a patent license to a prospective licensee, and because the proposed judgment would terminate CIBA's deserpidine patent, the government considers such a further provision unnecessary.

(c) The government considered a prohibition against each of the defendants agreeing to restrict any persons from selling any drug product in bulk form or under a name other than a specified tradename. However, the legality of a prohibition on the resale of bulk drugs is also in issue before Judge Meanor, the same judge presiding over this litigation, in United States v. CIBA-GEIGY Corp., Civil No. 791-69 (D.N.J., filed July 9, 1969). Moreover, the evidence obtained in the instant case did not appear to indicate that these restrictions in the deserpidine license to Abbott had (at least at present) a significant economic effect. Thus, the government considers the relief obtained to be adequate.

(d) The government also considered an injunction against each of the defendants agreeing, or requiring another party to agree, not to contest the validity of a licensed patent. In view of the termination of the deserpidine patent by the proposed consent judgment, such an injunction is not necessary in the present circumstances.

VI. DETERMINATIVE DOCUMENTS

There are no materials or documents that the government considered determinative in formulating the proposed consent judgment. Therefore, none is being filed with this Competitive Impact Statement.

VII. PROCEDURES AVAILABLE FOR MODIFICATION OF THE PROPOSED CONSENT JUDGMENT

The proposed consent judgment is subject to a stipulation between the United States and the defendants that provides that the United States may withdraw its consent to the proposed consent judgment at any time before the Court has found that entry of the judgment is in the public interest. The district court would retain jurisdiction of the case to permit any necessary construction or modification of the judgment, to enforce compliance and to punish any judgment violation.

As provided by the Antitrust Procedures and Penalties Act, any person believing that the proposed judgment should be modified may, during the sixty-day period prior to the effective date of the proposed judgment, submit written comments to the United States Department of Justice, Richard H. Stern, Chief, Intellectual Property Section, Antitrust Division, Washington, D.C. 20530, which will file such comments and its response to them with the Court and publish them in the Federal Register. The Department of Justice will evaluate any and all such comments and determine whether there is any reason for withdrawal of its consent to the proposed judgment.

Dated: MAR 8 1976

Richard H. Stern

Richard H. Stern

Kenneth M. Frankel

Kenneth M. Frankel
Attorneys,
Antitrust Division
U.S. Department of Justice