

**UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION**

COMMISSIONERS: Timothy J. Muris, Chairman
Sheila F. Anthony
Mozelle W. Thompson
Orson Swindle
Thomas B. Leary

In the Matter of

**HOECHST AG, a corporation
and
RHONE-POULENC S.A., a
corporation; renamed
AVENTIS, S.A., a corporation.**

Docket No. C-3919

ORDER REOPENING AND MODIFYING ORDER

On November 15, 2001, Aventis S.A. (“Aventis”) filed with the Commission its “Petition of Aventis S.A. To Reopen and Modify Order” (“Petition”). Aventis is the successor to Hoechst AG and Rhone-Poulenc S.A., the respondents named in the consent order issued by the Commission on January 18, 2000, in Docket No. C-3919 (“Order”). Aventis became the successor under the Order as a result of the merger of the two other parties. In the Petition, Aventis asks that the Commission modify the obligations under Paragraph II of the Order that require respondent to divest manufacturing facilities in Romainville, France and require respondent to divest all intellectual property related to “Refludan,” the product required to be divested by the Order. In place of those existing obligations, respondent requests that its supply obligations from the Romainville plant be extended and that it be permitted to retain rights to the intellectual property for the purpose of manufacturing a product that is unrelated to Refludan. For the reasons stated below, the Commission has determined to grant the Petition. The effect of this modification is to conform the requirements of the Order to the divestiture contract approved by the Commission on September 26, 2001.

I. THE ORDER

On January 18, 2000, the Commission issued its Order (“Order”) in Docket No. C-3919 regarding the merger between Rhone-Poulenc S.A. and Hoechst AG, which has been

renamed Aventis SA. The Order became final on January 28, 2000. The Order required Aventis to divest all rights related to a drug known as Revasc within six months and to maintain the value of the drug pending divestiture by, inter alia, seeking approval from the FDA to market the drug in the United States. The Order required the divestiture of Revasc because Hoechst's product, Refludan, and Rhone-Poulenc's product, Revasc, were the closest competitors in the direct thrombin inhibitor market. Direct thrombin inhibitors are used in the treatment of many blood clotting diseases, because of their unique mechanism of action in the blood clotting cascade of targeting thrombin. There are no acceptable substitutes for direct thrombin inhibitors because of their unique mechanism of action. The purpose of the Order is to ensure the continued research, development, manufacture and sale of direct thrombin inhibitors.

In the event that Aventis failed to divest Revasc within the time period required by the Order, Paragraph IV.A. provides that the Commission may appoint a trustee to divest either (1) all rights related to Revasc or (2) all rights related to a drug known as Refludan. Despite what appears to have been diligent efforts by Aventis, it did not find a buyer for the Revasc assets. As a result, on August 23, 2000, the Commission appointed Ferghana Partners as Divestiture Trustee to Divest the Refludan Assets.¹ On September 26, 2001, the Commission approved a divestiture by the Trustee to Schering AG of some, but not all, of the assets that are defined in the Order as "Refludan Assets."

Paragraph V.A. of the Order requires the divestiture of the Refludan Assets "as a competitively viable, ongoing product line in North America." The product is manufactured in Marburg, Germany and Romainville, France for distribution in Europe and North America. Paragraph I.V. defines the assets to include "all of Respondent's assets and rights relating to the research, development and manufacture of Refludan, including regulatory approvals, physical assets necessary to manufacture Refludan (excluding the production assets in Marburg, Germany)" The definition goes on to list categories of assets that are specifically included, including all research materials, formulations, patent rights, inventory, and title to owned or leased property related to the research, development and manufacture of Refludan.

Paragraph V.B. requires that Aventis "contract manufacture on behalf of and deliver to the Acquirer . . . under reasonable conditions . . . a supply of Refludan, specified in the Divestiture Agreement at cost for a period not to exceed four (4) years . . ." but provides that the "four (4) year period may be extended by the Commission in twelve month increments for a period not to exceed two (2) years."

II. THE PETITION

Aventis has petitioned the Commission to modify Paragraph I and Paragraph V of the Order on public interest grounds. In its petition, Aventis asserts that the more limited divestiture

¹ Aventis did not object to the Commission's decision to require the divestiture of Refludan instead of Revasc.

contract negotiated by the Divestiture Trustee and approved by the Commission is more efficient and accomplishes the purposes of the Order better than a divestiture that included all of the assets specified in the Order. Aventis requests that it be permitted to retain its Romainville manufacturing facilities. As a partial replacement for not divesting those facilities, Aventis recommends that the Commission extend Aventis' obligation to supply Refludan for an additional two years to further ensure that Schering will be able to build its own facilities to produce Refludan. In addition, Aventis requests that it be permitted to retain limited rights to the intellectual property that it is divesting in order to continue its development of a product that is unrelated to Refludan. Aventis asserts that Schering would be disadvantaged by purchasing the Romainville plants and does not want them, and that consequently the public is better served by the deletion of this requirement. It also argues that the public would be better served by permitting Aventis to retain limited rights to intellectual property that is being divested to enable Aventis to continue its research and development of a product that is unrelated to Refludan.

III. STANDARD FOR REOPENING AND MODIFYING FINAL ORDERS

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. 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. S. Rep. No. 96-500, 96th Cong., 1st Sess. 9 (1979) (significant changes or changes causing unfair disadvantage); *Louisiana-Pacific Corporation*, Docket No. C-2956, Letter to John C. Hart (June 5, 1986), at 4 (unpublished) ("Hart Letter").² Aventis has not asserted that any changed condition of law or fact requires reopening the Order, and the Commission has, therefore, not considered that issue.

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. Hart Letter at 5; 16 C.F.R. § 2.51. The Commission has described the showing needed to obtain a modification based on the public interest standard:

[A] "satisfactory showing" requires, with respect to "public interest" requests, that the requester make a prima facie showing of a legitimate "public interest" reason or reasons justifying relief. . . . [T]his showing requires the requester to demonstrate, for example,

² 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.").

that there is a more effective or efficient way of achieving the purpose of the order³

The language of Section 5(b) plainly anticipates that the burden is 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 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." 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). 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. *See Federated Department Stores, Inc. v. Moitie*, 425 U.S. 394 (1981) (strong public interest considerations support repose and finality).

IV. IT IS IN THE PUBLIC INTEREST TO GRANT THE PETITION

Public interest considerations warrant modifying the Order for the reasons cited by Aventis. Having considered both the assertions of Aventis in its Petition and the confidential business plan submitted by Schering in connection with the Divestiture Trustee's Application to Divest, the Commission is persuaded that requiring Schering to purchase the Romainville plants would be disadvantageous to Schering and that it would be more consistent with Schering's business plan and more efficient to eliminate this requirement from the Order. Also, requiring divestiture of the Romainville facilities to a party other than Schering would interfere with Aventis' ability to supply Recludan to Schering as required by the Order. Accordingly, the Commission has determined to eliminate the requirement that Aventis sell the Romainville facilities.

Schering expects that it will have its own manufacturing facilities within four years, but has asked for additional protection against what it considers to be the remote contingency that its plans for new production facilities fail. Should that contingency occur, Schering might require a supply contract that exceeds the six years provided for in the Order. Aventis has agreed to this extension and included the change in its Petition. The Commission is persuaded that this contingency is remote by the fact that Schering is willing to pay a substantially higher amount for any Recludan that it might acquire after year six. That higher price provides assurance that the availability of extended supplies will not discourage Schering from developing its own supplies as quickly as it can. Accordingly, the Commission has determined to modify the Order to extend the supply contract for two years on a basis that is less advantageous to Schering.

³ 65 Fed. Reg. 50637 (August 21, 2000).

The Commission is also persuaded that Aventis should be permitted to retain certain rights derived from the intellectual property that is being divested to Schering. The research and development project concerns insulin products that are completely unrelated to thrombin inhibitor drugs. Accordingly, Aventis' retention of such rights should have no effect on Schering's development of the Refludan product. In contrast, requiring Aventis to divest such rights would likely severely hamper the insulin development project on which Aventis and a joint venture research partner have been working. The Order does not require the divestiture of the know-how associated with insulin, because insulin was not a product affected by the merger of Hoechst and Rhone-Poulenc. Accordingly, it would be in the public interest to permit Aventis to retain intellectual property rights to pursue the development of insulin products.

Because some of the intellectual property rights used in the insulin development project have been dedicated to the joint venture, it would be time consuming and expensive to extricate those rights from the joint venture and transfer the patent applications to Schering. These rights, however, have potential application to the production of Refludan and must therefore be divested to the buyer. They are, nevertheless, not currently used in that production and are not part of any existing plan of Schering to produce Refludan. In these circumstances, the Commission believes that the purposes of the Order can be effected more efficiently by granting Schering the exclusive right to use these rights in connection with Refludan and allowing Aventis to retain the title to the patent applications.

V. THE ORDER IS REOPENED AND MODIFIED

Accordingly, IT IS ORDERED that this matter be, and it hereby is, reopened and that the Order be, and it hereby is, modified in the manner set forth below. The provisions added to the Order are underlined and italicized. Other portions of the Order are repeated here solely to facilitate understanding the context of the additions.

I. IT IS ORDERED that, as used in this order, the following definitions shall apply:

* * * * *

W. "Refludan Assets" means all of Respondents' assets and rights relating to the research, development, and manufacture of Refludan for sale in North America, including the regulatory approvals, physical assets necessary to manufacture Refludan (excluding the production assets in Marburg, Germany *and Romainville, France*), and all of its brand names and trade names. Refludan Assets include the New Drug Application Number 20-807 on file with the Food and Drug Administration (FDA), and include but are not limited to:

1. manufacturing operations, machinery, fixtures, equipment, furniture, tools, and other tangible personal

property necessary to manufacture Refludan;

2. all intellectual property, inventions, technology, know-how, patents, trademarks, brand names, trade names, trade secrets, and copyrights, excluding the following Aventis patent applications: DE 19944870. 1-43; DE 10033195. 5-41; DE 10108100.6; DE 10108211.8; and DE 10108212.6 (provided, however, Aventis must grant an exclusive license to the Acquirer or New Acquirer for use of any patents granted under these applications for use in connection with the manufacture or sale of Refludan and a non-exclusive license for any other use except the manufacture and sale of Insulin Products);
3. all research materials, formulations, patent rights, trade secrets, specifications, protocols, technical information, management information systems, software, specifications, designs, drawings, processes and quality control data; . . .

* * * * *

11. all items of prepaid expense relating to the assets described in Definition W;

Provided however, that Respondents may receive a grant back from the Acquirer or New Acquirer of the following rights:

- a) an exclusive license (even as to the Acquirer or New Acquirer) to use the Product Patents, Process Patents, and Manufacturing Technology transferred to the Acquirer or New Acquirer for the production and sale of Insulin Products; and
- (b) a non-exclusive license to use the Product Patents, Process Patents, and Manufacturing Technology transferred to the Acquirer or New Acquirer for the production and sale of Non-Refludan Products.

Provided, however, that the Refludan Assets shall also include all research, development, and manufacturing assets necessary to produce Refludan in an FDA Good Manufacturing Practice-approved facility if the person acquiring the Refludan Assets requests such assets.

* * * * *

CC. "Insulin Product" means any Product comprised of insulin and/or its derivatives and analogs or any precursor of any of the following (in particular human insulin or animal insulin) including, without limitation, any (or any combination) of the following: (1) natural insulins; (2) chemically synthesized insulins; (3) insulin analogs, including, by way of example, analogs of human or animal insulin which are distinguished from natural insulin by a combination of a substitution or addition of at least one natural or non-natural amino acid residue and/or deletion of at least one amino acid residue in comparison to the natural insulin; and (4) insulin derivatives, including, by way of example, derivatives of a natural insulin or insulin analogs obtained by chemical modification of the respective natural insulin or insulin analog.

DD. "Refludan Product" means any Product comprised of hirudin and/or its derivatives and analogs or any precursor of any of the following including, without limitation, any (or any combination) of the following: (1) natural hirudins; (2) chemically synthesized hirudins; (3) hirudin analogs, including, by way of example, analogs of hirudin which are distinguished from natural hirudin by a combination of a substitution or addition of at least one natural or non-natural amino acid residue and/or deletion of at least one amino acid residue in comparison to the natural hirudin; and (4) hirudin derivatives, including, by way of example, derivatives of a natural hirudin or hirudin analogs obtained by chemical modification of the respective natural hirudin or hirudin analog.

EE. "Non-Refludan Product" means any Product which is not a Refludan Product or an Insulin Product.

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V. IT IS FURTHER ORDERED that in the event that the Commission appoints a trustee to divest the Refludan Assets, the trustee shall divest the Refludan Assets on behalf of Respondents in the following manner:

* * * * *

B. Respondents' agreement with the Acquirer or the New Acquirer (as specified in Paragraph V.B.9-10) (hereinafter the "Divestiture Agreement") shall include the following provisions, and Respondents shall commit to satisfy the following:

1. Respondents shall contract manufacture on behalf of and deliver to the Acquirer or the New Acquirer, in a timely manner and under reasonable terms and conditions ("the Contract Manufacturing Arrangement"), a supply of Refludan, specified in the Divestiture Agreement at cost for a period not to exceed four (4) years from the date the Divestiture Agreement is approved, or three (3) months after the date the Acquirer or the New Acquirer obtains all necessary FDA approvals to manufacture and sell Refludan in the United States, whichever is earlier; provided, however, that the four (4) year period may be extended by the Commission in twelve (12) month increments for a period not to exceed *four (4) years. In the event that the Commission chooses to extend the initial four year period for more than two additional years - i.e., beyond a date six (6) years from the date the Divestiture Agreement is approved - the Purchase Price paid by the Acquirer or New Acquirer for Refludan shall be increased to an amount equal to Respondents' Fully Burdened Cost plus thirty percent (30%). The method of calculating Respondents' Fully Burdened Cost shall be determined by Respondents and the Acquirer.*

By the Commission, Chairman Muris not participating.

Donald S. Clark
Secretary

SEAL:

ISSUED: March 11, 2002