

UNITED STATES OF AMERICA  
BEFORE FEDERAL TRADE COMMISSION

COMMISSIONERS:     **Deborah Platt Majoras, Chairman**  
                          **Orson Swindle**  
                          **Thomas B. Leary**  
                          **Pamela Jones Harbour**  
                          **Jon Leibowitz**

<p><b>In the Matter of</b></p> <p style="padding-left: 40px;"><b>SANOFI-SYNTHÉLABO,</b> <i>a société anonyme;</i></p> <p style="padding-left: 40px;"><b>and</b></p> <p style="padding-left: 40px;"><b>AVENTIS,</b> <i>a société anonyme.</i></p>	<p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p>	<p><b>Docket No. C-4112</b> <b>DECISION AND ORDER</b> <b>[Public Record Version]</b></p>
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The Federal Trade Commission (“Commission”) having initiated an investigation of the proposed acquisition by Respondent Sanofi-Synthélabo (“Sanofi”) of Respondent Aventis (“Aventis”), hereinafter referred to as “Respondents,” and Respondents having been furnished thereafter with a copy of a draft of a Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondents with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondents, their attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Orders (“Consent Agreement”), containing an admission by Respondents of all the jurisdictional facts set forth in the aforesaid draft of a Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission’s Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondents have violated the said Acts, and that a Complaint should issue stating its charges in that respect, and having thereupon issued its Complaint and an Order to Maintain Assets, and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) Days for the receipt and

consideration of public comments, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby makes the following jurisdictional findings and issues the following Decision and Order (“Order”):

1. Respondent Sanofi is a French *société anonyme* organized, existing and doing business under and by virtue of the laws of the French Republic, with its registered office located at 174, avenue de France, 75013 Paris, France.

2. Respondent Aventis is a French *société anonyme* organized, existing and doing business under and by virtue of the laws of the French Republic, with its registered office located at 16, avenue de l’Europe, 67300 Schiltigheim, France.

3. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the Respondents, and the proceeding is in the public interest.

## ORDER

### I.

**IT IS ORDERED** that, as used in this Order, the following definitions shall apply:

- A. “Sanofi” means Sanofi-Synthélabo, a French *société anonyme*, its directors, officers, employees, agents, representatives, predecessors, successors, and assigns; its joint ventures, subsidiaries, divisions, groups, and affiliates in each case controlled by Sanofi-Synthélabo and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. After the Acquisition, Sanofi shall include Aventis.
- B. “Aventis” means Aventis, a French *société anonyme*, its directors, officers, employees, agents, representatives, predecessors, successors, and assigns; its joint ventures, subsidiaries, divisions, groups, and affiliates in each case controlled by Aventis, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- C. “Respondents” means Sanofi and Aventis, individually and collectively.
- D. “Acquisition” means the point in the transaction at which the shareholders of Respondent Aventis shall have sold to Respondent Sanofi more than 50 percent of the shares and voting rights of Respondent Aventis in furtherance of the tender offer launched by Respondent Sanofi with respect to Respondent Aventis on the terms set forth in the “*Note d’Information*” that received approval of the French *Autorité des Marchés Financiers*, under the Visa 04-384 dated May 7, 2004, as the same may be amended.
- E. “Commission” means the Federal Trade Commission.

- F. “GlaxoSmithKline” means GlaxoSmithKline plc, a corporation organized, existing, and doing business under and by virtue of the laws of the United Kingdom, with its offices and principal place of business located at 980 Great West Road, Brentford, Middlesex XO TW8 9GS, United Kingdom.
- G. “Pfizer” means Pfizer Inc., a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware, with its offices and principal place of business located at 235 East 42<sup>nd</sup> Street, New York, New York 10017.
- H. “Sepracor” means Sepracor Inc., a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware, with its offices and principal place of business located at 111 Locke Drive, Marlborough, Massachusetts 01752.
- I. “Yakult” means Yakult Honsha Co. Limited, a corporation organized, existing, and doing business under and by virtue of the laws of Japan, having its principal place of business at No. 1-19, Higashi-Shinbashi 1-chome, Minato-ku, Tokyo, Japan.
- J. “Agency(ies)” means any governmental regulatory authority or authorities in the world responsible for granting approval(s), clearance(s), qualification(s), license(s), or permit(s) for any aspect of the research, Development, manufacture, marketing, distribution, or sale of a Product. The term “Agency” includes, but is not limited to, the United States Food and Drug Administration (“FDA”).
- K. “Application,” “New Drug Application” (“NDA”), “Abbreviated New Drug Application” (“ANDA”), “Supplemental New Drug Application” (“SND A”), or “Marketing Authorization Application” (“MAA”) means the applications for a Product filed or to be filed with the FDA pursuant to 21 C.F.R. Part 314, or its foreign Agency equivalent, and all supplements, amendments, and revisions thereto, any preparatory work, drafts and data necessary for the preparation thereof, and all correspondence between Respondent(s) and the FDA or other Agency relative thereto.
- L. “Arixtra” means all Products that contain the active pharmaceutical ingredient Fondaparinux and any dose form, presentation, or line extension thereof. “Arixtra” includes, without limitation, any combination of Fondaparinux with any other Product.
- M. “Arixtra Assets” means all of Respondent Sanofi’s rights, title, and interest in and to all assets related to Respondent Sanofi’s worldwide business related to Arixtra, to the extent legally transferable, including the research, Development, manufacture, distribution, marketing, or sale of Arixtra, including, without limitation, the following:
1. all Product Intellectual Property;
  2. perpetual, fully paid-up and royalty-free worldwide license(s) with rights to sublicense to all Product Licensed Intellectual Property to use, make, distribute, offer for sale,

promote, advertise, sell, import, export, or have used, made, distributed, offered for sale, promoted, advertised, sold, imported, or exported Arixtra anywhere in the world; *provided, however*, that such license(s) shall be on an exclusive basis (even as to Respondents) in accordance with the Remedial Agreement(s);

3. all Product and all Product Registrations;
4. all Product Trade Dress;
5. a list of all targeted customers for the Product and the planned or proposed pricing of the Product for such customers;
6. at the Commission-approved Acquirer's option, each of the Product Assumed Contracts;
7. all Product Marketing Materials;
8. all Website(s) related to the Product;
9. a list of all of the NDC Numbers related to the Product;
10. all rights to the Drug Master Files including, but not limited to, the pharmacology and toxicology data contained in all NDAs, ANDAs, SNDAs, and MAAs;
11. all rights (if such rights exist) to information similar to the Drug Master Files submitted to any Agency other than the FDA;
12. Product Scientific and Regulatory Material;
13. all unfilled customer orders for finished goods as of the Closing Date (a list of such orders is to be provided to the Commission-approved Acquirer within two (2) Days after the Closing Date);
14. Product Manufacturing Technology, and Product manufacturing and manufacturing processes;
15. at the Commission-approved Acquirer's option, all inventories in existence as of the Closing Date, including, but not limited to, syringes, crude drug substance, finished drug substance (Fondaparinux), building blocks (including D<sub>11</sub> and EF<sub>9</sub>) and building block intermediates, and Product specific packaging and labels;

16. at the Commission-approved Acquirer's option, the Arixtra Manufacturing Facility (including, but not limited to, the real estate assets related to the Arixtra Manufacturing Facility);
17. at the Commission-approved Acquirer's option, all manufacturing and other equipment located at the Arixtra Manufacturing Facility that was used in, or suitable for use in, the research, Development, or manufacture of Arixtra; and
18. all Respondent Sanofi's books, records, and files related to the foregoing, including, but not limited to, the following specified documents: the Product Registrations; Drug Master Files, including, but not limited to, the pharmacology and toxicology data contained in all NDAs, ANDAs, SNDAs, and MAAs; all data submitted to and all correspondence with the FDA and other Agencies; all validation documents and data; all market studies; all sales histories, including, without limitation, clinical data, and sales force call activity, for Arixtra from January 1, 2001, through the Closing Date, and quality control histories pertaining to Arixtra owned by, or in the possession or control of, Respondent Sanofi, or to which Respondent Sanofi has a right of access, in each case such as is in existence as of the Closing Date;

*provided, however,* that, in cases in which documents or other materials included in the Arixtra Assets contain information: (1) that relates both to Arixtra and to other Products or businesses of Respondent Sanofi and cannot be segregated in a manner that preserves the usefulness of the information as it relates to Arixtra; or (2) for which Respondent Sanofi has a legal obligation to retain the original copies, Respondent Sanofi shall be required to provide only copies or relevant excerpts of the documents and materials containing this information. In instances where such copies are provided to the Commission-approved Acquirer, Respondent Sanofi shall provide the Commission-approved Acquirer access to original documents under circumstances where copies of documents are insufficient for evidentiary or regulatory purposes. The purpose of this proviso is to ensure that Respondent Sanofi provides the Commission-approved Acquirer with the above-described information without requiring Respondent Sanofi completely to divest itself of information that, in content, also relates to Products and businesses other than Arixtra;

*provided, however,* that the term "Arixtra Assets" does not include any rights, titles, or interests in or to owned or leased real property or buildings other than, at the Commission-approved Acquirer's option, the Arixtra Manufacturing Facility.

- N. “Arixtra Asset Purchase Agreement” means the “Master Asset Purchase Agreement between Sanofi-Synthélabo, Glaxo Group Limited, Glaxo Wellcome Production S.A.S. and GlaxoSmithKline plc” dated April 13, 2004, and all amendments, exhibits, attachments, agreements, and schedules thereto, related to the Arixtra Assets to be divested, that have been approved by the Commission to accomplish the requirements of this Order. The Arixtra Asset Purchase Agreement is attached to this Order as non-public Appendix II.
- O. “Arixtra Core Employee(s)” means the following employees related to Arixtra: (1) Product Manufacturing Employees; (2) Product Marketing Employees; and (3) Product Research and Development Employees, collectively; *provided, however*, that if the Arixtra Asset Purchase Agreement is the Remedial Agreement for the Arixtra Assets, then, for purposes other than the Moratorium/Waiting Period, as defined at Paragraph II.H of this Order, and those involving the treatment and use of Confidential Business Information, the Arixtra Core Employees shall be limited to those Arixtra employees identified by job title as “other relevant employees” under the Arixtra Asset Purchase Agreement.
- P. “Arixtra Manufacturing Facility” means Respondent Sanofi’s manufacturing and packaging facility located at Notre Dame de Bondeville, Seine-Maritime, France used by Respondent Sanofi in the manufacture of Arixtra and other Products.
- Q. “Arixtra Ongoing Clinical Development Employees” means those employees of Respondent Sanofi who are engaged in any ongoing clinical trials related to Arixtra.
- R. “Arixtra Releasees” means the Commission-approved Acquirer for Arixtra or any entity controlled by or under common control with such Commission-approved Acquirer, or any licensees, sublicensees, manufacturers, suppliers, distributors, and customers of such Commission-approved Acquirer, or of such Commission-approved Acquirer-affiliated entities.
- S. “Camptosar” means all Product(s) that contain the active pharmaceutical ingredient Irinotecan and any dose form, presentation, or line extension thereof. “Camptosar” includes, without limitation, any combination of Irinotecan with any other Product.
- T. “Camptosar Asset Purchase Agreement” means the “Asset Purchase Agreement by and between Sanofi-Synthélabo and Pfizer Inc.” dated June 25, 2004, and the letter agreement between Aventis and Pfizer dated July 1, 2004, and all amendments, exhibits, attachments, agreements, and schedules thereto, related to the Camptosar Assets to be divested, that have been approved by the Commission to accomplish the requirements of this Order. The Camptosar Asset Purchase Agreement is attached to this Order as non-public Appendix III.

- U. “Camptosar Assets” means all rights, title, and interest in and to (*except* as is otherwise provided below) all United States Patents and all assets related to the Development of Camptosar for the United States market that are owned or controlled by, or licensed to Respondent Aventis on or before the Effective Date, to the extent legally transferable, including, without limitation, the following:
1. all United States Patents related to Camptosar; *provided, however*, that, with respect to those United States Patents that relate to Camptosar and to other Products, Respondent Aventis shall grant to Pfizer an irrevocable, fully-paid-up, royalty-free license under such United States Patents;
  2. all rights to all Camptosar Key Clinical Trials; *provided, however*, Respondents may retain a Right of Reference or Use to information similar to the Drug Master Files submitted to any Agency (other than the FDA, including, but not limited to, the European Agency for the Evaluation of Medicinal Products) solely for the purposes of satisfying certain requirements contained in decisions of the Commission of the European Communities in Case COMP/M.3354, including the divestiture of such Right of Reference or Use to any acquirer approved by the Commission of the European Communities pursuant to such decisions;
  3. at Pfizer’s option, all contracts or agreements related to the Camptosar Key Clinical Trials;
  4. Right of Reference or Use in the United States (if such rights exist) to information similar to the Drug Master Files submitted to any Agency other than the FDA, including, but not limited to, such information submitted to the European Agency for the Evaluation of Medicinal Products;
  5. all Product Scientific and Regulatory Material related to the Camptosar Key Clinical Trials or to the United States Patents related to Camptosar; and
  6. all Respondent Aventis’ books, records and files related to the foregoing, owned by, or in the possession or control of, Respondent Aventis, or to which Respondent Aventis has a right of access, in each case such as is in existence as of the Closing Date; *provided, however*, that in cases in which documents or other materials included in the Camptosar Assets contain information: (1) that relates both to Camptosar and to other Products or businesses of Respondent Aventis and cannot be segregated in a manner that preserves the usefulness of the information as it relates to Camptosar; or (2) for which Respondent Aventis has a legal obligation to retain the original copies, Respondent Aventis shall be required to provide only copies or relevant excerpts of the documents and materials containing this information. In instances where such copies are provided to Pfizer, Respondent Aventis shall provide Pfizer access to original documents under circumstances where copies of documents are insufficient for evidentiary or regulatory purposes. The purpose of this proviso is to ensure that Respondent Aventis provides

Pfizer with the above-described information without requiring Respondent Aventis completely to divest itself of information that, in content, also relates to Products and businesses other than Camptosar.

- V. “Camptosar Core Employees” means the individuals identified as “Key Irinotecan Employees” in Schedule 7.10(e) (iii) to the Camptosar Asset Purchase Agreement contained in Appendix III of this Order.
- W. “Camptosar Key Clinical Trials” means the following clinical trials related to the Development of Camptosar (or Campto, under which tradename Camptosar is marketed in Europe), individually and collectively: (1) Aventis V307 (adjuvant therapy of early colon cancer); (2) Aventis ACCORD2 (adjuvant therapy of high-risk early colon cancer); (3) Aventis/EORTC Study 40986 (metastatic colon rectal cancer); (4) Aventis Study V306 (Phase II and Phase III, metastatic gastric cancer); and (5) Aventis oral irinotecan clinical studies. These trials are identified in the Camptosar Asset Purchase Agreement.
- X. “Closing Date” means the date on which Respondent(s) (or a Divestiture Trustee) and a Commission-approved Acquirer consummate a transaction to assign, grant, license, divest, transfer, deliver or otherwise convey the relevant assets pursuant to this Order.
- Y. “Commission-approved Acquirer” means the following: (1) an entity that is specifically identified in this Order to acquire particular assets that the Respondents are required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to this Order and that has been approved by the Commission to accomplish the requirements of this Order in connection with the Commission’s determination to make this Order final; or (2) an entity approved by the Commission to acquire particular assets that the Respondents are required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to this Order.
- Z. “Confidential Business Information” means all information owned by, or in the possession or control of, Respondents that is not in the public domain related to the research, Development, manufacture, marketing, commercialization, distribution, importation, exportation, cost, pricing, supply, sales, sales support, or use of a Product.
- AA. “Contract Manufacture” means the manufacture of a Product to be supplied by a Respondent or a Designee specifically identified in this Order for sale to the Commission-approved Acquirer.
- BB. “Day(s)” means the period of time prescribed under this Order as computed pursuant to 16 C.F.R. § 4.3 (a).
- CC. “Designee” means any entity other than the Respondents that will manufacture a Product for a Commission-approved Acquirer.
- DD. “Development” means all preclinical and clinical drug development activities (including



formulation), including test method development and stability testing, toxicology, formulation, process development, manufacturing scale-up, development-stage manufacturing, quality assurance/quality control development, statistical analysis and report writing, conducting clinical trials for the purpose of obtaining any and all approvals, licenses, registrations or authorizations from any Agency necessary for the manufacture, use, storage, import, export, transport, promotion, marketing, and sale of a Product (including any governmental price or reimbursement approvals), Product approval and registration, and regulatory affairs related to the foregoing. “Develop” means to engage in Development.

- EE. “Direct Cost” means the cost of direct labor and direct material used to provide the relevant assistance or service.
- FF. “Divestiture Trustee” means a trustee appointed by the Commission pursuant to the relevant provisions of this Order.
- GG. “Domain Name” means the domain name(s) (universal resource locators), and registration(s) thereof, issued by any entity or authority that issues and maintains the domain name registration. “Domain Name” shall not include any trademark or service mark rights to such domain names other than the rights to the Product Trademarks required to be divested.
- HH. “Drug Master Files” means the information submitted to the FDA as described in 21 C.F.R. § 314.420 related to a Product.
- II. “Effective Date” means the date on which the Acquisition occurs.
- JJ. “Eloxatin” means all Products that contain the active pharmaceutical ingredient oxalplatin and/or that are marketed or sold under the Product Trademark Eloxatin<sup>®</sup> or Eloxatine.<sup>®</sup> “Eloxatin” includes all such Products whether marketed within or outside the United States.
- KK. “Employee Notification” means the “Notice of Antitrust Remedy and Requirement for Confidentiality” attached to this Order as public Appendix I, and to the Order to Maintain Assets as public Appendix A.
- LL. “Estorra” means any Product that contains (+) zopiclone as an active pharmaceutical ingredient. “Estorra” includes any Product that contains (+) zopiclone and one or more other active ingredients.
- MM. “Estorra License Agreement” means the “License and Assignment Agreement” by and between Sepracor Inc. and Rhône-Poulenc Rorer SA, dated September 30, 1999, and all amendments, exhibits, attachments, agreements, and schedules thereto. The Estorra License Agreement includes the “Amendment and Patent Assignment Agreement” by and between Sepracor Inc. and Aventis Pharma SA (successor in interest to Rhône-Poulenc Rorer SA) to

the original Estorra License and Assignment Agreement dated July 2, 2004. The Estorra License Agreement is attached to this Order as non-public Appendix IV.

- NN. “Estorra Releasees” means Sepracor or any entity controlled by or under common control with Sepracor, or any licensees, sublicensees, manufacturers, suppliers, distributors, and customers of Sepracor, or of Sepracor-affiliated entities.
- OO. “Estorra Royalties” means any financial payment or other consideration from Sepracor related to the Estorra License Agreement that is either of the following:
1. based on the actual amount of sales or profits of Estorra realized at any time after the Effective Date; or
  2. a payment that is due upon the realization of any aggregate amount of sales or profits on Estorra.
- PP. “Fondaparinux” means fondaparinux sodium including all pharmaceutically active derivatives thereof, including, without limitation, esters, salts (including, without limitation, decakis salts), hydrates, solvates, polymorphs, prodrugs, metabolites, and isomers thereof, and all hydrates, solvates, polymorphs, prodrugs, and isomers of such salts.
- QQ. “Governmental Entity” means any Federal, state, local or non-U.S. government, or any court, legislature, governmental agency, or governmental commission, or any judicial or regulatory authority of any government.
- RR. “Interim Monitor” means any monitor appointed pursuant to Paragraph V of this Order or Paragraph III of the related Order to Maintain Assets.
- SS. “Investigational New Drug Application” (“IND”) means the application filed with the FDA pursuant to 21 C.F.R. § 312.1, et seq. (as defined in 21 C.F.R. § 312.3), or its foreign Agency equivalent, and all supplements, amendments, and revisions thereto, any preparatory work, drafts, and data necessary for the preparation thereof, and all correspondence between Respondent(s) and the FDA or other Agency relative thereto.
- TT. “Irinotecan” means irinotecan hydrochloride including all pharmaceutically active derivatives thereof, including, without limitation, esters, salts, hydrates, solvates, polymorphs, and isomers thereof and all hydrates, solvates, polymorphs, and isomers of such salts.
- UU. “Law” means all laws, statutes, rules, regulations, ordinances, and other pronouncements by any Governmental Entity having the effect of law.
- VV. “Lovenox” means all Product(s) that contain the active pharmaceutical ingredient enoxaparin and/or that are marketed or sold under the Product Trademark Lovenox.®

- WW. “NDC Numbers” means the National Drug Code numbers(s) assigned by the FDA to a Product.
- XX. “Patents” means all patents, patent applications, and statutory invention registrations, in each case existing as of the Effective Date (*except* where this Order specifies a different time), and includes all reissues, divisions, continuations, continuations-in-part, supplementary protection certificates, extensions and reexaminations thereof, all inventions disclosed therein, all rights therein provided by international treaties and conventions, and all rights to obtain and file for patents and registrations thereto in the world, related to any Product of or owned by Respondent(s) as of the Closing Date.
- YY. “Product” means any pharmaceutical, biological, or genetic composition containing any formulation or dosage of a compound referenced as its pharmaceutically, biologically, or genetically active ingredient.
- ZZ. “Product Assumed Contracts” means all of the following contracts or agreements:
1. pursuant to which any Third Party purchases the Product(s) from the Respondent(s);
  2. pursuant to which the Respondent(s) purchases any materials from any Third Party for use in connection with the manufacture of the Product(s);
  3. relating to any clinical trial involving the Product(s);
  4. constituting the material transfer agreements involving the transfer of the Product(s);
  5. relating to the marketing of the Product(s) or educational matters relating to the Product(s);
  6. relating to the manufacture of the Product(s);
  7. constituting confidentiality agreements involving the Product(s);
  8. involving any royalty, licensing, or similar arrangement involving the Product(s);
  9. pursuant to which any services are provided with respect to the Product(s) or the Product(s) business, including consultation arrangements; and/or
  10. pursuant to which any Third Party collaborates with the Respondent(s) in the performance of research or Development of the Product(s) or the Product(s) business;
- provided, however*, that where any such contract or agreement also relates to Product(s) of the Respondent(s) other than the Product(s) required to be divested pursuant to this Order, Respondent(s) shall assign the Commission-approved Acquirer all such rights

under the contract or agreement as are related to the Product(s) required to be divested pursuant to this Order, but concurrently may retain similar rights for the purposes of the other Product(s).

AAA. “Product Copyrights” means rights to all original works of authorship of any kind related to the Product(s) and any registrations and applications for registrations thereof, including, but not limited to, the following: all promotional materials for healthcare providers; all promotional materials for patients; educational materials for the sales force; copyrights in all pre-clinical, clinical and process development data and reports relating to the research and Development of the Product(s) or of any materials used in the research, Development, manufacture, marketing or sale of the Product(s), including all raw data relating to clinical trials of the Product(s), all case report forms relating thereto and all statistical programs developed (or modified in a manner material to the use or function thereof (other than through user references)) to analyze clinical data, all market research data, market intelligence reports and statistical programs (if any) used for marketing and sales research; customer information, promotional and marketing materials, the Product(s) sales forecasting models, medical education materials, sales training materials, Website content and advertising and display materials; all records relating to employees who accept employment with the Commission-approved Acquirer (excluding any personnel records the transfer of which is prohibited by applicable Law); all records, including customer lists, sales force call activity reports, vendor lists, sales data, reimbursement data, speaker lists, manufacturing records, manufacturing processes, and supplier lists; all data contained in laboratory notebooks relating to the Product(s) or relating to its biology; all adverse experience reports and files related thereto (including source documentation) and all periodic adverse experience reports and all data contained in electronic data bases relating to adverse experience reports and periodic adverse experience reports; all analytical and quality control data; and all correspondence with the FDA.

BBB. “Product Employee Information” means the following, as and to the extent permitted by the Law of the country in which the employee is employed:

1. a complete and accurate list containing the name of each relevant employee (including former employees who were employed by Respondent(s) within ninety (90) Days of the execution date of any Remedial Agreement). This list shall be organized by the relevant respective employee categories defined in this Order (*i.e.*, Product Manufacturing Employees, Product Marketing Employees, Product Research and Development Employees, or Product Sales Employees, as applicable);
2. with respect to each such employee, the following information:
  - a. the date of hire and effective service date;

- b. job title or position held;
  - c. a specific description of the employee's responsibilities related to the relevant Product; *provided, however*, in lieu of this description, Respondent(s) may provide the employee's most recent performance appraisal;
  - d. the base salary or current wages;
  - e. the most recent bonus paid, aggregate annual compensation for the Respondent's last fiscal year and current target or guaranteed bonus, if any;
  - f. employment status (*i.e.*, active or on leave or disability; full-time or part-time); and
  - g. any other material terms and conditions of employment in regard to such employee that are not otherwise generally available to similarly situated employees; and
3. at the Commission-approved Acquirer's option or the Proposed Acquirer's option (as applicable), copies of all employee benefit plans and summary plan descriptions (if any) applicable to the relevant employees.

CCC. "Product Intellectual Property" means all of the following related to the Product(s):

- 1. Patents;
- 2. Product Copyrights;
- 3. Product Software, other than Product Licensed Intellectual Property;
- 4. Product Trademarks;
- 5. trade secrets, know-how, techniques, data, inventions, practices, methods and other confidential or proprietary technical, business, research, Development and other information, and all rights in any jurisdiction to limit the use or disclosure thereof, other than Product Licensed Intellectual Property;
- 6. rights to obtain and file for Patents and registrations thereof; and
- 7. rights to sue and recover damages or obtain injunctive relief for infringement, dilution, misappropriation, violation, or breach of any of the foregoing;

*provided, however*, that "Product Intellectual Property" does not include the names "Sanofi," "Sanofi-Synthelabo," "Synthelabo," "Aventis," or the names of any other corporations or companies owned by Respondent Sanofi or Respondent Aventis or related logos to the extent used on other of Respondents' Products;

*provided further* that “Product Intellectual Property” does not include the name “Organon®” to the extent that Respondent Sanofi is licensed to use that name.

DDD. “Product Licensed Intellectual Property” means the following:

1. Patents that are related to a Product that is the subject of a divestiture under this Order and that Respondent(s) can demonstrate have been routinely used, prior to the Effective Date, by either Respondent Aventis or Respondent Sanofi (as applicable) for Product(s) other than the Product that is the subject of the relevant divestiture;
2. Product Software that is used in connection with the analysis of clinical trial data for a Product that is the subject of a divestiture under this Order that Respondent(s) can demonstrate has been routinely used, prior to the Effective Date, by either Respondent Sanofi or Respondent Aventis (as applicable) for Product(s) other than the Product that is the subject of the relevant divestiture; and
3. trade secrets, know-how, techniques, data, inventions, practices, methods, and other confidential or proprietary technical, business, research, Development, and other information, and all rights in any jurisdiction to limit the use or disclosure thereof, that are related to a Product that is the subject of a divestiture under this Order and that Respondent(s) can demonstrate have been routinely used, prior to the Effective Date, by either Respondent Aventis or Respondent Sanofi (as applicable) for Product(s) other than the Product that is the subject of the relevant divestiture.

EEE. “Product Manufacturing Employees” means all salaried employees of Respondent(s) who directly have participated (irrespective of the portion of working time involved) in the manufacture of the Product(s), including, but not limited to, those involved in the quality assurance and quality control of the Product(s), within the eighteen (18) month period immediately prior to the Closing Date.

FFF. “Product Manufacturing Technology” means all technology, trade secrets, know-how, and proprietary information related to the manufacture, validation, packaging, release testing, stability, and shelf life of the Product(s), including the Product(s)’ formulation, in existence and in the possession of Respondent(s) as of the Closing Date, including, but not limited to, manufacturing records, sampling records, standard operating procedures, and batch records related to the manufacturing process, and supplier lists.

GGG. “Product Marketing Employees” means all management level employees of Respondent(s) who directly have participated (irrespective of the portion of working time involved) in the marketing, contracting, or promotion of the Product(s) in the United States within the eighteen (18) month period immediately prior to the Closing Date. These employees include, without limitation, all management level employees having any responsibilities in the areas of sales management, brand management, sales training, market research, managed care contracting, hospital market and other specialty markets, but excluding administrative

assistants.

- HHH. “Product Marketing Materials” means all marketing materials used anywhere in the world related to the Product(s) as of the Closing Date, including, without limitation, all advertising materials, training materials, product data, price lists, mailing lists, sales materials (e.g., detailing reports; vendor lists; sales data; reimbursement data), marketing information (e.g., competitor information; research data; market intelligence reports; statistical programs (if any) used for marketing and sales research; customer information, including customer sales information; sales forecasting models; medical educational materials; Website content and advertising and display materials; speaker lists), promotional and marketing materials, artwork for the production of packaging components, television masters and other similar materials related to the Product(s); *provided, however*, that “Product Marketing Materials” does not include any such material with the Organon<sup>®</sup> trademark or label.
- III. “Product Registrations” means all registrations, permits, licenses, consents, authorizations, and other approvals, and pending applications and requests therefor, required by applicable Agencies related to the research, Development, manufacture, distribution, finishing, packaging, marketing, or sale of the Product worldwide, including all INDs, NDAs, ANDAs, SNDAs, MAAs, in existence for the Product as of the Closing Date.
- JJJ. “Product Research and Development Employees” means all employees of Respondent(s) who directly have participated (irrespective of the portion of working time involved) in the research, Development, regulatory approval process, or clinical studies of the Product(s) within the eighteen (18) month period immediately prior to the Closing Date.
- KKK. “Product Sales Employees” means all employees of Respondent(s) who directly have participated (irrespective of the portion of working time involved) in the detailing, marketing or promotion of the Product(s) in the United States directly to physicians, pharmacists, professional distributors, managed care, or other insurance providers, hospitals, employers, or governmental entities within the twelve (12) month period immediately prior to the Closing Date. This includes employees trained to perform such detailing for the Product within the twelve (12) month period immediately prior to the Closing Date.
- LLL. “Product Scientific and Regulatory Material” means all technological, scientific, chemical, biological, pharmacological, toxicological, regulatory, and clinical trial materials and information related to the Product(s), and all rights thereto, in any and all jurisdictions.
- MMM. “Product Software” means computer programs, including all software implementations of algorithms, models, and methodologies whether in source code or object code form, databases and compilations, including any and all data and collections of data, all documentation, including user manuals and training materials, related to any of the foregoing and the content and information contained on any Website; *provided, however*, that “Product Software” does not include software that is readily purchasable or licensable and which has not been modified in a manner material to the use or function thereof (other

than through user preference settings).

- NNN. “Product Trade Dress” means the current trade dress of the Product(s), including, but not limited to, product packaging associated with the sale of the Product(s) worldwide and the lettering of the Product(s)’ trade name or brand name.
- OOO. “Product Trademark(s)” means all proprietary names or designations, trademarks, tradenames, and brand names, including registrations and applications for registration therefor (and all renewals, modifications, and extensions thereof) and all common law rights, and the goodwill symbolized thereby and associated therewith, for the Product(s).
- PPP. “Proposed Acquirer” means an entity proposed by the Respondent(s) (or a Divestiture Trustee) to the Commission and submitted for the approval of the Commission as the acquirer for particular assets required to be assigned, granted, licensed, divested, transferred, delivered or otherwise conveyed by Respondent(s) pursuant to this Order.
- QQQ. “Remedial Agreement” means the following: (1) any agreement between Respondent(s) and a Commission-approved Acquirer that is specifically referenced and attached to this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, related to the relevant assets to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed, and that has been approved by the Commission to accomplish the requirements of the Order in connection with the Commission’s determination to make this Order final; and/or (2) any agreement between the Respondent(s) and a Commission-approved Acquirer (or between a Divestiture Trustee and a Commission-approved Acquirer) that has been approved by the Commission to accomplish the requirements of this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, related to the relevant assets to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed, and that has been approved by the Commission to accomplish the requirements of this Order.
- RRR. “Right of Reference or Use” means the authority to rely upon, and otherwise use, an investigation for the purpose of obtaining approval of an Application, including the ability to make available the underlying raw data from the investigation for FDA (or the European Agency for the Evaluation of Medicinal Products or other comparable Agency) audit.
- SSS. “Royalty Monetization Firm” means any Third Party that acquires the right from the Respondent(s) to receive the payment of royalties, *excluding* any entity that engages in scientific research, Development, manufacture, distribution, marketing, or selling of a Product.
- TTT. “Supply Cost” means the manufacturer’s average direct per unit cost of manufacturing the Product plus costs of manufacturing the Product that are directly attributable to regulatory, quality control and compliance requirements imposed by the FDA (or the European Agency for the Evaluation of Medicinal Products or other comparable Agency). “Supply Cost” shall



expressly exclude any intracompany business transfer profit.

UUU. “Third Party(ies)” means any private entity other than the following: (1) the Respondents, or (2) the Commission-approved Acquirer for the relevant assets to be divested related to a particular Product(s).

VVV. “Website” means the content of the Website(s) located at the Domain Names, the Domain Names, and all copyrights in such Website(s), to the extent owned by Respondents; *provided, however*, “Website” shall not include the following: (1) content owned by Third Parties and other Product Intellectual Property not owned by Respondent(s) that are incorporated in such Website(s), such as stock photographs used in the Website(s), *except* to the extent that Respondent(s) can convey its rights, if any, therein; or (2) content unrelated to the Product(s).

## II.

### **IT IS FURTHER ORDERED** that:

A. Not later than twenty (20) Days after the Effective Date or September 1, 2004, whichever is later, Respondents shall divest the Arixtra Assets, absolutely and in good faith, to GlaxoSmithKline pursuant to and in accordance with the Arixtra Asset Purchase Agreement (which agreement shall not vary or contradict, or be construed to vary or contradict, the terms of this Order, it being understood that nothing in this Order shall be construed to reduce any rights or benefits of GlaxoSmithKline or to reduce any obligations of the Respondents under such agreement), and such agreement, if it becomes the Remedial Agreement related to the Arixtra Assets, is incorporated by reference into this Order and made a part hereof. If Respondents do not divest the Arixtra Assets to GlaxoSmithKline within twenty (20) Days after the Effective Date, or September 1, 2004, whichever is later, the Commission may appoint a Divestiture Trustee to divest the Arixtra Assets;

*provided, however*, that if Respondents have divested the Arixtra Assets to GlaxoSmithKline prior to the date this Order becomes final, and if, at the time the Commission determines to make this Order final, the Commission notifies Respondents that GlaxoSmithKline is not an acceptable purchaser of the Arixtra Assets, then Respondents shall immediately rescind the transaction with GlaxoSmithKline and shall divest the Arixtra Assets within six (6) months from the date the Order becomes final, absolutely and in good faith, at no minimum price, to a Commission-approved Acquirer and only in a manner that receives the prior approval of the Commission;

*provided further* that if the Respondents have divested the Arixtra Assets to GlaxoSmithKline prior to the date this Order becomes final, and if, at the time the Commission determines to make this Order final, the Commission notifies the Respondents that the manner in which the divestiture was accomplished is not acceptable, the

Commission may direct the Respondents, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the Arixtra Assets to GlaxoSmithKline (including, but not limited to, entering into additional agreements or arrangements) as the Commission may determine are necessary to satisfy the requirements of this Order.

- B. Any Remedial Agreement related to the Arixtra Assets shall be deemed incorporated into this Order, and any failure by Respondents to comply with any term of such Remedial Agreement related to the Arixtra Assets shall constitute a failure to comply with this Order.
- C. Respondents shall include in any Remedial Agreement related to the Arixtra Assets the following provisions:
  - 1. Respondents shall Contract Manufacture and deliver to the Commission-approved Acquirer, in a timely manner and under reasonable terms and conditions, a supply of any of the ingredients (including, but not limited to, crude drug substance (Fondaparinux), building blocks (including D<sub>11</sub> and EF<sub>9</sub>) and building block intermediates) necessary to manufacture Arixtra finished drug product, at Respondent Sanofi's Supply Cost, for a period of time sufficient to allow the Commission-approved Acquirer (or the Designee of the Commission-approved Acquirer) to obtain all the relevant Agency approvals necessary to manufacture Arixtra finished drug product independently of Respondents and secure sources of supply of such ingredients from entities other than the Respondents;
  - 2. Respondents shall make representations and warranties to the Commission-approved Acquirer that the ingredients supplied through Contract Manufacture pursuant to the Remedial Agreement meet the relevant Agency-approved specifications. For those Product(s) to be marketed or sold in the United States, Respondents shall agree to indemnify, defend and hold the Commission-approved Acquirer harmless from any and all suits, claims, actions, demands, liabilities, expenses or losses alleged to result from the failure of the ingredients supplied to the Commission-approved Acquirer pursuant to the Remedial Agreement by the Respondents to meet current good manufacturing practices of the FDA, as set forth in 21 C.F.R. Parts 210 and 211. This obligation shall be contingent upon the Commission-approved Acquirer's giving Respondents prompt, adequate notice of such claim and cooperating fully in the defense of such claim. The Remedial Agreement shall be consistent with the obligations assumed by Respondents under this Order; *provided, however*, that Respondents may reserve the right to control the defense of any such litigation, including the right to settle the litigation, so long as such settlement is consistent with the Respondents' responsibilities to supply the ingredients in the manner required by this Order; *provided further* that this obligation shall not require Respondents to be liable for any negligent act or omission of the Commission-approved Acquirer or for any representations and warranties, express or implied, made by the Commission-approved Acquirer that exceed the representations and warranties made by the Respondents to the Commission-approved Acquirer; *provided further* that if the Arixtra Asset Purchase Agreement is the Remedial

Agreement for the Arixtra Assets, then such agreement may contain limits on Respondents' aggregate liability resulting from the failure of the ingredients supplied to the Commission-approved Acquirer pursuant to the Remedial Agreement by the Respondents to meet current good manufacturing practices of the FDA, as set forth in 21 C.F.R. Parts 210 and 211;

3. Respondents shall make representations and warranties to the Commission-approved Acquirer that Respondents shall hold harmless and indemnify the Commission-approved Acquirer for any liabilities or loss of profits resulting from the failure by Respondents to deliver the ingredients in a timely manner as required by the Remedial Agreement unless the Respondents can demonstrate that their failure was entirely beyond the control of the Respondents and in no part the result of negligence or willful misconduct by Respondents; *provided, however*, if the Arixtra Asset Purchase Agreement is the Remedial Agreement for the Arixtra Assets, then such agreement may contain limits on Respondents' aggregate liability for such a breach;
4. during the term of the Contract Manufacture between Respondent(s) and the Commission-approved Acquirer, upon request of the Commission-approved Acquirer or Interim Monitor (if applicable), Respondents shall make available to the Commission-approved Acquirer and the Interim Monitor (if applicable) all records that relate to the manufacture of the ingredients for Arixtra that are generated or created after the Closing Date;
5. upon reasonable notice and request from the Commission-approved Acquirer to the Respondents, Respondents shall provide in a timely manner at no greater than Direct Cost the following:
  - a. assistance and advice to enable the Commission-approved Acquirer (or the Designee of the Commission-approved Acquirer) to obtain all necessary permits and approvals from any Agency or Governmental Entity to manufacture and sell Arixtra;
  - b. assistance to the Commission-approved Acquirer (or the Designee of the Commission-approved Acquirer) to manufacture Arixtra in substantially the same manner and quality employed or achieved by Respondent Sanofi; and
  - c. consultation with knowledgeable employees of Respondents and training, at the request of the Commission-approved Acquirer and at a facility chosen by the Commission-approved Acquirer, until the Commission-approved Acquirer (or the Designee of the Commission-approved Acquirer) obtains all FDA approvals necessary to manufacture Arixtra independently of the Respondents and sufficient to satisfy management of the Commission-approved Acquirer that its personnel (or

the Designee's personnel) are adequately trained in the manufacture of Arixtra;

6. upon reasonable notice and request from the Commission-approved Acquirer to Respondents, Respondents shall provide, in a timely manner, at no greater than Direct Cost, assistance of knowledgeable employees of the Respondents to assist the Commission-approved Acquirer to defend against, respond to, or otherwise participate in any litigation related to the Product Intellectual Property;
7. Respondents shall covenant to the Commission-approved Acquirer that Respondents shall not join, file, prosecute or maintain any suit, in law or equity, against the Commission-approved Acquirer under Patents that: (1) are owned or licensed by Respondents as of the Effective Date; or (2) may be assigned, granted, licensed, or otherwise conveyed to Respondents after the Effective Date, if such suit would have the potential to interfere with the Commission-approved Acquirer's freedom to practice in the research, Development, manufacture, use, import, export, distribution or sale of Arixtra; and
8. Respondents shall covenant to the Commission-approved Acquirer that: (1) any Third Party assignee, transferee or licensee of the above-described Patents shall agree to provide a covenant not to sue the Arixtra Releasees, at least as protective as those extended pursuant to the preceding Paragraph II.C.7, as a condition of such assignment, transfer or license; and (2) with respect to any Third Party rights licensed to Respondents as of or after the Effective Date, and as to which Respondents do not control the right of prosecution of any legal action, Respondents shall not actively induce, assist or participate in any legal action or proceeding relating to Arixtra against the Arixtra Releasees, unless required by Law or contract (such contract not to be solicited or entered into for the purpose of circumventing any of the requirements of this Order);

*provided, however*, that if the Arixtra Asset Purchase Agreement is the Remedial Agreement for the Arixtra Assets, then Respondents shall be deemed to have complied with any of the Supply Cost and Direct Cost requirements described in Paragraphs II.C.1, II.C.5, and II.C.6 by complying with the cost provisions as provided in the Arixtra Asset Purchase Agreement.

D. Respondents shall:

1. submit to the Commission-approved Acquirer, at Respondents' expense, all Confidential Business Information related to Arixtra;
2. deliver such Confidential Business Information as follows: (1) in good faith; (2) as soon as practicable, avoiding any delays in transmission of the respective information; and (3) in a manner that ensures its completeness and accuracy and that fully preserves its usefulness;
3. pending complete delivery of all such Confidential Business Information to the Commission-approved Acquirer, provide the Commission-approved Acquirer and the Interim Monitor (if any has been appointed) with access to all such Confidential Business Information and employees who possess or are able to locate such information for the purposes of identifying the books, records, and files related to Arixtra that contain such Confidential Business Information and facilitating the delivery in a manner consistent with this Order;
4. not use, directly or indirectly, any such Confidential Business Information related to the research, Development, manufacturing, marketing, or sale of Arixtra (other than as necessary to comply with the following: (1) the requirements of this Order; (2) the Respondents' obligations to the Commission-approved Acquirer under the terms of any Remedial Agreement related to the Arixtra Assets; or (3) applicable Law); and
5. not disclose or convey any such Confidential Business Information, directly or indirectly, to any person except the Commission-approved Acquirer;

*provided, however*, this Paragraph II.D shall not apply to any Confidential Business Information related to Arixtra that Respondent Aventis can demonstrate it obtained without the assistance of Respondent Sanofi prior to the Effective Date.

E. Respondents shall:

1. for a period of at least six (6) months from the earlier of the following dates: (1) ten (10) Days after notice by staff of the Commission to the Respondents to provide the opportunity to enter into employment contracts; or (2) the Closing Date, provide the Commission-approved Acquirer with the opportunity to enter into employment contracts with the Product Marketing Employees and Product Sales Employees; and for a period of at least twelve (12) months from the earlier of the following dates: (1) ten (10) Days after notice by staff of the Commission to provide the opportunity to enter into employment contracts; or (2) the Closing Date, provide the Commission-approved Acquirer with the opportunity to enter into employment contracts with the Product Manufacturing Employees and Product Research and Development Employees. These periods are hereinafter referred to as the "Arixtra Access Period";

*provided, however,* that any such employment contracts entered into prior to the Closing Date shall be contingent upon approval by the Commission of the agreements relating to the Arixtra Assets (*i.e.*, those agreements proposed by Respondents (or the Divestiture Trustee) to the Commission) as the Remedial Agreements for the Arixtra Assets; and

2. not later than the earlier of the following dates: (1) ten (10) Days after notice by staff of the Commission to the Respondents to provide the Product Employee Information; or (2) ten (10) Days after the Closing Date, provide the Commission-approved Acquirer or the Proposed Acquirer with the Product Employee Information related to the Arixtra Core Employees. Failure by Respondents to provide the Product Employee Information for any relevant employee within the time provided herein shall extend the Arixtra Access Period with respect to that employee in an amount equal to the delay.

F. Respondents shall:

1. during the Arixtra Access Period, not interfere with the hiring or employing by the Commission-approved Acquirer of Arixtra Core Employees, and remove any impediments within the control of Respondents that may deter these employees from accepting employment with the Commission-approved Acquirer, including, but not limited to, any noncompete provisions of employment or other contracts with Respondents that would affect the ability or incentive of those individuals to be employed by the Commission-approved Acquirer. In addition, Respondents shall not make any counteroffer to an Arixtra Core Employee who receives a written offer of employment from the Commission-approved Acquirer;

*provided, however,* that this Paragraph II.F.1 shall not prohibit the Respondents from making offers of employment to or employing any Arixtra Core Employee during the Arixtra Access Period where the Commission-approved Acquirer has notified the Respondents in writing that the Commission-approved Acquirer does not intend to make an offer of employment to that employee;

*provided further* that if the Respondents notify the Commission-approved Acquirer in writing of their desire to make an offer of employment to a particular Arixtra Core Employee and the Commission-approved Acquirer does not make an offer of employment to that employee within twenty (20) Days of the date the Commission-approved Acquirer receives such notice, the Respondents may make an offer of employment to that employee;

2. until the Closing Date, provide all Arixtra Core Employees with reasonable financial incentives to continue in their positions. Such incentives shall include a continuation of all employee benefits offered by Respondents until the Closing Date for the divestiture of the Arixtra Assets has occurred, including regularly scheduled raises, bonuses, and vesting of pension benefits (as permitted by Law). In addition to the foregoing, Respondents shall provide to each Arixtra Core Employee (other than those employees

who transfer to the Commission-approved Acquirer by operation of Law) who accepts employment with the Commission-approved Acquirer, an incentive equal to three (3) months of such employee's base annual salary to be paid upon the employee's completion of one (1) year of employment with the Commission-approved Acquirer;

*provided, however*, that nothing in this Order requires or shall be construed to require the Respondents to terminate the employment of any employee; and

3. for a period of one (1) year from the Closing Date, not:

- a. directly or indirectly, solicit or otherwise attempt to induce any employee of the Commission-approved Acquirer with any amount of responsibility related to Arixtra ("Arixtra Employee") to terminate his or her employment relationship with the Commission-approved Acquirer; or
- b. hire any Arixtra Employee; *provided, however*, Respondents may hire any former Arixtra Employee whose employment has been terminated by the Commission-approved Acquirer or who independently applies for employment with the Respondents, as long as such employee was not solicited in violation of the nonsolicitation requirements contained herein;

*provided, however*, Respondents may do the following: (1) advertise for employees in newspapers, trade publications or other media not targeted specifically at the Arixtra Employees; or (2) hire an Arixtra Employee who contacts Respondents on his or her own initiative without any direct or indirect solicitation or encouragement from the Respondents.

G. Prior to the Closing Date, Respondents shall secure all consents and waivers from all Third Parties that are necessary for the divestiture of the Arixtra Assets to the Commission-approved Acquirer, or for the continued research, Development, manufacture, sale, marketing or distribution of Arixtra by the Commission-approved Acquirer;

*provided, however*, Respondents may satisfy this requirement by certifying that the Commission-approved Acquirer has executed all such agreements directly with each of the relevant Third Parties.

H. For the periods as set forth in this Paragraph II.H. (collectively, the "Moratorium/Waiting Period"), Respondents shall not market or promote Lovenox in the United States using the services of any employee who has directly participated in the marketing, contracting, promotion or sale of Arixtra, regardless of the portion of work time expended on Arixtra, within the eighteen (18) month period immediately prior to the Closing Date. The Moratorium/Waiting Period shall be as follows: (1) at least six (6) months from the Closing Date with respect to the Product Sales Employees related to Arixtra; and (2) at least twelve (12) months from the Closing Date for all Product Marketing Employees related to Arixtra.

- I. For a period of at least six (6) months after the completion of any clinical trials related to Arixtra that were ongoing as of the Effective Date, Respondents shall not use any Arixtra Ongoing Clinical Development Employee for any purpose related to the Development of Lovenox.
- J. Respondents shall require, as a condition of continued employment post-divestiture, that each Arixtra Core Employee sign a confidentiality agreement pursuant to which such employee shall be required to maintain all Confidential Business Information related to Arixtra strictly confidential, including the nondisclosure of such information to all other employees, executives or other personnel of Respondents (other than as necessary to comply with the requirements of this Order).
- K. Respondents shall provide written notification of the restrictions on the use of the Confidential Business Information related to Arixtra by Respondents' personnel to all of Respondents' employees who:
  - 1. are or were involved in the research, Development, manufacturing, distribution, sale or marketing of Arixtra;
  - 2. are involved in the research, Development, manufacturing, distribution, sale or marketing of Lovenox; and/or
  - 3. may have Confidential Business Information related to Arixtra.

Such notification shall be in substantially the form set forth in the Employee Notification. Respondents shall give such notification by e-mail with return receipt requested or similar transmission, and keep a file of such receipts for one (1) year after the Closing Date. Respondents shall provide a copy of such notification to the Commission-approved Acquirer. Respondents shall maintain complete records of all such agreements at Respondents' corporate headquarters and shall provide an officer's certification to the Commission stating that such acknowledgment program has been implemented and is being complied with. Respondents shall provide the Commission-approved Acquirer with copies of all certifications, notifications and reminders sent to Respondents' personnel.

- L. Upon reasonable notice and request by the Commission-approved Acquirer, Respondents shall make available to the Commission-approved Acquirer, at no greater than Direct Cost (or, if the Arixtra Asset Purchase Agreement is the Remedial Agreement for the Arixtra Assets, then at such cost as provided therein), such personnel, assistance and training as the Commission-approved Acquirer might reasonably need to transfer the Arixtra Assets, and shall continue providing such personnel, assistance and training, at the request of the Commission-approved Acquirer, until the Commission-approved Acquirer (or the Designee of the Commission-approved Acquirer) is fully validated, qualified, and approved by the FDA, and able to manufacture Arixtra independently of the Respondents;



*provided, however,* the Commission may eliminate, or limit the duration of, the Respondents' obligation under this provision if the Commission determines that the Commission-approved Acquirer is not using commercially reasonable best efforts to secure the FDA approvals necessary to manufacture Arixtra finished drug product in a facility that is independent of Respondents.

- M. Pending divestiture of the Arixtra Assets, Respondents shall take such actions as are necessary to maintain the full economic viability and marketability of the business associated with the Arixtra Assets, to minimize any risk of loss of competitive potential for such business, and to prevent the destruction, removal, wasting, deterioration, or impairment of any of the Arixtra Assets except for ordinary wear and tear.
- N. Counsel for Respondents (including in-house counsel under appropriate confidentiality arrangements) may retain unredacted copies of all documents or other materials provided to the Commission-approved Acquirer and may have access to original documents (under circumstances where copies of documents are insufficient or otherwise unavailable) provided to the Commission-approved Acquirer only in order to do the following:
1. comply with any Remedial Agreement, this Order, any Law (including, without limitation, any requirement to obtain regulatory licenses or approvals), any data retention requirement of any applicable Governmental Entity, or any taxation requirements; or
  2. defend against, respond to, or otherwise participate in any litigation, investigation, audit, process, subpoena or other proceeding relating to the divestiture or any other aspect of the Arixtra Assets or Arixtra business; *provided, however,* that Respondents may disclose such information as necessary for the purposes set forth in this Paragraph pursuant to an appropriate confidentiality order, agreement or arrangement;

*provided, however,* that pursuant to this Paragraph II.N., Respondents shall: (1) require those who view such unredacted documents or other materials to enter into confidentiality agreements with the Commission-approved Acquirer (but shall not be deemed to have violated this requirement if the Commission-approved Acquirer withholds such agreement unreasonably); and (2) use their best efforts to obtain a protective order to protect the confidentiality of such information during any adjudication.

- O. Respondents shall maintain manufacturing facilities for the Arixtra finished drug product that are validated, qualified and approved by the FDA, and fully capable of producing Arixtra finished drug product until the Commission-approved Acquirer (or the Designee of the Commission-approved Acquirer) has acquired the Arixtra Manufacturing Facility or is otherwise fully validated, qualified and approved by the FDA and able to manufacture Arixtra finished drug product in a facility that is independent of Respondents;

*provided, however,* the Commission may eliminate, or limit the duration of, the

Respondents' obligation under this provision if the Commission determines that the Commission-approved Acquirer is not using commercially reasonable best efforts to secure the FDA approvals necessary to manufacture Arixtra finished drug product in a facility that is independent of Respondents.

- P. Respondents shall maintain manufacturing facilities for any of the ingredients that are necessary to manufacture Arixtra finished drug product and that, at any time prior to the Effective Date, were manufactured by the Respondents, until the Commission-approved Acquirer (or the Designee of the Commission-approved Acquirer) has secured sources of supply of these ingredients that are independent of Respondents. Such ingredients include, but are not limited to, crude drug substance (Fondaparinux), building blocks (including D<sub>11</sub> and EF<sub>9</sub>) and building block intermediates;

*provided, however,* that if GlaxoSmithKline receives all its requirements for any of the ingredients that are necessary to manufacture Arixtra finished drug product from a Third Party, as provided for in the Arixtra Asset Purchase Agreement, then Respondents shall cause that Third Party to maintain the manufacturing facilities for any of those ingredients;

*provided further* that the Commission may eliminate, or limit the duration of, the Respondents' obligation under this provision if the Commission determines that the Commission-approved Acquirer is not using commercially reasonable best efforts to secure sources of supply of the ingredients necessary to manufacture Arixtra finished drug product that are independent of Respondents.

- Q. Respondents shall not join, file, prosecute or maintain any suit, in law or equity, against the Commission-approved Acquirer or the Arixtra Releasee(s) for the research, Development, manufacture, use, import, export, distribution, or sale of Arixtra under the following:
1. any Patents owned or licensed by Respondents as of the Effective Date or acquired after the Effective Date that claim the use of Arixtra;
  2. any Patents owned or licensed at any time after the Effective Date by Respondents that claim any aspect of the research, Development, manufacture, use, import, export, distribution, or sale of Arixtra, other than such Patents that claim inventions conceived by and reduced to practice by Respondents' employees after the Effective Date.
- R. Respondents shall not, in any jurisdiction throughout the world: (1) use the Product Trademarks related to Arixtra or any mark confusingly similar to the Product Trademarks, as a trademark, tradename, or service mark; (2) attempt to register the Product Trademarks; (3) attempt to register any mark confusingly similar to the Product Trademarks; (4) challenge or interfere with the Commission-approved Acquirer's use and registration of the Product Trademarks; or (5) challenge or interfere with the Commission-approved Acquirer's efforts to enforce its trademark registrations for and trademark rights in the

Product Trademarks against Third Parties.

- S. The purpose of the divestiture of the Arixtra Assets is to ensure the continued use of the Arixtra Assets in the same business, independent of Respondents, in which the Arixtra Assets were engaged at the time of the announcement of the Acquisition, and to remedy the lessening of competition resulting from the Acquisition as alleged in the Commission's Complaint.

### III.

**IT IS FURTHER ORDERED** that:

- A. Not later than twenty (20) Days after the Effective Date or September 1, 2004, whichever is later, Respondents shall divest the Camptosar Assets (to the extent that such assets are not already owned, controlled or in the possession of Pfizer), absolutely and in good faith, to Pfizer pursuant to and in accordance with the Camptosar Asset Purchase Agreement (which agreement shall not vary or contradict, or be construed to vary or contradict, the terms of this Order, it being understood that nothing in this Order shall be construed to reduce any rights or benefits of Pfizer or to reduce any obligations of the Respondents under such agreement), and such agreement, if it becomes the Remedial Agreement for the Camptosar Assets, is incorporated by reference into this Order and made a part hereof. If Respondents do not divest the Camptosar Assets to Pfizer within twenty (20) Days after the Effective Date or September 1, 2004, whichever is later, the Commission may appoint a Divestiture Trustee to divest the Camptosar Assets;

*provided, however,* that if the Respondents have divested the Camptosar Assets to Pfizer prior to the date this Order becomes final, and if, at the time the Commission determines to make this Order final, the Commission notifies the Respondents that the manner in which the divestiture was accomplished is not acceptable, the Commission may direct the Respondents, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the Camptosar Assets to Pfizer (including, but not limited to, entering into additional agreements or arrangements) as the Commission may determine are necessary to satisfy the requirements of this Order.

- B. Any Remedial Agreement related to the Camptosar Assets shall be deemed incorporated into this Order, and any failure by Respondents to comply with the terms of such Remedial Agreement to the extent that such terms relate to the Camptosar Assets shall constitute a failure to comply with this Order.
- C. Respondents shall include in any Remedial Agreement related to the Camptosar Assets a provision that provides that upon reasonable notice and request from Pfizer to the Respondents, Respondents shall provide, in a timely manner at no greater than Direct Cost, assistance and advice of knowledgeable employees of the Respondent(s) for the following

purposes: (1) to facilitate Pfizer in obtaining approvals from the FDA for indications on Camptosar that were the subject of the Camptosar Key Clinical Trials; and (2) to defend against, respond to, or otherwise participate in any litigation related to the United States Patents related to Camptosar.

- D. Prior to the Closing Date, Respondents shall secure all consents and waivers from all Third Parties (including, but not limited to, Yakult) that are necessary for the divestiture of the Camptosar Assets to Pfizer, or for the continued research, Development, manufacture, sale, marketing, or distribution of Camptosar in the United States by Pfizer;

*provided, however*, Respondents may satisfy this requirement by certifying that Pfizer has executed all such agreements directly with each of the relevant Third Parties.

- E. Respondents shall:

1. submit to Pfizer, at Respondents' expense, all Confidential Business Information related to the Camptosar Assets;
2. deliver such Confidential Business Information as follows: (1) in good faith; (2) as soon as practicable, avoiding any delays in transmission of the respective information; and (3) in a manner that ensures its completeness and accuracy and that fully preserves its usefulness;
3. pending the complete delivery of all such Confidential Business Information to Pfizer, provide Pfizer and the Interim Monitor (if any has been appointed) with access to all such Confidential Business Information and employees who possess or are able to locate such information for the purposes of identifying the books, records, and files related to the Camptosar Assets that contain such Confidential Business Information and facilitating the delivery in a manner consistent with this Order;
4. not use, directly or indirectly, any such Confidential Business Information related to the Camptosar Assets (other than as necessary to comply with the following: (1) the requirements of this Order; (2) the Respondents' obligations to Pfizer under the terms of any Remedial Agreement related to the Camptosar Assets; (3) the Respondents' obligations to Yakult related to the Camptosar Assets; or (4) applicable Law); and
5. not disclose or convey any such Confidential Business Information, directly or indirectly, to any person except Pfizer;

*provided, however*, this Paragraph III.E shall not apply to any Confidential Business Information related to the Camptosar Assets that Respondent Sanofi can demonstrate it obtained without the assistance of Respondent Aventis prior to the Effective Date.

- F. Respondents shall:

1. for a period of at least twelve (12) months from the earlier of the following dates: (1) ten (10) Days after notice by staff of the Commission to the Respondents to provide the opportunity to enter into employment contracts; or (2) the Closing Date, provide Pfizer with the opportunity to enter into employment contracts with the Camptosar Core Employees. This period is hereinafter referred to as the “Camptosar Access Period”;

*provided, however,* that any such employment contracts entered into prior to the Closing Date shall be contingent upon approval by the Commission of the agreements relating to the Camptosar Assets (*i.e.*, those agreements proposed by Respondents (or the Divestiture Trustee) to the Commission) as the Remedial Agreements for the Camptosar Assets; and

2. not later than the earlier of the following dates: (1) ten (10) Days after notice by staff of the Commission to the Respondents to provide the Product Employee Information; or (2) ten (10) Days after the Closing Date, provide Pfizer with the Product Employee Information related to the Camptosar Core Employees. Failure by Respondents to provide the Product Employee Information for any relevant employee within the time provided herein shall extend the Camptosar Access Period with respect to that employee in an amount equal to the delay.

G. Respondents shall:

1. during the Camptosar Access Period, not interfere with the hiring or employing by Pfizer of Camptosar Core Employees, and remove any impediments within the control of Respondents that may deter these employees from accepting employment with Pfizer, including, but not limited to, any noncompete provisions of employment or other contracts with Respondents that would affect the ability or incentive of those individuals to be employed by Pfizer. In addition, Respondents shall not make any counteroffer to a Camptosar Core Employee who receives a written offer of employment from Pfizer;

*provided, however,* that this Paragraph III.G.1 shall not prohibit the Respondents from making offers of employment to or employing any Camptosar Core Employee during the Camptosar Access Period where Pfizer has notified the Respondents in writing that Pfizer does not intend to make an offer of employment to that employee;

*provided further* that if the Respondents notify Pfizer in writing of their desire to make an offer of employment to a particular Camptosar Core Employee and Pfizer does not make an offer of employment to that employee within twenty (20) Days of the date Pfizer receives such notice, the Respondents may make an offer of employment to that employee;

2. until the Closing Date for the divestiture of the Camptosar Assets has occurred, provide all Camptosar Core Employees with reasonable financial incentives to continue in their positions until the Closing Date. Such incentives shall include a continuation of all

employee benefits offered by Respondents, including regularly scheduled raises, bonuses, and vesting of pension benefits (as permitted by Law). In addition to the foregoing, Respondents shall provide to each Camptosar Core Employee (other than those employees who transfer to Pfizer by operation of Law) who accepts employment with Pfizer, an incentive equal to three (3) months of such employee's base annual salary to be paid upon the employee's completion of one (1) year of employment with Pfizer;

*provided, however*, that nothing in this Order requires or shall be construed to require the Respondents to terminate the employment of any employee; and

3. for a period of one (1) year from the Closing Date, not:

- a. directly or indirectly, solicit or otherwise attempt to induce any employee of Pfizer with any amount of responsibility related to the Camptosar Assets ("Camptosar Employee") to terminate his or her employment relationship with Pfizer; or
- b. hire any Camptosar Employee; *provided, however*, Respondents may hire any former Camptosar Employee whose employment has been terminated by Pfizer or who independently applies for employment with the Respondents, as long as such employee was not solicited in violation of the nonsolicitation requirements contained herein;

*provided, however*, Respondents may do the following: (1) advertise for employees in newspapers, trade publications or other media not targeted specifically at the Camptosar Employees; or (2) hire a Camptosar Employee who contacts Respondents on his or her own initiative without any direct or indirect solicitation or encouragement from the Respondents.

- H. For a period of at least twelve (12) months after the Closing Date, Respondents shall not use any Product Research and Development Employee related to the Camptosar Assets for any purpose related to the Development of Eloxatin.
- I. Respondents shall require, as a condition of continued employment post-divestiture, that each Product Research and Development Employee related to the Camptosar Assets sign a confidentiality agreement pursuant to which such employee shall be required to maintain all Confidential Business Information related to the Camptosar Assets strictly confidential, including the nondisclosure of such information to all other employees, executives or other personnel of Respondents (other than as necessary to comply with the requirements of this Order or the requirements contained in the decisions of the Commission of the European Communities in Case COMP/M.3354).
- J. Respondents shall provide written notification of the restrictions on the use of the Confidential Business Information related to the Camptosar Assets by Respondents'

personnel to all of Respondents' employees who:

1. are or were involved in the research, Development, manufacturing, distribution, sale or marketing of Camptosar;
2. are involved in the research, Development, manufacturing, distribution, sale or marketing of Eloxatin; and/or
3. may have Confidential Business Information related to the Camptosar Assets. Such notification shall be in substantially the form set forth in the Employee Notification.

Respondents shall give such notification by e-mail with return receipt requested or similar transmission, and keep a file of such receipts for one (1) year after the Closing Date. Respondents shall provide a copy of such notification to Pfizer. Respondents shall maintain complete records of all such agreements at Respondents' corporate headquarters and shall provide an officer's certification to the Commission stating that such acknowledgment program has been implemented and is being complied with. Respondents shall provide Pfizer with copies of all certifications, notifications and reminders sent to Respondents' personnel.

- K. Upon reasonable notice and request by Pfizer, Respondents shall make available to Pfizer (at costs as described in the Camptosar Asset Purchase Agreement) such personnel, assistance and training as Pfizer might reasonably need to transfer the Camptosar Assets, and shall continue providing such personnel, assistance and training, at the request of Pfizer, until such assets are fully transferred to Pfizer.
- L. Counsel for Respondents (including in-house counsel under appropriate confidentiality arrangements) may retain unredacted copies of all documents or other materials provided to Pfizer and may have access to original documents (under circumstances where copies of documents are insufficient or otherwise unavailable) provided to Pfizer only in order to:
  1. comply with any Remedial Agreement, this Order, any Law (including, without limitation, any requirement to obtain regulatory licenses or approvals), any data retention requirement of any applicable Governmental Entity, or any taxation requirements; or
  2. defend against, respond to, or otherwise participate in any litigation, investigation, audit, process, subpoena or other proceeding relating to the divestiture or any other aspect of the Camptosar Assets; *provided, however*, that Respondents may disclose such information as necessary for the purposes set forth in this Paragraph pursuant to an appropriate confidentiality order, agreement or arrangement;

*provided, however*, that pursuant to this Paragraph III.L. Respondents shall: (1) require those who view such unredacted documents or other materials to enter into confidentiality

agreements with Pfizer (but shall not be deemed to have violated this requirement if Pfizer withholds such agreement unreasonably); and (2) use their best efforts to obtain a protective order to protect the confidentiality of such information during any adjudication.

- M. Pending divestiture of the Camptosar Assets, Respondents shall take such actions as are necessary to maintain the full economic viability and marketability of the Camptosar Assets, to minimize any risk of loss of competitive potential for such assets, and to prevent the destruction, removal, wasting, deterioration, or impairment of any of the Camptosar Assets except for ordinary wear and tear.
- N. The purpose of the divestiture of the Campostar Assets is to ensure the continued use of the Campostar Assets in the same business in which the Campostar Assets were engaged at the time of the announcement of the Acquisition, and to remedy the lessening of competition resulting from the Acquisition as alleged in the Commission's Complaint.

#### IV.

##### **IT IS FURTHER ORDERED** that:

- A. Not later than ninety (90) Days after the date this Order becomes final, Respondents shall divest the Estorra Royalties, absolutely and in good faith, at no minimum price, to either of the following:
  - 1. Sepracor in a manner that receives the prior approval of the Commission; or
  - 2. a Royalty Monetization Firm that receives the prior approval of the Commission and only in a manner that receives the prior approval of the Commission.
- B. After the Effective Date, Respondents shall cease and desist from receiving, accepting, or being entitled to receive or accept any Estorra Royalties *except* for the purposes of transferring such Estorra Royalties to a Royalty Monetization Firm.
- C. Respondents shall abide in good faith by all rights, representations, warranties and covenants as granted in favor of Sepracor under the Estorra License Agreement (which agreement shall not vary or contradict, or be construed to vary or contradict, the terms of this Order, it being understood that nothing in this Order shall be construed to reduce any rights or benefits of Sepracor or to reduce any obligations of the Respondents under such agreement). Respondents shall provide that all such benefits to Sepracor remain in full force and effect as if the Estorra Royalties had been paid by Sepracor to the Respondents in accordance with the Estorra License Agreement and shall perform as such under the Estorra License Agreement. Such rights to Sepracor include, but are not limited to, the following:
  - 1. the exclusive right (even as to Respondents) under the terms of the Estorra License



Agreement to import Products containing (+) zopiclone into the United States, or to make, have made, use, market, sell, offer for sale, have sold, import, and distribute Products containing (+) zopiclone within the United States;

2. the right to the assistance of knowledgeable employees of the Respondents to assist Sepracor to defend against, respond to, or otherwise participate in any litigation related to the Product Intellectual Property within the United States that is the subject of the Estorra License Agreement and to the extent provided in the Estorra License Agreement; and
3. the right to restrict the use or disclosure by the Respondents of the Confidential Business Information related to Estorra to the extent provided in the Estorra License Agreement.

D. Respondents shall:

1. at Sepracor's request, submit to Sepracor, at Respondents' expense, all Confidential Business Information related to the business of researching, Developing, manufacturing, marketing or sale of Estorra to the extent that Respondent Aventis has not already provided such Confidential Business Information to Sepracor and to the extent provided for in the Estorra License Agreement;
2. deliver such Confidential Business Information as follows: (1) in good faith; (2) as soon as practicable, avoiding any delays in transmission of the respective information; and (3) in a manner that ensures its completeness and accuracy and that fully preserves its usefulness; and
3. pending complete delivery of all such Confidential Business Information to Sepracor, provide Sepracor and the Interim Monitor (if any has been appointed) with access to all such Confidential Business Information and employees who possess or are able to locate such information for the purposes of identifying the books, records, and files related to Estorra that contain such Confidential Business Information and facilitating the delivery in a manner consistent with this Order.

E. Respondents shall not join, file, prosecute or maintain any suit, in law or equity, against Sepracor or the Estorra Releasee(s) for the research, Development, manufacture, use, import, export, distribution, or sale of Estorra in the United States under the following:

1. any United States Patents owned or licensed by Respondents as of the Effective Date or acquired after the Effective Date that claim the use of Estorra;
2. any United States Patents owned or licensed at any time after the Effective Date by Respondents that claim any aspect of the research, Development, manufacture, use, import, export, distribution, or sale of Estorra other than such Patents that claim inventions conceived by and reduced to practice by Respondents' employees after the

Effective Date.

- F. The purpose of the remedy is to ensure an independent, viable and effective competitor in the relevant market in which Estorra competed at the time of the announcement of the Acquisition, and to remedy the lessening of competition resulting from the Acquisition as alleged in the Commission's Complaint.

V.

**IT IS FURTHER ORDERED** that:

- A. At any time after Respondents sign the Consent Agreement in this matter, the Commission may appoint an Interim Monitor to assure that Respondents expeditiously comply with all of their obligations and perform all of their responsibilities as required by this Order and the Order to Maintain Assets (collectively "the Orders") and the Remedial Agreements. The Commission may appoint one or more Interim Monitors to assure Respondents' compliance with the requirements of the Orders and the related Remedial Agreements.
- B. The Commission shall select the Interim Monitor, subject to the consent of Respondents, which consent shall not be unreasonably withheld. If neither Respondent has opposed, in writing, including the reasons for opposing, the selection of a proposed Interim Monitor within ten (10) Days after notice by the staff of the Commission to Respondents of the identity of any proposed Interim Monitor, Respondents shall be deemed to have consented to the selection of the proposed Interim Monitor.
- C. Not later than ten (10) Days after the appointment of the Interim Monitor, Respondents shall execute an agreement that, subject to the prior approval of the Commission, confers on the Interim Monitor all the rights and powers necessary to permit the Interim Monitor to monitor Respondents' compliance with the relevant requirements of the Orders in a manner consistent with the purposes of the Orders.
- D. If one or more Interim Monitors are appointed pursuant to this Paragraph or pursuant to the relevant provisions of the Order to Maintain Assets in this matter, Respondents shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of each Interim Monitor:
  - 1. The Interim Monitor shall have the power and authority to monitor Respondents' compliance with the divestiture and asset maintenance obligations and related requirements of the Orders, and shall exercise such power and authority and carry out the duties and responsibilities of the Interim Monitor in a manner consistent with the purposes of the Orders and in consultation with the Commission;
  - 2. The Interim Monitor shall act in a fiduciary capacity for the benefit of the Commission;

3. The Interim Monitor shall serve until the latest of:
- a. with respect to the Arixtra Assets, the completion by Respondents of the divestiture of the Arixtra Assets required to be divested pursuant to the Decision and Order in a manner that fully satisfies the requirements of the Orders and notification by the Commission-approved Acquirer to the Interim Monitor that it is fully capable of producing the relevant Product(s) acquired pursuant to a Remedial Agreement independently of Respondents (including, but not limited to, the manufacture of all registered steps necessary to produce Arixtra finished drug product);
  - b. with respect to the Camptosar Assets, the completion by Respondents of the divestiture of the Camptosar Assets required to be divested pursuant to the Decision and Order in a manner that fully satisfies the requirements of the Orders and notification by Pfizer to the Interim Monitor that it is fully capable of completing the Camptosar Key Clinical Trials; and
  - c. the completion by Respondents of the last obligation under the Orders pertaining to the Interim Monitor's service;

*provided, however,* that the Commission may extend or modify this period as may be necessary or appropriate to accomplish the purposes of the Orders;

4. Subject to any demonstrated legally recognized privilege, the Interim Monitor shall have full and complete access to Respondents' personnel, books, documents, records kept in the normal course of business, facilities and technical information, and such other relevant information as the Interim Monitor may reasonably request, related to Respondents' compliance with their obligations under the Orders, including, but not limited to, their obligations related to the relevant assets. Respondents shall cooperate with any reasonable request of the Interim Monitor and shall take no action to interfere with or impede the Interim Monitor's ability to monitor Respondents' compliance with the Orders;
5. The Interim Monitor shall serve, without bond or other security, at the expense of Respondents on such reasonable and customary terms and conditions as the Commission may set. The Interim Monitor shall have authority to employ, at the expense of the Respondents, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Interim Monitor's duties and responsibilities;
6. Respondents shall indemnify the Interim Monitor and hold the Interim Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Interim Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability,

except to the extent that such losses, claims, damages, liabilities, or expenses result from misfeasance, gross negligence, willful or wanton acts, or bad faith by the Interim Monitor;

7. Respondents shall report to the Interim Monitor in accordance with the requirements of this Order and/or as otherwise provided in any agreement approved by the Commission. The Interim Monitor shall evaluate the reports submitted to the Interim Monitor by Respondents, and any reports submitted by the Commission-approved Acquirer with respect to the performance of Respondents' obligations under the Orders or the Remedial Agreement. Within one (1) month from the date the Interim Monitor receives these reports, the Interim Monitor shall report in writing to the Commission concerning performance by Respondents of their obligations under the Orders; and
  8. Respondents may require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, that such agreement shall not restrict the Interim Monitor from providing any information to the Commission.
- E. The Commission may, among other things, require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Interim Monitor's duties.
  - F. If the Commission determines that the Interim Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Interim Monitor in the same manner as provided in this Paragraph or the relevant provisions of the Order to Maintain Assets in this matter.
  - G. The Commission may on its own initiative, or at the request of the Interim Monitor, issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Orders.
  - H. The Interim Monitor appointed pursuant to this Order or the relevant provisions of the Order to Maintain Assets in this matter may be the same person appointed as a Divestiture Trustee pursuant to the relevant provisions of this Order.

## VI.

**IT IS FURTHER ORDERED** that:

- A. If Respondents have not fully complied with the obligations to assign, grant, license, divest, transfer, deliver or otherwise convey relevant assets as required by this Order, the Commission may appoint a Divestiture Trustee(s) to assign, grant, license, divest, transfer, deliver or otherwise convey the assets required to be assigned, granted, licensed, divested, transferred, delivered or otherwise conveyed pursuant to each of the relevant Paragraphs in a manner that satisfies the requirements of each such Paragraph. The Commission may appoint a different Divestiture Trustee to accomplish each of the divestitures described in Paragraphs II, and III, and IV, respectively. In the event that the Commission or the Attorney General brings an action pursuant to § 5(l) of the Federal Trade Commission Act, 15 U.S.C. § 45(l), or any other statute enforced by the Commission, Respondents shall consent to the appointment of a Divestiture Trustee in such action to assign, grant, license, divest, transfer, deliver or otherwise convey the relevant assets. Neither the appointment of a Divestiture Trustee nor a decision not to appoint a Divestiture Trustee under this Paragraph shall preclude the Commission or the Attorney General from seeking civil penalties or any other relief available to it, including a court-appointed Divestiture Trustee, pursuant to § 5(l) of the Federal Trade Commission Act or any other statute enforced by the Commission, for any failure by Respondents to comply with this Order.
- B. The Commission shall select the Divestiture Trustee, subject to the consent of Respondents, which consent shall not be unreasonably withheld. The Divestiture Trustee shall be a person with experience and expertise in acquisitions and divestitures. If Respondents have not opposed, in writing, including the reasons for opposing, the selection of any proposed Divestiture Trustee within ten (10) Days after notice by the staff of the Commission to Respondents of the identity of any proposed Divestiture Trustee, Respondents shall be deemed to have consented to the selection of the proposed Divestiture Trustee.
- C. Not later than ten (10) Days after the appointment of a Divestiture Trustee, Respondents shall execute a trust agreement that, subject to the prior approval of the Commission, transfers to the Divestiture Trustee all rights and powers necessary to permit the Divestiture Trustee to effect the divestiture required by the Order.
- D. If a Divestiture Trustee is appointed by the Commission or a court pursuant to this Paragraph, Respondents shall consent to the following terms and conditions regarding the Divestiture Trustee's powers, duties, authority, and responsibilities:
1. Subject to the prior approval of the Commission, the Divestiture Trustee shall have the exclusive power and authority to assign, grant, license, divest, transfer, deliver or otherwise convey the assets that are required by this Order to be assigned, granted, licensed, divested, transferred, delivered or otherwise conveyed.
  2. The Divestiture Trustee shall have one (1) year after the date the Commission approves the trust agreement described herein to accomplish the divestiture, which shall be subject to the prior approval of the Commission. If, however, at the end of the twelve-month period, the Divestiture Trustee has submitted a plan of divestiture or

believes that the divestiture can be achieved within a reasonable time, the divestiture period may be extended by the Commission, or, in the case of a court-appointed Divestiture Trustee, by the court; *provided, however*, the Commission may extend the divestiture period only two (2) times.

3. Subject to any demonstrated legally recognized privilege, the Divestiture Trustee shall have full and complete access to the personnel, books, records and facilities related to the relevant assets that are required to be assigned, granted, licensed, divested, delivered or otherwise conveyed by this Order and to any other relevant information, as the Divestiture Trustee may request. Respondents shall develop such financial or other information as the Divestiture Trustee may request and shall cooperate with the Divestiture Trustee. Respondents shall take no action to interfere with or impede the Divestiture Trustee's accomplishment of the divestiture. Any delays in divestiture caused by Respondents shall extend the time for divestiture under this Paragraph in an amount equal to the delay, as determined by the Commission or, for a court-appointed Divestiture Trustee, by the court.
4. The Divestiture Trustee shall use commercially reasonable best efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission, subject to Respondents' absolute and unconditional obligation to divest expeditiously and at no minimum price. Each divestiture shall be made in the manner and to an acquirer as required by this Order; *provided, however*, if the Divestiture Trustee receives bona fide offers from more than one acquiring entity, and if the Commission determines to approve more than one such acquiring entity, the Divestiture Trustee shall divest to the acquiring entity selected by Respondents from among those approved by the Commission; *provided further* that Respondents shall select such entity within five (5) Days after receiving notification of the Commission's approval.
5. The Divestiture Trustee shall serve, without bond or other security, at the cost and expense of Respondents, on such reasonable and customary terms and conditions as the Commission or a court may set. The Divestiture Trustee shall have the authority to employ, at the cost and expense of Respondents, such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are necessary to carry out the Divestiture Trustee's duties and responsibilities. The Divestiture Trustee shall account for all monies derived from the divestiture and all expenses incurred. After approval by the Commission and, in the case of a court-appointed Divestiture Trustee, by the court, of the account of the Divestiture Trustee, including fees for the Divestiture Trustee's services, all remaining monies shall be paid at the direction of the Respondents, and the Divestiture Trustee's power shall be terminated. The compensation of the Divestiture Trustee shall be based at least in significant part on a commission arrangement contingent on the divestiture of all of the relevant assets that are required to be divested by this Order.
6. Respondents shall indemnify the Divestiture Trustee and hold the Divestiture Trustee

harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Divestiture Trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of, any claim, whether or not resulting in any liability, *except* to the extent that such losses, claims, damages, liabilities, or expenses result from misfeasance, gross negligence, willful or wanton acts, or bad faith by the Divestiture Trustee.

7. In the event that the Divestiture Trustee determines that he or she is unable to assign, grant, license, divest, transfer, deliver or otherwise convey the relevant assets required to be assigned, granted, licensed, divested, transferred, delivered or otherwise conveyed in a manner that preserves their marketability, viability and competitiveness and ensures their continued use in the research, Development, manufacture, distribution, marketing, promotion, sale, or after-sales support of the relevant Product, the Divestiture Trustee may assign, grant, license, divest, transfer, deliver or otherwise convey such additional assets of Respondents and effect such arrangements as are necessary to satisfy the requirements of this Order.
  8. The Divestiture Trustee shall have no obligation or authority to operate or maintain the relevant assets required to be assigned, granted, licensed, divested, transferred, delivered or otherwise conveyed by this Order.
  9. The Divestiture Trustee shall report in writing to Respondents and to the Commission every sixty (60) Days concerning the Divestiture Trustee's efforts to accomplish the divestiture.
  10. Respondents may require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, such agreement shall not restrict the Divestiture Trustee from providing any information to the Commission.
- E. If the Commission determines that a Divestiture Trustee has ceased to act or failed to act diligently, the Commission may appoint a substitute Divestiture Trustee in the same manner as provided in this Paragraph.
- F. The Commission or, in the case of a court-appointed Divestiture Trustee, the court, may on its own initiative or at the request of the Divestiture Trustee issue such additional orders or directions as may be necessary or appropriate to accomplish the divestiture required by this Order.
- G. The Divestiture Trustee appointed pursuant to this Paragraph may be the same person

appointed as Interim Monitor pursuant to the relevant provisions of this Order or the relevant provisions of the Order to Maintain Assets in this matter.

## VII.

**IT IS FURTHER ORDERED** that:

- A. Within five (5) Days of the Acquisition, Respondents shall submit to the Commission a letter certifying the date on which the Acquisition occurred.
- B. Within thirty (30) Days after the date this Order becomes final, and every sixty (60) Days thereafter until Respondents have fully complied with Paragraphs II.A., III.A., and IV.A, Respondents shall submit to the Commission a verified written report setting forth in detail the manner and form in which they intend to comply, are complying, and have complied with this Order. Respondents shall submit at the same time a copy of their report concerning compliance with this Order to the Interim Monitor, if any Interim Monitor has been appointed. Respondents shall include in their reports, among other things that are required from time to time, a full description of the efforts being made to comply with the relevant Paragraphs of the Order, including a description of all substantive contacts or negotiations related to the divestiture of the relevant assets and the identity of all parties contacted. Respondents shall include in their reports copies of all written communications to and from such parties, all internal memoranda, and all reports and recommendations concerning completing the obligations.
- C. One (1) year after the date this Order becomes final, annually for the next nine (9) years on the anniversary of the date this Order becomes final, and at other times as the Commission may require, Respondents shall file a verified written report with the Commission setting forth in detail the manner and form in which they have complied and are complying with this Order.

## VIII.

**IT IS FURTHER ORDERED** that Respondents shall notify the Commission at least thirty (30) Days prior to any proposed (1) dissolution of the Respondents, (2) acquisition, merger, or consolidation of Respondents, or (3) other change in the Respondents that may affect compliance obligations arising out of the order, including, but not limited to, assignment, the creation or dissolution of subsidiaries, or any other change in Respondents.



**IX.**

**IT IS FURTHER ORDERED** that, for the purpose of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request with reasonable notice to Respondents made to their principal United States offices, Respondents shall permit any duly authorized representative of the Commission:

- A. Access, during office hours of Respondents and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda and all other records and documents in the possession or under the control of Respondents related to compliance with this Order; and
- B. Upon five (5) Days' notice to Respondents and without restraint or interference from Respondents, to interview officers, directors, or employees of Respondents, who may have counsel present, regarding such matters.

**X.**

**IT IS FURTHER ORDERED** that this Order shall terminate ten (10) years from the date on which the Order becomes final.

By the Commission.

Donald S. Clark  
Secretary

SEAL  
ISSUED: September 20, 2004

**PUBLIC  
APPENDIX I  
TO THE DECISION AND ORDER**

**NOTICE OF ANTITRUST REMEDY AND REQUIREMENT FOR CONFIDENTIALITY**

On [INSERT], Sanofi-Synthélabo, S.A. (“Sanofi”) and Aventis (“Aventis”) hereinafter referred to as “Respondents,” entered into an Agreement Containing Consent Orders (“Consent Agreement”) with the Federal Trade Commission (“FTC”) relating to the divestiture of certain assets. That Consent Agreement includes two orders: the Decision and Order and the Order to Maintain Assets.

The Decision and Order requires the divestiture of assets relating to Arixtra<sup>®</sup>. These assets are hereinafter referred to as the “Sanofi Divested Assets.” The Decision and Order also requires the divestiture of certain assets relating to certain Aventis products including Camptosar<sup>®</sup> (marketed under the tradename Campto<sup>®</sup> in Europe), and the enantiomer of Imovane<sup>®</sup> known as Estorra<sup>®</sup> (a product owned by Sepracor in the United States but subject to a licensing agreement with Aventis). These assets are hereinafter referred to as the “Aventis Divested Assets.” Both the Decision and Order and the Order to Maintain Assets require Respondents to commit that no Confidential Business Information relating to the Sanofi Divested Assets or the Aventis Divested Assets will be disclosed to or used by any employee of the combined entity formed by the acquisition of a controlling interest in Aventis by Sanofi (“Combined Entity”). In particular, this is to protect such information from being used in any way for the research, development, sale or manufacture of any product that competes or may compete with any product that is marketed by the Respondents after the proposed acquisition. The Decision and Order also requires the complete divestiture of ALL documents (including electronically stored material) that contain Confidential Business Information related to the Sanofi Divested Assets and Aventis Divested Assets. Accordingly, no employee of the Combined Entity may maintain copies of documents containing such information, except as otherwise required by law or to the extent necessary (1) in the case of Arixtra, to supply drug substance and to continue the Arixtra Ongoing Clinical Development, on behalf of GlaxoSmithKine as provided for in the Arixtra Asset Purchase Agreement, and (2) in the case of Camptosar/Campto, to comply with the requirements contained in decisions of the Commission of the European Communities in Case COMP/M.3354, or to comply with Sanofi’s obligations in the Camptosar Asset Purchase Agreement.

Under the Decision and Order, the Respondents are required to divest the Sanofi Divested Assets and Aventis Divested Assets to acquirers that must be approved by the FTC. Companies have been proposed to the FTC as the acquirers for these assets. Until a complete divestiture of all of the Sanofi Divested Assets and Aventis Divested Assets occurs, the requirements of the second order – the Order to Maintain Assets – are in place to ensure the continued marketability, viability and competitive vigor of the Sanofi Divested Assets and Aventis Divested Assets. This includes preserving the work force that performs functions related to the Sanofi Divested Assets and Aventis Divested Assets. You are receiving this notice because you are one or more of the following: (i) an employee with work responsibilities related to the Sanofi Divested Assets; (ii) an employee with work responsibilities related to the Aventis

Divested Assets; (iii) an employee for Sanofi, Aventis or the Combined Entity who has work responsibilities in some way related to products that compete or may compete with the Sanofi Divested Assets or Aventis Divested Assets; or (iv) an employee or former employee of Aventis or Sanofi who might have Confidential Business Information in your possession related to the Sanofi Divested Assets or Aventis Divested Assets.

All Confidential Business Information related to Sanofi Divested Assets and Aventis Divested Assets must be retained and maintained by the persons involved in the operation of that business on a confidential basis, and such persons must not provide, discuss, exchange, circulate, or otherwise disclose any such information to or with any other person whose employment involves responsibilities unrelated to the Sanofi Divested Assets or Aventis Divested Assets (such as persons with job responsibilities related to Sanofi or Aventis products that compete or may compete with the Sanofi Divested Assets or Aventis Divested Assets). In addition, any person who possesses such Confidential Business Information related to the Aventis Divested Assets or Sanofi Divested Assets and who becomes involved in the Combined Entity's business related to any product that competes or may compete with the Sanofi Divested Assets or Aventis Divested Assets must not provide, discuss, exchange, circulate, or otherwise disclose any such information to or with any other person whose employment relates to such businesses. Finally, any Sanofi, Aventis or former Sanofi or Aventis employee with documents that contain information that he or she believes might be considered Confidential Business Information related to the Aventis Divested Assets or Sanofi Divested Assets and who has not received specific instructions as to how the documents in his or her possession should be disposed of should contact the contact person identified at the end of this notice.

Furthermore, the Decision and Order places restrictions upon the functions that management level employees of Sanofi or Aventis can perform for the Combined Entity for one (1) year from the closing of the Sanofi/Aventis transaction, as follows: any employee of Sanofi who was involved in the marketing of Arixtra may not perform a similar function for the Combined Entity relating to Lovenox. In addition, any employee involved in sales efforts for Arixtra may not perform a similar function for the Combined Entity regarding Lovenox for six (6) months from the closing of the Sanofi/Aventis transaction.

The Decision and Order also places restrictions upon the functions that research and development employees related to Campto can perform for the Combined Entity for one (1) year from the closing of the Sanofi/Aventis transaction, as follows: any employee of Aventis who was involved in the research and development of Campto may not perform any functions for the Combined Entity relating to Eloxatin.

Any violation of the Decision and Order or the Order to Maintain Assets may subject Sanofi, Aventis, or the Combined Entity to civil penalties and other relief as provided by law. If you have any questions regarding the contents of this notice, the confidentiality of information, the Decision and Order or the Order to Maintain Assets, you should contact Jean-Claude Armbruster, Senior Vice President, Human Resources.

#### **ACKNOWLEDGMENT**

I, \_\_\_\_\_ (print name), hereby acknowledge that I  
have read the above notification and agree to abide by its provisions.

**NON-PUBLIC**

**APPENDIX II**

**TO THE DECISION AND ORDER**

**ARIXTRA ASSET PURCHASE AGREEMENT**

**[Redacted From the Public Record Version But Incorporated By Reference]**

**NON-PUBLIC**

**APPENDIX III**

**TO THE DECISION AND ORDER**

**CAMPTOSAR ASSET PURCHASE AGREEMENT**

**[Redacted From the Public Record Version But Incorporated By Reference]**

**NON-PUBLIC**

**APPENDIX IV**

**TO THE DECISION AND ORDER**

**ESTORRA LICENSE AGREEMENT**

**[Redacted From the Public Record Version But Incorporated By Reference]**