

Complaint

IN THE MATTER OF

**KING PHARMACEUTICALS, INC.,
AND
ALPHARMA INC.****CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS
OF SEC. 7 OF THE CLAYTON ACT AND SEC. 5 OF THE FEDERAL
TRADE COMMISSION ACT***Docket C-4246; File No. 081 0240**Complaint, February 2, 2009 – Decision, February 2, 2009*

This consent order addresses the acquisition of Alpharma Inc. by King Pharmaceuticals, Inc. Both companies are engaged in the research, development, manufacture and sale of human pharmaceutical products. The acquisition would eliminate competition in the market for oral long-acting morphine sulfate in which King's Avinza and Alpharma's Kadian compete with each other. The order requires King to divest Kadian to Actavis Elizabeth, L.L.C., or another Commission-approved acquirer. Currently, Actavis manufactures Kadian for Alpharma. With the divestiture, Actavis will continue to sell Kadian in competition with Avinza and other oral long-acting opioids. The assets to be divested include all intellectual property and regulatory approvals, inventory, books and records, marketing materials, and assumed contracts necessary for Actavis to sell Kadian as either a branded or generic product. Because Actavis already manufactures Kadian, no divestiture of fixed assets, interim supply agreement, provision of technical assistance, or asset maintenance order are required. The consent order restricts King's use of confidential business information relating to Kadian. The order provides that the Commission may appoint a divestiture trustee to effectuate such modifications as are necessary to satisfy the requirements of the order. Additionally, the order allows the Commission to appoint an Interim Monitor to ensure the respondents' compliance.

Participants

For the Commission: Sylvia M. Brooks, Leslie Farber, Jacqueline Mendel, Michael R. Moiseyev, Loren Smith, and James Southworth.

For the Respondents: Michael McFalls and Philip Proger, Jones Day LLP; and Joseph Tringali, Simpson, Thatcher & Bartlett LLP.

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COMPLAINT

Pursuant to the Clayton Act and the Federal Trade Commission Act, and its authority thereunder, the Federal Trade Commission (“Commission”), having reason to believe that Respondent King Pharmaceuticals, Inc. (“King”), a corporation subject to the jurisdiction of the Commission, has offered to acquire the common shares of Alpharma Inc. (“Alpharma”), a corporation subject to the jurisdiction of the Commission, in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act (“FTC Act”), as amended, 15 U.S.C. § 45, and it appearing to the Commission that a proceeding in respect thereof would be in the public interest, hereby issues its Complaint, stating its charges as follows:

I. DEFINITIONS

1. “Oral long-acting opioids” or “oral LAOs” mean orally-administered extended-release formulations of potent pure opioid agonists, including, but not limited to, oxycodone, morphine sulfate and oxymorphone.
2. “Kadian” means any oral extended-release morphine sulfate product in any dose form, presentation or line extension thereof marketed or sold by Alpharma under the trademark Kadian.
3. “Avinza” means any oral extended-release morphine sulfate product in any dose form, presentation or line extension thereof marketed or sold by King under the trademark Avinza.
4. “Commission” means the Federal Trade Commission.
5. “FDA” means the United States Food and Drug Administration.
6. “Respondents” means King and Alpharma, individually and collectively.

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II. RESPONDENTS

7. Respondent King Pharmaceuticals, Inc. (“King”) is a corporation organized, existing and doing business under and by virtue of the laws of Tennessee, with its office and principal place of business located at 501 Fifth Street, Bristol, Tennessee 37620. King is engaged in the research, development, manufacture and sale of human pharmaceutical products.

8. Respondent Alpharma Inc. (“Alpharma”) is a corporation organized, existing and doing business under and by virtue of the laws Delaware, with its office and principal place of business located at 440 Route 22 East, Bridgewater, New Jersey 08807. Alpharma, is engaged in the research, development, manufacture and sale of human pharmaceutical products and animal health products.

9. Respondents are, and at all times relevant herein have been, engaged in commerce, as “commerce” is defined in Section 1 of the Clayton Act, as amended, 15 U.S.C. § 12, and are corporations whose business is in or affects commerce, as “commerce” is defined in Section 4 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 44.

III. THE PROPOSED ACQUISITION

10. On September 11, 2008, King announced its intention to acquire up to 100 percent of the outstanding share of Alpharma through a cash tender offer. On November 23, 2008, King, Albert Acquisitions Corp., a wholly-owned subsidiary of King, and Alpharma executed an Agreement and Plan of Merger (“Acquisition Agreement”) pursuant to which King will acquire all of the outstanding shares of Alpharma. The acquisition is valued at approximately \$1.6 billion.

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IV. THE RELEVANT MARKET

11. For the purposes of this Complaint, the relevant line of commerce in which to analyze the effects of the Acquisition is no broader than the manufacture and sale of oral LAOs, and includes the narrower market for oral long-acting morphine sulfate in which Kadian and Avinza compete directly with each other.

12. For the purposes of this Complaint, the United States is the relevant geographic area in which to analyze the effects of the Acquisition in the relevant line of commerce.

V. THE STRUCTURE OF THE MARKET

13. The United States market for oral LAOs is highly concentrated. Purdue Pharma L.P.'s OxyContin is the dominant product in the market. King's Avinza and Alpharma's Kadian are the only two significant branded morphine sulfate products in the market.

VI. ENTRY CONDITIONS

14. Entry into the relevant line of commerce described in Paragraph 11 would not be timely, likely or sufficient in its magnitude, character and scope to deter or counteract the anticompetitive effects of the Acquisition. Developing and obtaining FDA approval for a new oral LAO takes more than two years due to significant regulatory and intellectual property barriers.

VII. EFFECTS OF THE ACQUISITION

15. The effects of the Acquisition, if consummated, may be to substantially lessen competition and to tend to create a monopoly in the relevant market in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, by eliminating actual, direct, and substantial competition between King and Alpharma in the relevant market, thereby (1) increasing the likelihood that King will be able to exercise

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unilaterally market power in this market, and (2) increasing the likelihood that customers would be forced to pay higher prices.

VIII. VIOLATIONS CHARGED

16. The tender offer and the Acquisition Agreement described in Paragraph 10 constitute violations of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

17. The Acquisition described in Paragraph 10, if consummated, would constitute a violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this second day of February, 2009, issues its Complaint against said Respondents.

By the Commission, Commissioner Harbour recused.

DECISION AND ORDER

The Federal Trade Commission (“Commission”) having initiated an investigation of the proposed acquisition by Respondent King Pharmaceuticals, Inc. (“King”) and its subsidiary Albert Acquisition Corporation (“Albert”) of Respondent Alpharma Inc. (“Alpharma”), hereinafter referred to as “Respondents,” and Respondents having been furnished thereafter with a copy of a draft 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

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Respondents, their attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Order (“Consent Agreement”), containing an admission by Respondents of all the jurisdictional facts set forth in the aforesaid draft 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 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 King is a corporation organized, existing and doing business under and by virtue of the laws of the State of Tennessee, with its principal address located at 501 Fifth Street, Bristol, Tennessee 37620.
2. Respondent Alpharma is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its principal address located at 440 Route 22 East, Bridgewater, New Jersey 09907.
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

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I.

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

- A. “King” means King Pharmaceuticals, Inc., its directors, officers, employees, agents, representatives, successors, and assigns; its subsidiaries (including Albert Acquisition Corp., a wholly owned subsidiary formed solely for the purpose of acquiring Respondent Alharma), divisions, groups, and affiliates controlled by King Pharmaceuticals, Inc., and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- B. “Alharma” means Alharma Inc., its directors, officers, employees, agents, representatives, successors, and assigns; its subsidiaries, divisions, groups, and affiliates controlled by Alharma Inc., and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- C. “Respondents” means King, and Alharma, individually and collectively.
- D. “Acquisition” means the Agreement and Plan of Merger, dated November 23, 2008, by and among King, Albert Acquisition Corp., and Alharma.
- E. “Commission” means the Federal Trade Commission.
- F. “Actavis” means Actavis Elizabeth, L.L.C., a limited liability company, organized, existing, and doing business under and by virtue of the laws of Delaware, with its offices and principal address located at 60 Columbia Road, Building B, Morristown, New Jersey 07960.
- G. “Kadian” means the pharmaceutical Product approved for distribution under New Drug Application 20-616 (including

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all additions, amendments, supplements, extensions and modifications thereto and the official regulatory files relating thereto), in the dosage strengths and formulations approved for distribution as of the Closing Date, or that is marketed or sold under the Kadian® Trademark as of the Closing Date.

- H. “Kadian Asset Purchase Agreement” means the “Asset Purchase Agreement by and between King Pharmaceuticals, Inc. and Actavis Elizabeth, L.L.C. dated as of December, 2008, and all amendments, exhibits, attachments, agreements, and schedules thereto, related to the Kadian Assets, that have been approved by the Commission to accomplish the requirements of this Order. The Kadian Asset Purchase Agreement is attached to this Order as non-public Appendix II.
- I. “Kadian Assets” means all of Respondent Alpharma’s rights, title, and interest in and to the following Kadian assets:
 - 1. Kadian Intellectual Property;
 - 2. perpetual, fully paid-up and royalty-free exclusive license(s) with rights to sublicense to all Kadian Licensed Intellectual Property to use, make, distribute, offer for sale, promote, advertise, sell, import, or have used, made, distributed, offered for sale, promoted, advertised, sold, or imported Kadian in the United States, which includes its territories and possessions, including Washington, D.C. and Puerto Rico;
 - 3. at the Commission-approved Acquirer’s option, each of the Kadian Contracts;
 - 4. all Kadian Marketing Materials;
 - 5. all Kadian Scientific and Regulatory Materials;
 - 6. all Website(s) solely related to Kadian;

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7. a list of all the NDC Numbers solely related to Kadian;
8. 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;
9. all rights (if such rights exist) to information similar to the Drug Master Files submitted to any agency other than the United States Food and Drug Administration (“FDA”);
10. Kadian inventory;
11. a list of all targeted customers for Kadian and the planned or proposed pricing of Kadian for such customers;
12. 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 four (4) Days after the Closing Date);
13. at the Commission-approved Acquirer’s option, all inventories in existence as of the Closing Date, including, but not limited to, crude drug substance, finished drug substance (morphine sulfate), building blocks and building block intermediates, and Kadian specific packaging and labels;
14. Kadian Manufacturing Technology, and Kadian manufacturing and manufacturing processes; and
15. all Respondents books, records, and files related to the foregoing, including, but not limited to, the following specified documents: the Kadian 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

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sales histories, including, without limitation, clinical data, and sales force call activity, for Kadian from January 1, 2001, through the Closing Date, and quality control histories pertaining to Kadian owned by, or in the possession or control of, Respondents or to which Respondents have 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 Kadian Assets contain information: (1) that relates both to Kadian and to other Products or businesses of Respondents and cannot be segregated in a manner that preserves the usefulness of the information as it relates to Kadian; or (2) for which Respondents have a legal obligation to retain the original copies, Respondents 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, Respondents 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 Respondents provide the Commission-approved Acquirer with the above-described information without requiring Respondents completely to divest itself of information that, in content, also relates to Products and businesses other than Kadian.

- J. “Kadian Contracts” means all of the following contracts or agreements:
1. pursuant to which any Third Party purchases Kadian from the Respondents;
 2. pursuant to which the Respondents purchase any materials from any Third Party for use in connection with the manufacture of Kadian;

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3. relating solely to any clinical trial involving Kadian;
4. constituting the material transfer agreements involving the transfer of Kadian;
5. relating to the marketing of Kadian or educational matters relating to Kadian;
6. relating to the manufacture of Kadian;
7. constituting confidentiality agreements involving Kadian;
8. involving any royalty, licensing, or similar arrangement involving Kadian;
9. pursuant to which any services are provided with respect to Kadian or Kadian's business, including consultation arrangements; and/or
10. pursuant to which any Third Party collaborates with the Respondents in the performance of research or Development of Kadian or the Kadian business;

provided, however, that where any such contract or agreement also relates to Products of the Respondents other than Kadian pursuant to this Order, Respondents shall assign the Commission-approved Acquirer all such rights under the contract or agreement as are related to Kadian pursuant to this Order, but concurrently may retain similar rights for the purposes of the other Products.

- K. "Kadian Copyrights" means rights to all original works of authorship of any kind solely related to Kadian 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

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development data and reports relating to the research and Development of Kadian or of any materials used in the research, Development, manufacture, marketing or sale of Kadian, including all raw data relating to clinical trials of Kadian, 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, Kadian 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 solely relating to Kadian 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.

- L. “Kadian Core Employee(s)” means the Kadian Manufacturing Employees, the Kadian Marketing Employees, and the Kadian Research and Development Employees related to the Kadian Assets.
- M. “Kadian Intellectual Property” means all of the following solely related to Kadian:
 - 1. Kadian Patents;

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2. Kadian Copyrights;
3. Kadian Software, other than Kadian Licensed Intellectual Property;
4. Kadian 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 Kadian 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 “Kadian Intellectual Property” does not include the names “Alpharma,” or “King,” or the names of any other corporations or companies owned by Respondent Alpharma or Respondent King or related logos to the extent used on other of Respondents’ Products.

N. “Kadian Licensed Intellectual Property” means the following:

1. Patents that are related to Kadian and that Respondents can demonstrate have been routinely used, prior to the Effective Date, by Respondent Alpharma for Product(s) other than Kadian, or are likely to be used for Products other than Kadian by Respondents;
2. Kadian Software that is used in connection with the analysis of clinical trial data for Kadian that Respondents can demonstrate has been routinely used, prior to the

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Effective Date, by Respondent Alpharma for Product(s) other than Kadian, or is likely to be used for Products other than Kadian by Respondents; 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 Kadian and that Respondents can demonstrate have been routinely used, prior to the Effective Date, by Respondent Alpharma for Product(s) other than Kadian, or are likely to be used for Products other than Kadian by Respondents.
- O. “Kadian 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 Kadian, including, but not limited to, those involved in the quality assurance and quality control of Kadian, within the eighteen (18) month period immediately prior to the Closing Date.
- P. “Kadian 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 Kadian, including Kadian’s formulation, in existence and in the possession of Respondents 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.
- Q. “Kadian Marketing Materials” means all marketing materials related to Kadian as of the Closing Date, including, without limitation, all advertising materials, training materials, Kadian data, price lists, mailing lists, sales materials (e.g., detailing reports, vendor lists, sales data, reimbursement

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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.

- R. “Kadian Ongoing Clinical Development Employees” means those employees of Respondent Alpharma who are engaged in any ongoing clinical trials related to Kadian.
- S. “Kadian 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 worldwide of Kadian, including all INDs, NDAs, ANDAs, SNDAs, MAAs, in existence for Kadian as of the Closing Date.
- T. “Kadian Releasee(s)” means the Commission-approved Acquirer for Kadian, 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.
- U. “Kadian Research and Development Employees” means all employees of Respondents who directly have participated (irrespective of the portion of working time involved) in the research, Development, regulatory approval process, or clinical studies of Kadian within the eighteen (18) month period immediately prior to the Closing Date.

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- V. “Kadian Sales and Marketing Employees” means all management level employees of Respondents who directly have participated (irrespective of the portion of working time involved) in the marketing, contracting, or promotion or sale of Kadian 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.
- W. “Kadian Scientific and Regulatory Material” means all technological, scientific, chemical, biological, pharmacological, toxicological, regulatory, and clinical trial materials and information related to Kadian, and all rights thereto, in any and all United States jurisdictions.
- X. “Kadian 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 “Kadian 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).
- Y. “Kadian Trade Dress” means the current trade dress of Kadian, including, but not limited to, Product packaging associated with the sale of Kadian and the lettering of Kadian’s trade name or brand name.
- Z. “Kadian Trademark(s)” means all proprietary names or designations, trademarks, tradenames, and brand names, including registrations and applications for registration

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therefor (and all renewals, modifications, and extensions thereof), and all common law rights, and the goodwill symbolized thereby and associated therewith, for Kadian.

- AA. “Closing Date” means the date on which Respondents (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.
- BB. “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.
- CC. “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.
- DD. “Day(s)” means the period of time prescribed under this Order as computed pursuant to 16 C.F.R. § 4.3 (a).
- EE. “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,

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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.

FF. “Direct Cost” means the cost of direct labor and direct material used to provide the relevant assistance or service.

GG. “Divestiture Trustee” means a trustee appointed by the Commission pursuant to the relevant provisions of this Order.

HH. “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.

II. “Drug Master Files” means the information submitted to the FDA as described in 21 C.F.R. _ 314.420 related to Kadian.

JJ. “Effective Date” means the date on which the Acquisition occurs.

KK. “Employee Notification” means the “Notice of Antitrust Remedy and Requirement for Confidentiality” attached to this Order as Appendix I.

LL. “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.

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- MM. “Interim Monitor” means any monitor appointed pursuant to Paragraph III of this Order.
- NN. “Law” means all laws, statutes, rules, regulations, ordinances, and other pronouncements by any Governmental Entity having the effect of law.
- OO. “NDC Numbers” means the National Drug Code numbers(s) assigned by the FDA to a Product.
- PP. “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 United States, related to Kadian as of the Closing Date.
- QQ. “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.
- RR. “Remedial Agreement” means the following: (1) any agreement between Respondents 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 Respondents and a Commission-approved Acquirer (or between a Divestiture Trustee and a Commission-approved

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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.

SS. “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) required to be divested.

TT. “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 Kadian Intellectual Property not owned by Respondents that are incorporated in such Website(s), such as stock photographs used in the Website(s), *except* to the extent that Respondents can convey their rights, if any, therein; or (2) content unrelated to Kadian.

II.

IT IS FURTHER ORDERED that:

A. Not later than ten (10) Days after the Effective Date, or December 31, 2008, whichever is later, Respondents shall divest the Kadian Assets, absolutely and in good faith, to Actavis pursuant to and in accordance with the Kadian 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 Actavis or to reduce any obligations of the Respondents under such agreement), and such agreement, if it becomes the Remedial

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Agreement related to the Kadian Assets, is incorporated by reference into this Order and made a part hereof. If Respondents do not divest the Kadian Assets to Actavis within ten (10) Days after the Effective Date, or December 31, 2008, whichever is later, the Commission may appoint a Divestiture Trustee to divest the Kadian Assets;

provided, however, that if Respondents have divested the Kadian Assets to Actavis 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 Actavis is not an acceptable purchaser of the Kadian Assets, then Respondents shall immediately rescind the transaction with Actavis and shall divest the Kadian 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 Kadian Assets to Actavis 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 Kadian Assets to Actavis (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 Kadian 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 Kadian Assets shall constitute a failure to comply with this Order.

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- C. Respondents shall include in any Remedial Agreement related to the Kadian Assets the following provisions:
1. 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 Kadian Intellectual Property;
 2. 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 Kadian;® and
 3. 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 Kadian Releasee(s), at least as protective as those extended pursuant to the preceding Paragraph II.C.2, 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 Kadian against the Kadian Releasees, unless required by Law or contract (such contract not to be solicited or entered into

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for the purpose of circumventing any of the requirements of this Order).

D. Respondents shall:

1. submit to the Commission-approved Acquirer, at Respondents' expense, all Confidential Business Information related to Kadian;
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 Kadian 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 Kadian (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 Kadian Assets; or (3) applicable Law; and

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5. not disclose or convey any such Confidential Business Information, directly or indirectly, to any person except the Commission-approved Acquirer.
- E. For a period of one (1) year from the Closing Date, Respondents shall not:
1. directly or indirectly, solicit or otherwise attempt to induce any employee of the Commission-approved Acquirer with any amount of responsibility related to Kadian ("Kadian Employee") to terminate his or her employment relationship with the Commission-approved Acquirer; or
 2. hire any Kadian Employee; *provided, however,* Respondents may hire any former Kadian 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, further,* Respondents may do the following: (1) advertise for employees in newspapers, trade publications or other media not targeted specifically at the Kadian Employees; or (2) hire a Kadian Employee who contacts Respondents on his or her own initiative without any direct or indirect solicitation or encouragement from the Respondents.
- F. Prior to the Closing Date, Respondents shall secure all consents and waivers from all Third Parties that are necessary for the divestiture of the Kadian Assets to the Commission-approved Acquirer, or for the continued research, Development, manufacture, sale, marketing or distribution of Kadian by the Commission-approved Acquirer;
- provided, however,* Respondents may satisfy this requirement by certifying that the Commission-approved Acquirer has

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executed all such agreements directly with each of the relevant Third Parties.

- G. For the periods as set forth in this Paragraph II.G (collectively, the “Moratorium/Waiting Period”), if the Commission-approved Acquirer is not Actavis, Respondents shall not market or promote Avinza in the United States using the services of any Kadian Sales or Marketing Employee, regardless of the portion of work time expended on Kadian, within the eighteen (18) month period immediately prior to the Closing Date. The Moratorium/Waiting Period shall be at least twelve (12) months from the Closing Date with respect to the Sales or Marketing Employees related to Kadian.
- H. For a period of at least six (6) months after the completion of any clinical trials related to Kadian that were ongoing as of the Effective Date, Respondents shall not use any Kadian Ongoing Clinical Development Employee for any purpose related to the Development of Avinza.
- I. Respondents shall require, as a condition of continued employment post-divestiture, that each Kadian Core Employee sign a confidentiality agreement pursuant to which such employee shall be required to maintain all Confidential Business Information related to Kadian 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).
- J. Respondents shall provide written notification of the restrictions on the use of the Confidential Business Information related to Kadian by Respondents’ personnel to all of Respondents’ employees who:
 - 1. are or were involved in the research, Development, manufacturing, distribution, sale or marketing of Kadian;

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2. are involved in the research, Development, manufacturing, distribution, sale or marketing of Avinza; and/or
3. may have Confidential Business Information related to Kadian.

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.

- K. 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 Kadian Asset Purchase Agreement is the Remedial Agreement for the Kadian Assets, then at such cost as provided therein), such personnel, assistance and training as the Commission-approved Acquirer might reasonably need to transfer the Kadian 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 Kadian independently of the Respondents;

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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 Kadian finished drug product in a facility that is independent of Respondents.

- L. Pending divestiture of the Kadian Assets, Respondents shall take such actions as are necessary to maintain the full economic viability and marketability of the business associated with the Kadian 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 Kadian Assets except for ordinary wear and tear.
- M. 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 Kadian Assets or Kadian business; *provided, however*, that Respondents may disclose such information as necessary for the purposes set forth in this Paragraph

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pursuant to an appropriate confidentiality order, agreement or arrangement;

provided, however, that pursuant to this Paragraph II.M, 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.

- N. Respondents shall maintain manufacturing facilities for any of the ingredients that are necessary to manufacture Kadian 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;

provided, however, that if Actavis receives all its requirements for any of the ingredients that are necessary to manufacture Kadian finished drug product from a Third Party, as provided for in the Kadian 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 Kadian finished drug product that are independent of Respondents.

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- O. Respondents shall not join, file, prosecute or maintain any suit, in law or equity, against the Kadian Releasee(s) for the research, Development, manufacture, use, import, export, distribution, or sale of Kadian 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 Kadian; or
 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 Kadian, other than such Patents that claim inventions conceived by and reduced to practice by Respondents' employees after the Effective Date.
- P. Respondents shall not, in any jurisdiction throughout the world: (1) use the Kadian Trademarks or any mark confusingly similar to the Kadian Trademarks, as a trademark, tradename, or service mark; (2) attempt to register the Kadian Trademarks; (3) attempt to register any mark confusingly similar to the Kadian Trademarks; (4) challenge or interfere with the Commission-approved Acquirer's use and registration of the Kadian Trademarks; or (5) challenge or interfere with the Commission-approved Acquirer's efforts to enforce its trademark registrations for and trademark rights in the Kadian Trademarks against Third Parties.
- Q. The purpose of the divestiture of the Kadian Assets is to ensure the continued use of the Kadian Assets in the same business, independent of Respondents, in which the Kadian 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.

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IT IS FURTHER ORDERED that:

- A. At any time after Respondents sign the Consent Agreement in this matter, the Commission may appoint one or more Interim Monitors to assure that Respondents expeditiously comply with all of their obligations and perform all of their responsibilities as required by this Order and the Remedial Agreement.
- B. The Commission shall select the Interim Monitor, subject to the consent of Respondents, which consent shall not be unreasonably withheld. If Respondents have not 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 Order in a manner consistent with the purpose of the Order.
- D. If one or more Interim Monitors are appointed pursuant to this Paragraph, 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 Order, and shall exercise such power and authority and carry out the duties and responsibilities of the Interim Monitor in a manner consistent with the

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purposes of the Order, and in consultation with the Commission, including, recommending that the Commission direct the Respondents to effect such modifications to the manner of divestiture of the Kadian Assets to Actavis (including, but not limited to, entering into additional agreements or arrangements) as are necessary to satisfy the requirements of this Order;

2. The Interim Monitor shall act in a fiduciary capacity for the benefit of the Commission;
 3. The Interim Monitor shall serve until the completion by Respondents of the divestiture of the Kadian Assets, or, to the Commission-approved Acquirer, if Actavis is not the Commission-approved Acquirer, pursuant to the Decision and Order in a manner that fully satisfies the requirements of the Order and notification by the Commission-approved Acquirer to the Interim Monitor that it is fully capable of implementing and marketing the Kadian Assets and, if Actavis is not the Commission-approved Acquirer, the Supplemental Assets independently of Respondents. As necessary or appropriate, the Commission may extend or modify this period to accomplish the purposes of the Order;
- D. 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 Order, 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 Order;

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- E. 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;
- F. 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 gross negligence, willful or wanton acts, or bad faith by the Interim Monitor;
- G. 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 Order 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;
- H. 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

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agreement shall not restrict the Interim Monitor from providing any information to the Commission.

- I. 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.
- J. 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.
- K. 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 this Order.
- L. The Interim Monitor appointed pursuant to this Order may be the same person appointed as a Divestiture Trustee pursuant to the relevant provisions of this Order.

IV.**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. In the event that the

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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:

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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.

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4. The Divestiture Trustee shall use commercially reasonable best efforts to negotiate the most favorable price and terms available in the contract that is submitted to the Commission, subject to Respondents' absolute and unconditional obligation to divest expeditiously and at no minimum price. The 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

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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 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, 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.

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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.

V.**IT IS FURTHER ORDERED** that:

- A. Within ten (10) 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 Paragraph II of this Order, 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

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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 Paragraph II, 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, and annually on the anniversary of the date this Order becomes final, until the earlier of nine (9) years, or a final judicial determination of the validity of the Avinza® patent, 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.

VI.**IT IS FURTHER ORDERED** that:

- A. At the earlier of nine (9) years from the date this Order becomes final, or a final judicial determination of the validity of the Avinza® patent, Respondents shall submit to the Commission at least thirty (30) days prior to entering into a settlement related to the infringement of that patent, a copy of the settlement agreement;
- B. The absence of notice that the proposed settlement has been rejected shall not be construed as a determination by the Commission, or its staff, that the proposed settlement has been approved; and

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- C. Receipt by the Commission of any settlement agreement pursuant to this Paragraph VI is not to be construed as a determination by the Commission, or its staff, that the proposed settlement does or does not violate this Order or any law enforced by the Commission.

VII.

IT IS FURTHER ORDERED that Respondents shall provide a copy of this Order to each of Respondent's officers, employees, or agents having managerial responsibility for any of Respondent's obligations under Paragraphs II through V of this Order, no later than ten days from the date this Order becomes final.

VIII.

IT IS FURTHER ORDERED that each Respondent shall notify the Commission:

- A. Of any change in its principal address within twenty (20) days of such change in address; and
- B. At least thirty (30) days prior to any proposed: (a) dissolution of Respondent; (b) acquisition, merger, or consolidation of Respondent; or (c) any other change in Respondent including, but not limited to, assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of this Order.

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 and upon five (5) days notice to a Respondent, that Respondent shall, without restraint or interference, permit any duly authorized representative of the Commission:

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- A. Access, during office hours of Respondent, 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 Respondent relating to compliance with this Order, which copying services shall be provided by Respondent at its expense; and
- B. To interview officers, directors, or employees of Respondent, who may have counsel present, regarding such matters.

X.

IT IS FURTHER ORDERED that this Order shall terminate on February 2, 2019.

By the Commission, Commissioner Harbour recused.

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APPENDIX I**PUBLIC
APPENDIX I
TO THE DECISION AND ORDER****NOTICE OF ANTITRUST REMEDY AND REQUIREMENT FOR CONFIDENTIALITY**

On [INSERT DATE], King Pharmaceuticals, Inc. ("King") and Alpha Inc. ("Alpha") 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 a Decision and Order ("Order").

The Order requires the divestiture of assets relating to Kadian®. The Order requires Respondents to commit that no Confidential Business Information relating to Kadian® will be disclosed to or used by any employee of the combined entity formed by the acquisition of a controlling interest in Alpha by King ("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 Order also requires the complete divestiture of ALL documents (including electronically stored material) that contain Confidential Business Information related to Kadian®. Accordingly, no employee of the Combined Entity may maintain copies of documents containing such information, except as otherwise required by law.

Under the Order, the Respondents are required to divest Kadian® to an acquirer that must be approved by the FTC. Until a complete divestiture of all of Kadian® occurs, the Order requires the continued marketability, viability and competitive vigor of Kadian®. This includes preserving the work force that performs functions related to Kadian®. You are receiving this notice because you are one or more of the following: (i) an employee with work responsibilities related to Kadian®; (ii) an employee for Alpha, King or the Combined Entity who has work responsibilities in some way related to products that compete or may compete with Kadian®; or (iii) an employee or former employee of King or Alpha who might have Confidential Business Information in your possession related to Kadian®.

All Confidential Business Information related to Kadian® 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 Kadian® (such as persons with job responsibilities related to Alpha or King products that compete or may compete with Kadian®). In addition, any person who possesses such Confidential Business Information related to Kadian® and who becomes involved in the Combined Entity's business related to any product that competes or may compete with Kadian® must not provide, discuss, exchange, circulate, or otherwise disclose any such information to or with any other person whose employment relates to such business. Finally, any Alpha, King or former Alpha or King employee with documents that contain information that he or she believes might be considered Confidential Business Information related to Kadian® and who has

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

[ADD ONLY IF ACTAVIS IS NOT THE BUYER]: Furthermore, the Order places restrictions upon the functions that management level employees of Alpharma and King can perform for the Combined Entity for one (1) year from the closing of the King/Alpharma transaction, as follows: any employee of Alpharma who was involved in the marketing of Kadian® may not perform a similar function for the Combined Entity relating to Avinza®. In addition, any employee involved in sales efforts for Kadian® may not perform a similar function for the Combined Entity regarding Avinza® for six (6) months from the closing of the King/Alpharma transaction.]

Any violation of the Order may subject King, Alpharma, 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 or the Order, you should contact _____.

ACKNOWLEDGMENT

I, _____ (print name), hereby acknowledge that I

have read the above notification and agree to abide by its provisions.

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Appendix II

NON-PUBLIC APPENDIX II TO THE DECISION AND ORDER

KADIAN ASSET PURCHASE AGREEMENT

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

*Analysis to Aid Public Comment***ANALYSIS OF CONSENT ORDER TO AID PUBLIC COMMENT****I. Introduction**

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an Agreement Containing Consent Order (“Consent Agreement”) from King Pharmaceuticals, Inc. (“King”) and Alpharma Inc. (“Alpharma”), which is designed to remedy the anticompetitive effects of King’s acquisition of Alpharma. Under the terms of the Consent Agreement, the companies would be required to divest to Actavis all rights to Kadian, Alpharma’s branded long-acting morphine sulfate opioid analgesic product. Kadian’s patent runs until April of 2010. The divestiture gives Actavis all rights to Kadian, restoring the competition between Kadian and King’s Avinza that would be lost with the acquisition.

The proposed Consent Agreement has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the proposed Consent Agreement and the comments received, and will decide whether it should withdraw from the proposed Consent Agreement, modify it, or make final the Decision and Order (“Order”).

Pursuant to a merger agreement executed on November 23, 2008, King intends to acquire all the outstanding shares of Alpharma for approximately \$1.6 billion. Both parties sell branded pharmaceuticals in the United States. The Commission’s Complaint alleges that the proposed acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45. The proposed Consent Agreement remedies the alleged violations by maintaining existing competition between branded Kadian and Avinza, and permitting an authorized generic version of branded Kadian to be launched prior to when the patent expires.

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II. The Competitive Effects of the Proposed Acquisition

The proposed acquisition would cause significant anticompetitive harm by eliminating actual, direct and substantial competition between King and Alpharma in the market for oral long acting opioid analgesics (“oral LAOs”). The merging firms today offer the only two competitively significant branded morphine sulfate oral LAOs, and the evidence shows that they are particularly close competitors within the larger oral LAO market. The loss of head-to-head competition between King’s Avinza and Alpharma’s Kadian would result in higher prices for branded ER morphine sulfate.

While King and Alpharma oral LAO products compete most directly with each other, they also compete, to a lesser extent, with other oral LAOs. Oral LAOs have become the standard of care for the management of moderate-to-severe chronic pain because of their effectiveness, ease of titration and favorable risk-to-benefit ratio. Other oral LAOs are based on distinct chemical compounds, but all of these products have the same mechanisms of action, similar indications, similar dosage forms and similar dosage frequency. The most significant of the other oral LAOs is Purdue Pharma L.P.’s OxyContin, which is four times larger than Avinza and Kadian, combined. A fourth product, Endo Pharmaceutical’s Opana ER, also competes in the market.

As with most pharmaceutical products, entry into the manufacture and sale of oral LAOs, is difficult, expensive and time consuming. Developing and obtaining U.S. Food and Drug Administration (“FDA”) approval for the manufacture and sale of oral LAOs takes at least two years due to substantial regulatory, technological and intellectual property barriers. As a result, new entry is unlikely to ameliorate the anticompetitive effects of the acquisition.

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III. The Consent Agreement

The order would remedy the competitive concerns raised by the proposed acquisition by requiring King to divest Kadian to Actavis no later than ten days after its acquisition of Alpharma is consummated. Headquartered in Iceland, Actavis is one of the world's largest generic pharmaceutical companies. Currently, Actavis manufactures Kadian for Alpharma at its plant located in Elizabeth, New Jersey. With the divestiture, Actavis will continue to sell Kadian in competition with Avinza and other oral LAOs, and be able to introduce an "authorized" generic version of Kadian earlier than would have been otherwise possible, as Kadian's patent expires in April of 2010. An "authorized" generic is a pharmaceutical product that was originally marketed and sold by a brand company but is relabeled and marketed under a generic product name. As the current manufacturer of Kadian for Alpharma, Actavis has the incentive and ability to launch the first generic Kadian product prior to patent expiry.

The assets to be divested include all intellectual property and regulatory approvals, inventory, books and records, marketing materials, and assumed contracts necessary for Actavis to sell Kadian as either a branded or generic product. Because Actavis already manufactures Kadian, no divestiture of fixed assets, interim supply agreement, provision of technical assistance is required, or asset maintenance order are required.¹ The proposed order also contains provisions designed to restrict King's use of confidential business information relating to Kadian.

The FTC's prior orders involving the divestiture of branded pharmaceutical products have required that any buyer of branded products have the requisite brand marketing experience to replace the competition that would have been eliminated through the transactions. However, the Commission has determined that the

¹ The proposed order requires the respondents to maintain the assets pending divestiture.

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divestiture of Kadian to the generic drug manufacturer Actavis is an appropriate remedy in this case because (1) with only a little over a year left to Kadian's patent life, further innovation of the Kadian product is unlikely, and (2) the proposed remedy not only prevents the loss of price competition between Avinza and Kadian which was the competitive concern identified in our investigation, but also makes possible early introduction of a generic product – with lower pricing for consumers – before the patent expires.

In the event that the Commission determines that Actavis is not an acceptable acquirer, the proposed order requires the parties to unwind the sale and then divest Kadian within six months of the date the order becomes final to another Commission-approved acquirer. The proposed order also provides that, in the event that the Commission determines that the manner of the divestiture is not acceptable, that the Commission may appoint a divestiture trustee to effectuate such modifications as are necessary to satisfy the requirements of the order. Additionally, the proposed order allows the Commission to appoint an Interim Monitor to ensure the respondents' compliance with the terms of the order.

The purpose of this analysis is to facilitate public comment on the proposed Consent Agreement, and it is not intended to constitute an official interpretation of the proposed Consent Agreement or to modify its terms in any way.

Complaint

IN THE MATTER OF

**TEVA PHARMACEUTICAL INDUSTRIES LTD.
AND
BARR PHARMACEUTICALS, INC.****CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS
OF SEC. 7 OF THE CLAYTON ACT AND SEC. 5 OF THE FEDERAL
TRADE COMMISSION ACT***Docket C-4242; File No. 081 0224**Complaint, December 18, 2008 – Decision, February 9, 2009*

This consent order addresses the acquisition of Barr Pharmaceuticals, Inc., by Teva Pharmaceutical Industries Ltd. Both companies are engaged in the research, development, manufacture, and sale of generic pharmaceutical products. The acquisition would lessen competition in the U.S. markets for the manufacture and sale of a number of generic drugs. The order requires the respondents to assign and divest to Watson Pharmaceuticals Teva's rights and assets necessary to manufacture and market these generic products: chlorzoxazone tablets, deferoxamine injection, fluoxetine weekly capsules, carboplatin injection, and metronidazole tablets. The order requires the respondents to assign and divest to Watson all of Barr's rights and assets necessary to manufacture and market these generic products: metoclopramide hydrochloride (HCl) tablets, cyclosporine liquid, cyclosporine capsules, desmopressin acetate tablets, epoprostenol sodium injection, flutamide capsules, glipizide/metformin HCl tablets, mirtazapine orally disintegrating tablets, tamoxifen citrate tablets, and tetracycline HCl capsules. The order requires the respondents to divest Teva's rights and assets necessary to manufacture and market generic trazodone HCl tablets and thirteen oral contraceptive products to Qualitest Pharmaceuticals. If the Commission determines that either Watson or Qualitest is not an acceptable acquirer, the assets must be divested to another Commission-approved acquirer. Teva and Barr must provide transitional services to enable the acquirers to obtain all of the necessary approvals from the U.S. Food and Drug Administration. These transitional services include technology transfer assistance to manufacture the products in substantially the same manner and quality employed or achieved by Teva or Barr. The order also requires Teva and Barr to file reports with the Commission periodically until the divestitures and transfers are accomplished.