

FEDERAL TRADE COMMISSION DECISIONS

**FINDINGS, OPINIONS, AND ORDERS
JANUARY 1, 2009, TO JUNE 30, 2009**

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MEMBERS OF THE FEDERAL TRADE COMMISSION

DURING THE PERIOD JANUARY 1, 2009, TO JUNE 30, 2009

WILLIAM E. KOVACIC, *Chairman*

Took oath of office January 4, 2006.

PAMELA JONES HARBOUR, *Commissioner*

Took oath of office August 4, 2003.

JON LEIBOWITZ, *Commissioner*

Took oath of office September 3, 2004.

J. THOMAS ROSCH, *Commissioner*

Took oath of office January 5, 2006.

DONALD S. CLARK, *Secretary*

Appointed August 28, 1988.

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FEDERAL TRADE COMMISSION DECISIONS

FINDINGS, OPINIONS, AND ORDERS
JANUARY 1, 2009, TO JUNE 30, 2009

IN THE MATTER OF

INVERNESS MEDICAL INNOVATIONS, INC.

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS
OF SEC. 5 OF THE FEDERAL TRADE COMMISSION ACT

*Docket C-4244; File No. 061 0123
Complaint, January 23, 2009 – Decision, January 23, 2009*

This consent order addresses charges that Inverness Medical Innovations, Inc., engaged in unlawful maintenance of its monopoly power in the research, development, manufacture, and sale of consumer pregnancy tests through its acquisition of certain assets of ACON Laboratories, Inc., a rival manufacturer of consumer pregnancy tests. The order prevents Inverness from interfering with the digital consumer pregnancy test product joint venture between ACON and Church & Dwight Co., Inc., and enables ACON and Church & Dwight to maintain their competitive viability after the joint venture ends. The order requires that Inverness disclaim any ownership rights on intellectual property developed during the joint venture. The order further requires that Inverness not interfere with ACON's transfer or licensing of digital consumer pregnancy test technology to Church & Dwight, and that Inverness not interfere with ACON's ability to manufacture digital consumer pregnancy tests for Church & Dwight during their collaboration. In addition, the order requires Inverness to divest, to Aemoh Products, LLC, a fully paid perpetual exclusive sub-license to Inverness' water-soluble dye intellectual property. It also requires Inverness not to assert intellectual property infringement claims against certain lateral flow products that use Inverness' water-soluble dye technology. These provisions, among others, will give Aemoh the ability to complete the commercialization of water-soluble dye based consumer pregnancy tests. The order provides that Inverness shall notify the Commission before acquiring any ownership interest in any entity engaged in the manufacture, distribution, and marketing of consumer pregnancy tests for sale in the United States; and before any proposed dissolution; any proposed acquisition, merger or consolidation; or any other change that might affect compliance obligations. The order also provides that the Commission may appoint an Interim Monitor to ensure that Inverness complies with all of its obligations and performs all of its responsibilities as required by the order. Inverness is also required to file periodic reports with the Commission detailing its compliance.

Complaint

Participants

For the *Commission*: *Renee Henning, Tom Mays, Karen Mills, Michael R. Moiseyev, Morris Morke, James Southworth, Brian Telpner, Steven Tenn, Lore Unt, David von Nirschl, and Stephanie Wilkinson.*

For the *Respondent*: *Paul B. Hewitt, Daniel F. McInnis, and Anthony Swisher, Akin, Gump, Strauss, Hauer & Feld LLP.*

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act, as amended, 15 U.S.C. § 41 et seq., and by virtue of the authority vested in it by said Act, the Federal Trade Commission (“Commission”), having reason to believe that respondent Inverness Medical Innovations, Inc. (“Inverness”) has violated Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, hereby issues this Complaint, stating its charges as follows:

1. This action challenges Inverness’s unlawful maintenance of its monopoly power in the market for the research, development, manufacture, and sale of consumer pregnancy tests through its acquisition of certain assets of ACON Laboratories, Inc. (“ACON”), a rival manufacturer of consumer pregnancy tests. Inverness’s conduct threatened to stifle future competition from digital consumer pregnancy test products and from a potentially competing consumer pregnancy test based on water-soluble dye technology.

RESPONDENT

2. Inverness is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware, with its headquarters address at 51 Sawyer Road, Suite 200, Waltham, Massachusetts 02453.

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3. Inverness is the leader in the research, development, manufacture, and sale of consumer pregnancy tests. Inverness manufactures and sells consumer pregnancy tests under several brand names, including Clearblue, Accu-Clear, and FactPlus. Inverness is also the leader in the research, development, manufacture, and sale of digital consumer pregnancy tests.

4. Inverness is, and at all relevant times has been, a person, partnership, or corporation within the meaning of Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45, and at all times relevant herein, Inverness has been, and is now, engaged in commerce as “commerce” is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

INDUSTRY BACKGROUND

5. Consumer pregnancy tests rely on immunoassay-based “lateral flow” technology, which tests a urine sample for the presence of a hormone (called human chorionic gonadotropin (“hCG”)) produced by pregnant women.

6. Consumer pregnancy tests typically include a test strip that contains an agent that reacts when exposed to any hCG present in the sample. The agent itself is bound to a colored label, typically a small gold or latex particle, in a complex called a “conjugate.” If hCG is present, the agent in the conjugate binds to the hCG, and a second antibody or antigen immobilized in the test strip then captures the complex. The test strip is imbedded inside a plastic handheld stick device that has an indicator window. If the test is positive, a colored line develops within the indicator window.

7. There are no viable substitutes for consumer pregnancy tests based on lateral flow technology. Lateral flow pregnancy tests are more accurate, easier to use, and less costly than other pregnancy tests, which resemble laboratory test kits.

8. “Digital” consumer pregnancy tests use and improve upon lateral flow technology. Rather than a colored line indicator, a

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digital pregnancy test indicates results through a digital display of words, such as “PREGNANT” or “NOT PREGNANT.”

9. Digital consumer pregnancy tests have been a growing segment of the consumer pregnancy test market.

10. Digital consumer pregnancy tests are more difficult to develop and manufacture than standard consumer pregnancy tests. They require more extensive know-how and more exacting manufacturing tolerances than analog tests.

RELEVANT MARKET & MARKET STRUCTURE

11. A relevant product market is the research, development, manufacture, and sale of consumer pregnancy tests. A relevant geographic market is the United States.

12. Intellectual property, know-how, and advertising are barriers to entry into the consumer pregnancy test market.

13. Inverness is the dominant player in the market for consumer pregnancy tests. Inverness maintains an approximately 70% share of the U.S. consumer pregnancy test market.

14. Inverness also is the dominant player in the digital consumer pregnancy test segment. At the time of the acquisition, Inverness also was one of only three independent firms manufacturing or marketing digital consumer pregnancy tests. The other firms exited the market in 2006.

COMPETITION BETWEEN INVERNESS AND ACON

15. ACON Laboratories, Inc. (“ACON”) developed, manufactured, and sold rapid diagnostic tests in competition with Inverness.

16. Before the acquisition, ACON was developing digital consumer pregnancy tests in a joint venture with Church & Dwight

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Co., Inc. (“Church & Dwight”), Inverness’s leading competitor. The collaboration with Church & Dwight envisioned that ACON would manufacture and supply the resulting digital consumer pregnancy test products on Church & Dwight’s behalf.

17. Before the acquisition, ACON had invested in the development of a new lateral flow consumer pregnancy test, which used a water-soluble dye as the label in the conjugate on the test strip. ACON had completed prototypes of the product, and supplied sample quantities to U.S. customers.

18. ACON also was one of the only, if not the only, firm involved in the development of consumer pregnancy tests that used water-soluble dye technology.

INVERNESS’S ANTI-COMPETITIVE CONDUCT AND ITS EFFECTS

19. In 2006, Inverness acquired several assets from ACON, including its water-soluble dye product and assets relating to its digital consumer pregnancy test joint venture with Church & Dwight.

20. Inverness’s 2006 acquisition made a significant contribution to maintaining its power in this market. As outlined below, the acquisition of the ACON assets enabled Inverness to maintain its monopoly power by jeopardizing the development of consumer pregnancy test products that could pose future competition to Inverness.

21. At the time of the acquisition, Inverness’s actions reasonably appeared capable of making a significant contribution to maintaining its monopoly power by restricting competition from new consumer pregnancy tests.

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DIGITAL CONSUMER PREGNANCY TESTS

22. Inverness's acquisition of the ACON assets interfered with ACON's ability and incentive to develop and manufacture digital consumer pregnancy tests. Among other things:

- a. Inverness imposed a substantial covenant not to compete on ACON, which limited the term and scope of ACON's digital joint venture with Church & Dwight;
- b. Inverness required ACON to remit to Inverness any profits from its digital consumer pregnancy test venture with Church & Dwight; and
- c. Inverness acquired certain rights to intellectual property developed by ACON and Church & Dwight during their joint venture.

23. Inverness's acquisition of the ACON assets protected Inverness's monopoly power in consumer pregnancy tests by weakening future competition from digital consumer pregnancy test products. Inverness's acquisition of the ACON assets impaired ACON's ability and incentive to serve as an independent developer and supplier of digital consumer pregnancy tests. Inverness's acquisition of the ACON assets also hampered Church & Dwight's ability and incentive to develop and introduce competing digital consumer pregnancy test products.

**WATER-SOLUBLE DYE
CONSUMER PREGNANCY TESTS**

24. Inverness's acquisition of the ACON assets eliminated competition from ACON's water-soluble dye consumer pregnancy test product.

25. After Inverness acquired the rights to ACON's water-soluble dye consumer pregnancy test product, Inverness made no use of the test and ceased development and marketing efforts for it.

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26. Inverness's acquisition protected Inverness's monopoly power in consumer pregnancy tests by weakening potential competition from competing water-soluble dye consumer pregnancy tests.

VIOLATIONS ALLEGED

27. The acts and practices of Inverness, as described in Paragraphs 1-26 above, incorporated herein by reference, constitute unfair methods of competition in or affecting commerce in violation of Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45.

28. The conduct at issue in this action caused or threatens to cause substantial harm to competition and to consumers, absent the issuance of appropriate relief in the manner set forth below.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this twenty-third day of January, 2009, issues its complaint against Inverness.

By the Commission, Commissioner Harbour recused.

DECISION AND ORDER

The Federal Trade Commission ("Commission"), having initiated an investigation of certain acts and practices of Respondent Inverness Medical Innovations, Inc., hereinafter referred to as "Respondent," and Respondent having been furnished thereafter with a copy of a draft of Complaint which the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondent with violations of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

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Respondent, its attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Order (“Consent Agreement”), containing an admission by Respondent of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondent 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 Respondent has violated the said Act, 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 Inverness Medical Innovations, Inc. is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its headquarters address at 51 Sawyer Road, Suite 200, Waltham, Massachusetts 02453.

2. The Commission has jurisdiction of the subject matter of this proceeding and of Respondent, and the proceeding is in the public interest.

Decision and Order

ORDER**I.**

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

- A. “Inverness” or “Respondent” means Inverness Medical Innovations, Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Inverness Medical Innovations, Inc., and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- B. “Commission” means the Federal Trade Commission.
- C. “ACON” means ACON Laboratories, Inc., a corporation organized, existing and doing business under and by virtue of the laws of the State of California, with its headquarters address located at 4108 Sorrento Valley Boulevard, San Diego, California 92121. The term “ACON” includes ACON Laboratories, Inc., its parent, directors, officers, employees, agents, representatives, successors and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by ACON Laboratories, Inc., and the respective directors, officers, employees, agents, representatives, predecessors, successors, and assigns of each.
- D. “Acquisition” means Respondent Inverness’s acquisition of certain assets and rights of ACON pursuant to an Acquisition Agreement by and among Inverness Medical Innovations, Inc., ACON Laboratories, Inc., Azure Institute, Inc., LBI, Inc., Oakville Hong Kong Co., Ltd., ACON Biotech (Hangzhou) Co., Ltd., and Karsson Overseas, Ltd., dated as of February 24, 2006, and includes certain “Noncompetition Agreements” attached as exhibits thereto.

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- E. “Aemoh” means Aemoh Products, LLC, a limited liability company, organized, existing, and doing business under and by virtue of the laws of the State of Massachusetts, with its headquarters address at 12 Hopewell Farm Road, South Natick, MA 01760.
- F. “Agency(ies)” means any government 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, without limitation, the United States Food and Drug Administration (“FDA”).
- G. “Assays” means any qualitative or quantitative analysis of a substance to determine its components or characteristics, the results of such analysis, and all information necessary to replicate such analysis, including without limitation, the following: all data, observations, and records relating to the analysis, the methodologies and procedures used in such analysis, all experiments performed, all information related to the development and qualification of such an analysis, and the identities of the person or persons responsible for such development and qualification of such an analysis.
- H. “Bayer” means Bayer Healthcare LLC, a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware, with its headquarters address at 511 Benedict Avenue, Tarrytown, New York 10591-5097. The term “Bayer” includes Bayer Healthcare LLC, its parent, directors, officers, employees, agents, representatives, successors and assigns; and its joint ventures, subsidiaries (including Metrika, Inc.), divisions, groups and affiliates in each case controlled by Bayer Healthcare LLC, and the respective directors, officers, employees, agents, representatives, predecessors, successors, and assigns of each.

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- I. “Church & Dwight” means Church & Dwight Co., Inc., a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware, with its headquarters address at 469 N. Harrison Street, Princeton, New Jersey 08543-5297.
- J. “Church & Dwight/ACON R&D Agreement” shall mean the “Research and Development Agreement” between ACON and Church & Dwight (dated April 27, 2005), as amended.
- K. “Church & Dwight/ACON Supply Agreement” shall mean the “Supply Agreement” between ACON and Church & Dwight (dated June 23, 2006), as amended.
- L. “Confidential Business Information” means all information owned by, or in the possession or control of, Respondent that is not in the public domain and that is directly related to the research, Development, manufacture, marketing, commercialization, importation, exportation, cost, supply, sales, sales support or use of the Digital Consumer Pregnancy Test Products and was created, generated, or Developed by either ACON or Church & Dwight under the Church & Dwight/ACON R&D Agreement or the Church & Dwight/ACON Supply Agreement; *provided, however*, that the restrictions contained in this Order regarding the use, conveyance, provision or disclosure of “Confidential Business Information” shall not apply to the following:
 - 1. information that subsequently falls within the public domain through no violation of this Order or breach of confidentiality or non-disclosure agreement with respect to such information by Respondent;
 - 2. information related to the Digital Consumer Pregnancy Test Products that Respondent can demonstrate it obtained without the assistance of ACON prior to the Acquisition; and

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3. information that is required by Law to be publicly disclosed.
- M. “Consumer Pregnancy Test(s)” means any product marketed, or designed to be marketed, to an end user in the over-the-counter market that uses a lateral flow strip to detect the presence or absence of a pregnancy-indicating hormone in a urine sample.
- N. “Contract Manufacture” means the testing and manufacture of a Digital Consumer Pregnancy Test Product to be supplied by Respondent, ACON, or a Designee to Church & Dwight.
- O. “Designee” means any entity other than Respondent or ACON that will manufacture a Digital Consumer Pregnancy Test Product on behalf of Church & Dwight.
- P. “Development” means all product development activities, 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 tests or trials for 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 government price or reimbursement approvals); and regulatory affairs related to the foregoing. “Develop” means to engage in Development.
- Q. “Digital Consumer Pregnancy Test Product(s)” means the Consumer Pregnancy Test products that are the subject of Appendix 1 of Church & Dwight/ACON R&D Agreement and/or Attachment A-1 of the Church & Dwight/ACON Supply Agreement.

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- R. “Digital Consumer Pregnancy Test Product Assets” means all rights, title and interest in and to the following assets:
1. all Digital Consumer Pregnancy Test Product Intellectual Property;
 2. all Product Approvals directly related to the Digital Consumer Pregnancy Test Products;
 3. all Product Manufacturing Technology that was created, generated, or Developed by ACON and/or Church & Dwight under the Church & Dwight/ACON R&D Agreement or the Church & Dwight/ACON Supply Agreement;
 4. all Product Development Reports directly related to the Digital Consumer Pregnancy Test Products;
 5. all Trademarks used prior to, up to, and including, the Order Date by Church and Dwight and/or ACON to market or sell the Digital Consumer Pregnancy Test Products;
 6. all options acquired by Respondent from ACON to acquire or exercise rights in the Digital Consumer Pregnancy Test Products;
 7. all contingent interests or claims acquired by Respondent from ACON in the Digital Consumer Pregnancy Test Products; and
 8. all of ACON’s books, records, and files directly related to the foregoing;
 9. *Provided, however,* that the Digital Consumer Pregnancy Test Product Assets:

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- a. shall not include any and all technology, intellectual property or intellectual property right that was not created, generated, or Developed by ACON and/or Church & Dwight under the Church & Dwight/ACON R&D Agreement or the Church & Dwight/ACON Supply Agreement including the Reserved Patent Rights or the Metrika Patents;
 - b. shall not include administrative, financial, and accounting records;
 - c. shall include copies or relevant excerpts of documents and materials containing information relating to the Digital Consumer Pregnancy Test Product Assets in cases in which the documents or other materials included in the relevant assets to be provided to Church & Dwight contain information: (1) that relates both to any Digital Consumer Pregnancy Test Product and to other products or businesses of ACON or Respondent and cannot be segregated in a manner that preserves the usefulness of the information as it relates to such Digital Consumer Pregnancy Test Product; or (2) for which ACON or Respondent has a legal obligation to retain the original copies; and
 - d. shall include access to original documents under circumstances where copies of documents are insufficient for evidentiary or regulatory purposes.
- S. “Digital Consumer Pregnancy Test Product Core Employees” means the employees listed on Appendix A attached hereto.
- T. “Digital Consumer Pregnancy Test Product Intellectual Property” means all of the following intellectual property to the extent owned, controlled, held, or otherwise possessed by Respondent:

Decision and Order

1. any and all Patents that were or are filed by either Church & Dwight or ACON, after April 27, 2005, do not claim priority to a patent application filed before April 27, 2005 and claim an invention conceived, created, generated, or Developed under the Church & Dwight/ACON R&D Agreement;
 2. any and all Other Intellectual Property, including the rights to obtain, file, and prosecute applications for patents and copyrights and registrations thereof, that was, or the subject matter of which was, created, generated, or Developed, by Church & Dwight and/or ACON under the Church & Dwight/ACON R&D Agreement or Church & Dwight/ACON Supply Agreement; and
 3. rights to sue and recover damages or obtain injunctive relief for infringement, dilution, misappropriation, violation, or breach of any of the foregoing.
- U. “Government Entity” means any Federal, state, local or non-U.S. government, or any court, legislature, government agency, or government commission, or any judicial or regulatory authority of any government.
- V. “Interim Monitor” means any monitor appointed pursuant to Paragraph V of this Order.
- W. “Law” means all laws, statutes, rules, regulations, ordinances, and other pronouncements by any Government Entity having the effect of law.
- X. “May-Davis Patents” means any United States Patent claiming priority from British patent application numbers GB 8725457 and GB 8709873 (May), or GB 8903627 (Davis).

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- Y. “Metrika Patents” means the following United States Patents:
1. US Patent No. 5,580,794; and
 2. US Patent No. 5,837,546.
- Z. “Order Date” means the date on which this Order becomes final.
- AA. “Other Intellectual Property” means trade secrets, copyrights (and right to obtain, file and prosecute copyrights and registrations thereof), know-how, techniques, data, inventions, practices, methods, and other confidential or proprietary technical, business, research, Development and other information.
- BB. “Ownership Interest” means any and all rights, present or contingent, of Respondent to hold any voting or nonvoting stock, share capital, assets, equity or other interests or beneficial ownership in a Person.
- CC. “Patents” means all patents, patent applications, including provisional patent applications, statutory invention registrations, and inventor’s certificates, and rights to obtain, file and prosecute applications for patents, in each case existing as of the Order Date (*except* where this Order specifies a different date or time), and includes all reissues, divisions, continuations, continuations-in-part, supplementary protection certificates, extensions and reexaminations thereof, all inventions disclosed therein, and all rights therein provided by international treaties and conventions.
- DD. “Person” means any individual, partnership, joint venture, firm, corporation, association, trust, unincorporated organization, joint venture, or other business or Government

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Entity, and any subsidiaries, divisions, groups or affiliates thereof.

- EE. “Premarket Approval(s)” means the applications for a product filed or to be filed with the FDA pursuant to 21 C.F.R. § 814, and all supplements, amendments, and revisions thereto, any preparatory work, drafts and data necessary for the preparation thereof, all information submitted with or incorporated by reference, and all correspondence between Respondent and the FDA related thereto. The term “Premarket Approval(s)” includes all orders of approval and all reports and documents submitted to the FDA under postapproval requirements.
- FF. “Premarket Notification(s)” means a premarketing submission for a product filed or to be filed with the FDA pursuant to 21 C.F.R. § 807, and all supplements, amendments, and revisions thereto, any preparatory work, drafts and data necessary for the preparation thereof, all information submitted with or incorporated by reference, and all correspondence between Respondent and the FDA related thereto, to demonstrate that a device to be marketed is as safe and effective as, or substantially equivalent to, a legally marketed device that is not subject to Premarket Approval. The term “Premarket Notification(s)” includes all notices of registration and all reports and documents required to be submitted to the FDA related to the marketing of such product.
- GG. “Product Approval(s)” means any approvals, 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, sale, storage or transport of the product within the United States of America, and includes, without limitation, all approvals, registrations, licenses or

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authorizations granted in connection with any Premarket Approval and/or Premarket Notification.

HH. “Product Development Reports” means all of the following documents to the extent directly related to the Digital Consumer Pregnancy Test Products and Water-Soluble Consumer Pregnancy Test Products:

1. inventory of research and development records, research history, research efforts, research notebooks, research reports, technical service reports, testing methods, invention disclosures, and know how;
2. all correspondence to or from the FDA related to such product(s);
3. annual and periodic reports;
4. approved product labeling;
5. currently used product package inserts;
6. customer circulars and information;
7. summary of product complaints from customers; and
8. product recall reports.

II. “Product Manufacturing Technology” means, to the extent owned, controlled, held, or otherwise possessed by Respondent, any and all of the following:

1. all technology, trade secrets, know-how, and proprietary information (whether patented, patentable or otherwise) directly related to the manufacture of the specified products including, without limitation, the following: all techniques and specifications, quality control processes, analytical methods for process controls, product designs, plans, trade secrets, ideas, concepts, manufacturing,

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engineering, and other manuals and drawings, standard operating procedures, flow diagrams, chemical, safety, quality assurance, quality control, research records, clinical data, compositions, annual product reviews, regulatory communications, control history, current and historical information associated with the Product Approvals, and labeling and all other information related to the manufacturing process;

2. the identity of all suppliers and subcontractors;
3. all Assays; and
4. all Product Development Reports.

JJ. “Reserved Patent Rights” means, collectively, any and all Respondent’s rights in, to or under any and all patents and patent applications claiming the benefit of or priority to (i) U.S. Patent Application Serial No. 07/211,582, including, without limitation, U.S. Patent Nos. 5,714,389; 5,989,921; and 6,485,982; (ii) one or more of GB Patent Application Serial Nos. 8709873 and 8725457, including, without limitation, U.S. Patent Nos. 5,602,040; 5,622,871; 5,656,503; 6,187,598; 6,228,660; 6,818,455; and 7,109,042; (iii) GB Patent Application Serial No. 8903627, and including, without limitation, U.S. Patent Nos. 6,352,862; 7,238,537; 7,384,796; and 7,407,813; (iv) U.S. Patent Application Serial No. 07/072,459, including, without limitation, U.S. Patent Nos. 5,120,643; 5,578,577; and 6,534,320; and (v) any and all continuations, divisionals, reissues, reexaminations, and foreign counterparts or equivalents of any and all of the foregoing.

KK. “Technology Transfer Standards” means requirements and standards sufficient to ensure that the information and assets required to be delivered pursuant to this Order are delivered in an organized, comprehensive, complete, useful, timely (*i.e.*, ensuring no unreasonable delays in transmission), and

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meaningful manner. Such standards and requirements may include, *inter alia*,

- a. designating employees knowledgeable about the Product Manufacturing Technology and intellectual property included in either the Digital Consumer Pregnancy Test Assets or the Water-Soluble Consumer Pregnancy Test Assets, as applicable, who will be responsible for communicating directly with any Person designated to receive such information and assets, including the Interim Monitor (if one has been appointed), for the purpose of effecting such delivery;
- b. preparing technology transfer protocols and transfer acceptance criteria for both the processes and analytical methods related to the specified product(s) that are acceptable to any Person designated to receive such information and assets;
- c. preparing and implementing a detailed technological transfer plan that contains, *inter alia*, the transfer of all relevant information, all appropriate documentation, all other materials, and projected time lines for the delivery of all such Product Manufacturing Technology and all such intellectual property to any Person designated to receive such information and assets; and
- d. providing, in a timely manner, assistance and advice to enable any Person designated to receive such information and assets (or its Designee) to:
 - (1) manufacture the specified product(s) in the quality and quantities achieved by ACON;
 - (2) obtain any Product Approvals necessary for any Person designated to receive such information

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and assets to manufacture, distribute, market, and sell the specified product(s) in commercial quantities; and

- (3) receive, integrate, and use all such Product Manufacturing Technology and all such intellectual property related to the specified product(s).

LL. “Third Party(ies)” means any private entity other than the following: (1) Respondent; (2) ACON; (3) Church & Dwight or (4) Aemoh.

MM. “Trademark(s)” means all United States 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.

NN. “Water-Soluble Consumer Pregnancy Test Product(s)” means the lateral flow immunoassay Consumer Pregnancy Tests based on the use of water-soluble dyes Developed or under Development by ACON prior to February 24, 2006 for sale in the United States and any improvement to such tests. The term “Water-Soluble Consumer Pregnancy Test Product(s)” shall not include lateral flow immunoassay pregnancy tests that use particulate labels, *e.g.*, colloidal gold or latex particles.

OO. “Water-Soluble Consumer Pregnancy Test Product ACON Patents” means the following United States Patents:

1. US Patent No. 6627460; and
2. US Patent No. 5543332.

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PP. “Water-Soluble Consumer Pregnancy Test Product Assets” means all Respondent’s rights, title in and interest in and to the following assets related directly to the Water-Soluble Consumer Pregnancy Test Products:

1. The sublicense described in Paragraph III.A.1 of this Order;
2. all Product Approvals directly related to the Water-Soluble Consumer Pregnancy Test Products;
3. all Product Manufacturing Technology that was created, generated, or Developed by ACON for the Water-Soluble Consumer Pregnancy Test Products;
4. copies of all Product Development Reports directly related to the Water-Soluble Consumer Pregnancy Test Products; and
5. copies of all of Respondent books, records, and files directly related to the foregoing;
6. *Provided, however,* that the Water-Soluble Consumer Pregnancy Test Product Assets:
 - a. shall not include the administrative, financial, and accounting records;
 - b. shall include copies or relevant excerpts of documents and materials containing information relating to the Water-Soluble Consumer Pregnancy Test Product Assets in cases in which the documents or other materials included in the relevant assets to be provided to Aemoh contain information: (1) that relates both to any Water-Soluble Consumer Pregnancy Test Product and to other products or businesses of Respondent or ACON and cannot be segregated in a manner that preserves the usefulness

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of the information as it relates to such Water-Soluble Consumer Pregnancy Test Product; or (2) for which Respondent or ACON has a legal obligation to retain the original copies; and

- c. shall include access to original documents under circumstances where copies of documents are insufficient for evidentiary or regulatory purposes.

QQ. “Water-Soluble Consumer Pregnancy Test Product Core Employees” means the employees listed in Appendix B attached hereto.

RR. “Water-Soluble Consumer Pregnancy Test Product Intellectual Property” means all of the following intellectual property to the extent owned, controlled, held, or otherwise possessed by Respondent:

1. any and all Water-Soluble Consumer Pregnancy Test Product ACON Patents and Patents that ACON filed that contain subject matter that relates directly to the Water-Soluble Consumer Pregnancy Test Product(s);
2. any and all Other Intellectual Property, including the rights to obtain, file, and prosecute applications for patents and copyrights and registrations thereof, that was, or the subject matter of which was, created, generated, or Developed, by ACON for the Water-Soluble Consumer Pregnancy Test Product(s); and
3. rights to sue and recover damages or obtain injunctive relief for infringement, dilution, misappropriation, violation, or breach of any of the foregoing.

SS. “Water-Soluble Consumer Pregnancy Test Product Releasee(s)” means Aemoh or any entity controlled by or under common control with Aemoh (“affiliated entities”), or

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any licensees, sublicensees, manufacturers, suppliers, distributors, or customers of Aemoh or its affiliated entities.

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

- A. Not later than ten (10) days after the Order Date, Respondent shall:
1. disclaim in writing any and all rights, title and interest in or to the Digital Consumer Pregnancy Test Product Assets in favor of Church & Dwight;
 2. to the extent owned or controlled, directly or indirectly, by or otherwise in the possession of Respondent, and at the expense of Respondent, transfer and deliver all Digital Consumer Pregnancy Test Product Assets to Church & Dwight;
 3. amend, or provide written clarification of, any contract(s) or agreement(s) between the Respondent and ACON, and enter into such other contract(s) or agreement(s) as may be necessary with ACON, in order to:
 - a. permit ACON fully to transfer and deliver all of the Digital Consumer Pregnancy Test Product Assets to Church & Dwight to the extent such assets are owned or controlled, directly or indirectly, by ACON, or are otherwise in the possession of ACON, in a manner consistent with the Technology Transfer Standards;
 - b. remove any prohibitions or impediments that would prevent ACON from transferring and delivering such Digital Consumer Pregnancy Test Product Assets to Church & Dwight;

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- c. permit, and provide all rights within Respondent's control necessary to allow, ACON to perform the Contract Manufacture of Digital Consumer Pregnancy Test Products on behalf of Church & Dwight on an uninterrupted basis for a period of time continuing at least until December 22, 2010;
- d. remove any prohibitions or impediments that would prevent ACON from performing the Contract Manufacture of Digital Consumer Pregnancy Test Products on behalf of Church & Dwight for a period of time continuing at least until December 22, 2010;
- e. remove any financial disincentives to the extent that such financial disincentives would prevent ACON from making and retaining a profit on any Contract Manufacture of Digital Consumer Pregnancy Test Products on behalf of Church & Dwight for a period continuing at least until December 22, 2010;
- f. permit, and provide all rights within Respondent's control necessary to allow, ACON to maintain the manufacturing and related testing, storage, and shipping facilities necessary to manufacture the Digital Consumer Pregnancy Test Products in finished form suitable for commercial sale for a period of time continuing at least until December 22, 2010; *provided however*, this requirement shall end if Church & Dwight exercises any rights it may have or otherwise determines to discontinue purchasing Digital Consumer Pregnancy Test Products from ACON at an earlier date;
- g. to the extent the foregoing ACON manufacturing and related testing, storage, and shipping facilities are subject to any rights held by the Respondent, permit Church & Dwight to continue purchasing Digital Consumer Pregnancy Test Products for a period of

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time continuing at least until December 22, 2010, or to discontinue purchasing Digital Consumer Product Pregnancy Test Products, from such facilities, without penalty, upon Church & Dwight providing agreed-to or otherwise reasonable notification to ACON or Respondent; and

- h. permit, and provide all rights within Respondent's control necessary to allow, ACON to provide all records that relate to the manufacture of the Digital Consumer Pregnancy Test Products by ACON on behalf of Church & Dwight that are generated or created after the Order Date, as such records are requested by Church & Dwight or the Interim Monitor (if one has been appointed);

provided, however, Paragraph II shall not require Respondent to transfer, disclaim, license, grant, or not assert, any technology, intellectual property or intellectual property right that was not created, generated, or Developed by ACON and/or Church & Dwight under the Church & Dwight/ACON R&D Agreement or the Church & Dwight/ACON Supply Agreement, including the Reserved Patent Rights.

B. Respondent shall:

1. cooperate with, and take no action that interferes with or impedes:
 - a. ACON's transfer and delivery of such Digital Consumer Pregnancy Test Product Assets to Church & Dwight in a manner consistent with the Technology Transfer Standards; or
 - b. ACON's performance of the Contract Manufacture of Digital Consumer Pregnancy Test Products on

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behalf of Church & Dwight during the period of time continuing until December 22, 2010; and

2. not seek to enforce, directly or indirectly, any of Respondent's rights under any contract or agreement with ACON that would interfere with or impede ACON's ability to transfer and deliver such Digital Consumer Pregnancy Test Product Assets to Church & Dwight, or that would interfere with or impede ACON's ability to Contract Manufacture Digital Consumer Pregnancy Test Products on behalf of Church & Dwight for a period of time continuing at least until December 22, 2010;
3. not enforce any agreement between Respondent and ACON, a Third Party, or Church & Dwight against the applicable counterparty to the extent that such agreement may limit or otherwise impair the ability of Church & Dwight to acquire the Digital Consumer Pregnancy Test Product Intellectual Property or the Product Manufacturing Technology included in the Digital Consumer Pregnancy Test Product Assets from any Third Party. Such agreements include, but are not limited to, agreements with respect to the disclosure of Confidential Business Information directly related to such Product Manufacturing Technology; and
4. not later than ten (10) days after the Order Date, grant a release to each Third Party that is subject to any agreement described in Paragraph II.B.3 allowing such Third Party to provide all such Digital Consumer Pregnancy Test Product Intellectual Property and/or, all such Product Manufacturing Technology included in the Digital Consumer Pregnancy Test Product Assets to Church & Dwight. Within five (5) days of the execution of each such release, Respondent shall provide a copy of the release to Church & Dwight.

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- C. For a period of up to twelve (12) months from the Order Date, Respondent shall not interfere with the hiring or employing by Church & Dwight of the Digital Consumer Pregnancy Test Product Core Employees, and shall remove any impediments within the control of Respondent that may deter these employees from accepting employment with Church & Dwight, including, but not limited to, any noncompete or nondisclosure provision of employment or other contracts with Respondent that would affect the ability or incentive of those individuals to be employed by Church & Dwight. In addition, Respondent shall not make any counteroffer to such a Digital Consumer Pregnancy Test Product Core Employee who has received a written offer of employment from Church & Dwight of which Respondent is aware.
- D. Respondent shall take no action that would interfere with or prohibit knowledgeable employees of ACON from assisting Church & Dwight to defend against, respond to, or otherwise participate in any litigation directly related to the Digital Consumer Pregnancy Test Product Intellectual Property.
- E. Respondent shall:
1. submit to Church & Dwight all Confidential Business Information;
 2. deliver such Confidential Business Information:
 - a. in good faith;
 - b. as soon as practicable, avoiding any delays in transmission of the respective information; and
 - c. in a manner that ensures its completeness and accuracy and that fully preserves its usefulness;

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3. pending complete delivery of all Confidential Business Information to Church & Dwight, provide Church & Dwight and the Interim Monitor (if one has been appointed) with access to all such Confidential Business Information, and to employees who possess or are able to locate such information, for the purpose of identifying the books, records and files related to the Digital Consumer Pregnancy Test Products that contain such Confidential Business Information and facilitating the delivery of such information in a manner consistent with this Order.

F. Respondent shall not:

1. use, directly or indirectly, any such Confidential Business Information directly related to the research, Development, manufacturing, marketing, or sale of the Digital Consumer Pregnancy Test Products other than as necessary to comply with the following:
 - a. the requirements of this Order;
 - b. obligations to Church & Dwight under the terms of any pre-existing agreement between ACON and Church & Dwight; or
 - c. applicable Law;
2. disclose or convey any Confidential Business Information, directly or indirectly, to any private-entity Person (including the Respondent) except Church & Dwight; and
3. provide, disclose or otherwise make available, directly or indirectly, any such Confidential Business Information to the employees of the Respondent associated with its business(es) related to rapid detection pregnancy tests.

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- G. Respondent shall require that each Digital Consumer Pregnancy Test Product Core Employee hired or retained by Respondent, the direct supervisor(s) of any such employee, and any other employee hired or retained by Respondent and designated by the Interim Monitor (if one has been appointed) sign a confidentiality agreement pursuant to which such employee shall be required to maintain all Confidential Business Information directly related to the Digital Consumer Pregnancy Test Products as strictly confidential, including the nondisclosure of such information to all other employees, executives or other personnel of Respondent (other than as necessary to comply with the requirements of this Order).
- H. Respondent shall assure, in any instance wherein its counsel (including in-house counsel under appropriate confidentiality arrangements) either retains unredacted copies of documents or other materials provided to Church & Dwight, or accesses original documents (under circumstances where copies of documents are insufficient or otherwise unavailable) provided to Church & Dwight, that Respondent's counsel does so only for the following purposes:
1. to assure Respondent's compliance with this Order, any Law (including, without limitation, any requirement to obtain regulatory licenses or approvals), any agreement with Church & Dwight, any data retention requirement of any applicable Government Entity, or any taxation requirements; or
 2. to defend against, respond to, or otherwise participate in any litigation, investigation, audit, process, subpoena or other proceeding relating to the transfer of the Product Manufacturing Technology directly related to the research, Development, or manufacture of the Digital Consumer Pregnancy Test Products or the Digital Consumer Pregnancy Test Product Intellectual Property

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or businesses associated with the Digital Consumer Pregnancy Test Products; *provided, however*, that Respondent may disclose such information as necessary for the purposes set forth in this Paragraph pursuant to an appropriate confidentiality order, agreement or arrangement;

provided further, however, that pursuant to this Paragraph, Respondent shall: (1) require those who view such unredacted documents or other materials to enter into confidentiality agreements with Church & Dwight (but shall not be deemed to have violated this requirement if Church & Dwight withholds such agreement unreasonably); and (2) use its best efforts to obtain a protective order to protect the confidentiality of such information during any adjudication.

- I. Not later than ten (10) days after the Order Date, Respondent shall amend any contract(s) or agreement(s) between the Respondent and Bayer (including, without limitation such contract(s) or agreement(s) with Metrika, Inc.), and enter such other contract(s) or agreement(s) as may be necessary with Bayer, in order to authorize Bayer to sell a co-exclusive license to the Metrika Patents, in the United States, to Church & Dwight (*i.e.*, a license to the Metrika Patents under which license the Respondent and Church & Dwight would be co-exclusive licensees); *provided however*, that Respondent may condition the authorization granted to Bayer upon payment to Respondent of an amount not to exceed the lesser of: (1) one-half of Respondent's original purchase price for Respondent's exclusive license to the Metrika Patents, or (2) one half of the license fee paid to Metrika by Church & Dwight.
- J. Respondent shall not enforce any agreement between Respondent and Bayer, a Third Party, or Church & Dwight against the applicable counterparty to the extent that such agreement may limit or otherwise impair the ability of Church & Dwight to acquire the above-described co-

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exclusive license to the Metrika Patents, and shall not interfere with, or take any action that might delay, such licensing of these patents to Church & Dwight.

- K. The purpose of Paragraph II of this Order is to ensure the continued use of the Digital Consumer Pregnancy Test Product Assets in the research, Development, and manufacture of the Digital Consumer Pregnancy Test Products, including variations and improvements thereto, fully independent of the Respondent, and to remedy the lessening of competition resulting from the acts and practices of the Respondent as alleged in the Commission's Complaint.

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

- A. Not later than ten (10) days after the Order Date, Respondent shall:
1. grant to Aemoh an exclusive, perpetual, fully paid-up and royalty-free sub-license in the United States, with rights to sub-license of all of Respondent's rights to the Water-Soluble Consumer Pregnancy Test Product Intellectual Property to the full extent of the fields of use for which Respondent is licensed to use such Water-Soluble Consumer Pregnancy Test Product Intellectual Property including, without limitation, the right and sub-license:
 - a. to use, make, distribute, offer for sale, promote, advertise, sell, import, or export the Water-Soluble Consumer Pregnancy Test Products; and
 - b. to have used, made, distributed, offered for sale, promoted, advertised, sold, imported, or exported the Water-Soluble Consumer Pregnancy Test Products;

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2. deliver all Water-Soluble Consumer Pregnancy Test Product Assets, or copies thereof, in the possession of or under the control of Respondent to Aemoh in a manner consistent with the Technology Transfer Standards;
 3. amend, and/or provide written clarification of, any contract(s) or agreement(s) between the Respondent and ACON, and enter such other contract(s) or agreement(s) as may be necessary with ACON, in order to permit ACON fully to deliver any and all Water-Soluble Consumer Pregnancy Test Product Assets to Aemoh to the extent such assets are owned or controlled, directly or indirectly, by ACON, or otherwise in the possession of ACON, in a manner consistent with the Technology Transfer Standards.
- B. Respondent shall take all actions within its control to secure all consents and waivers from Third Party(ies) to the extent such consents are necessary to permit Respondent and/or ACON to grant, transfer or deliver such Water-Soluble Consumer Pregnancy Test Product Assets to Aemoh, in a timely manner, and/or to permit Aemoh to research, Develop, manufacture, sale, market or distribute Water-Soluble Consumer Pregnancy Test Products;
- provided, however,* Respondent may satisfy this requirement by certifying that Aemoh has executed all such agreements directly with each of the relevant Third Parties.
- C. Respondent shall:
1. not enforce any agreement between Respondent and ACON, a Third Party, or Aemoh against the applicable counterparty to the extent that such agreement may limit or otherwise impair the ability of Aemoh to acquire the Water-Soluble Consumer Pregnancy Test Product Intellectual Property or the Product Manufacturing Technology included in the Water-Soluble Consumer

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Pregnancy Test Product Assets from any Third Party;
and

2. not later than ten (10) days after the Order Date, grant a release to each Third Party that is subject to any agreement described in Paragraph III.C.1 allowing such Third Party to provide all such Water-Soluble Consumer Pregnancy Test Product Intellectual Property and/or all such Product Manufacturing Technology included in the Water-Soluble Consumer Pregnancy Test Product Assets to Aemoh. Within five (5) days of the execution of each such release, Respondent shall provide a copy of the release to Aemoh.
 - a. For a period of up to twelve (12) months from the Order Date, Respondent shall not interfere with the hiring or employing by Aemoh of the Water-Soluble Consumer Pregnancy Test Product Core Employees, and shall remove any impediments within the control of Respondent that may deter these employees from accepting employment with Aemoh, including, but not limited to, any noncompete or nondisclosure provision of employment or other contracts with Respondent that would affect the ability or incentive of those individuals to be employed by Aemoh. In addition, Respondent shall not make any counteroffer to such a Water-Soluble Consumer Pregnancy Test Product Core Employee who has received a written offer of employment from Aemoh of which Respondent is aware.
 - b. Respondent shall take no action which would interfere with or prohibit knowledgeable employees of ACON from assisting Aemoh to defend against, respond to, or otherwise participate in any litigation directly related to the Water-Soluble Consumer Pregnancy Test Product Intellectual Property.

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- c. Respondent shall not join, file, prosecute or maintain any suit, in law or equity, against Aemoh or the Water-Soluble Soluble Consumer Pregnancy Test Product Releasee(s) for the research, Development, manufacture, use, import, export, distribution, or sale of the Water-Soluble Consumer Pregnancy Test Product(s) under the following:
3. any Patent owned or licensed by Respondent as of the Order Date that claims a method of making, using, or administering, or a composition of matter, relating to lateral flow immunoassay technology, or that claims a device relating to the use thereof, including, without limitation, the Reserved Patent Rights; or
 4. any Patent owned or licensed by Respondent at any time after the Order Date that claims any aspect of the research, Development, manufacture, use, import, export, distribution, or sale of the relevant lateral flow immunoassay technology, including, without limitation, the Reserved Patent Rights, other than Patents that claim inventions conceived by and reduced to practice after the Order Date;

if such suit would have the potential to interfere with Aemoh's freedom to practice the following: (1) the research, Development, or manufacture of the relevant Water-Soluble Consumer Pregnancy Test Product(s); or (2) the use, import, export, supply, distribution, sale, or offer for sale of the relevant Water-Soluble Consumer Pregnancy Test Product(s) within the United States. Respondent shall also covenant to Aemoh that as a condition of any assignment, transfer, or exclusive license to a Third Party of the above-described Patents, the Third Party shall agree to provide a covenant to Aemoh whereby the Third Party covenants not to sue Aemoh or the related Water-Soluble Consumer Pregnancy Test Product Releasee(s) under such Patents, if the suit would have the potential to interfere with Aemoh's freedom to

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practice the following: (1) the research, Development, or manufacture of the relevant Water-Soluble Consumer Pregnancy Test Product(s); or (2) the use, import, export, supply, distribution, sale, or offer for sale of the relevant Water-Soluble Consumer Pregnancy Test Product(s) within the United States;

provided however, this Paragraph III.F shall have no force or effect with respect to any product that uses particulate labels, *e.g.*, colloidal gold or latex particles, whether or not such product uses (i) conjugates claimed or described in the Water-Soluble Consumer Pregnancy Test Product Intellectual Property and/or (ii) Water-Soluble Consumer Pregnancy Test Product Intellectual Property created, generated, or Developed by ACON for the Water-Soluble Consumer Pregnancy Test Products.

- a. The purpose of Paragraph III of this Order is to provide for the future use of the Water-Soluble Consumer Pregnancy Test Product Assets in the research, Development, manufacture, distribution, sale and marketing of Consumer Pregnancy Tests, and to remedy the lessening of competition resulting from the acts and practices of the Respondent as alleged in the Commission's Complaint.

IV.

IT IS FURTHER ORDERED that for a period commencing on the Order Date and continuing for the term of this Order, Respondent shall not, without providing advance written notification to the Commission, acquire, through subsidiaries or otherwise, directly or indirectly (including, without limitation, acquisitions by any joint venture in which Inverness is a partner from any other partner(s) of such joint venture), the following:

- A. any Ownership Interest in any Person that is not already included within the definition of Respondent and that

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engages in manufacture, distribution, marketing of Consumer Pregnancy Tests for sale in the United States; *provided, however*, that this provision shall not apply to an acquisition of assets that are not used in the manufacture, distribution, or marketing of Consumer Pregnancy Tests for sale in the United States;

- B. any right, title, or interest under exclusive license or assignment from any Person that is not already included within the definition of Respondent under a United States Patent that: (1) includes the term “hCG” or “chorionic gonadotropin,” and (2) contains a claim directed to a lateral flow immunoassay technology for the detection of human chorionic gonadotropin (hCG); or
- C. any right, title, or interest under exclusive license or assignment from any Person that is not already included within the definition of Respondent under a United States Trademark that has been used to market, sell or distribute a Consumer Pregnancy Test of such Person in the United States at any time since February 24, 2006.

Said notifications shall be given on the Notification and Report Form set forth in the Appendix to Part 803 of Title 16 of the Code of Federal Regulations as amended (hereinafter referred to as “the Notification”), and shall be prepared and transmitted in accordance with the requirements of that part, except that no filing fee will be required for any such Notification, Notification shall be filed with the Secretary of the Commission with a copy to the Assistant Director, Bureau of Competition, Division of Compliance. Notification need not be made to the United States Department of Justice, and Notification is required only of the Respondent and not of any other party to the transaction. Respondent shall provide three (3) complete copies (with all attachments and exhibits) of the Notification at least thirty (30) days prior to consummating any such transaction (hereinafter referred to as the “first waiting period”), as follows: one (1) such copy to the Assistant Director of the Bureau of Competition, Division of Compliance, and two (2) such copies to the

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Secretary of the Commission. If, within the first waiting period, representatives of the Commission make a written request for additional information or documentary material (within the meaning of 16 C.F.R. § 803.20), Respondent shall not consummate the transaction until thirty (30) days after substantially complying with such request. Early termination of the waiting periods in this Paragraph may be requested and, where appropriate, granted by letter from the Bureau of Competition; *provided, however*, that prior notification shall not be required by this Paragraph for a transaction for which notification is required to be made, and has been made, pursuant to Section 7A of the Clayton Act, 15 U.S.C. § 18a; *provided however*, that the notification requirements of this Paragraph IV shall not apply to the acquisition by Respondent of any of the assets and rights of ACON that are or were the subject of the Acquisition.

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

- A. At any time after Respondent signs the Consent Agreement in this matter, the Commission may appoint a monitor (“Interim Monitor”) to assure that Respondent expeditiously complies with all of its obligations and performs all of its responsibilities as required by this Order.
- B. The Commission shall select the Interim Monitor, subject to the consent of Respondent, which consent shall not be unreasonably withheld. If Respondent has 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 Respondent of the identity of any proposed Interim Monitor, Respondent 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, Respondent shall execute an agreement

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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 Respondent's compliance with the relevant requirements of the Order in a manner consistent with the purposes of the Order.

- D. If an Interim Monitor is appointed, Respondent shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Interim Monitor:
1. The Interim Monitor shall have the power and authority to monitor Respondent's compliance with the transfer of the Product Manufacturing Technology and the related intellectual property, and with the 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 purposes of the Order 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 later of:
 - a. the completion of Respondent's obligations regarding the transfer of the Product Manufacturing Technology included in the Digital Consumer Pregnancy Test Assets and the Digital Consumer Pregnancy Test Product Intellectual Property to Church & Dwight (or the Designee(s) of Church & Dwight) in a manner that fully satisfies the requirements of the Order; or
 - b. the completion of Respondent's obligations regarding the transfer of the Product Manufacturing

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Technology included in the Water-Soluble Consumer Pregnancy Test Assets and the Water-Soluble Consumer Pregnancy Test Product Intellectual Property to Aemoh (or the Designee(s) of Aemoh) in a manner that fully satisfies the requirements of the Order;

provided, however, that the Commission may shorten or extend this period as may be necessary or appropriate to accomplish the purposes of the Order.

4. Subject to any demonstrated legally recognized privilege, the Interim Monitor shall have full and complete access to Respondent's personnel, books, documents, records kept in the ordinary course of business, facilities and technical information, and such other relevant information as the Interim Monitor may reasonably request, related to Respondent's compliance with its obligations under the Order, including, but not limited to, its obligations related to the relevant assets. Respondent 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 Respondent's compliance with the Order.
5. The Interim Monitor shall serve, without bond or other security, at the expense of Respondent, 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 Respondent, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Interim Monitor's duties and responsibilities.
6. Respondent shall indemnify the Interim Monitor and hold the Interim Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or

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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.

7. Respondent 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 Respondent, and any reports submitted by Church & Dwight with respect to the performance of Respondent's obligations under the Order. Within thirty (30) days from the date the Interim Monitor receives these reports, the Interim Monitor shall report in writing to the Commission concerning performance by Respondent of its obligations under the Order.
 8. Respondent 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.

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- 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.
- 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 Order.

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

- A. Within thirty (30) days after the Order Date, and every sixty (60) days thereafter until Respondent has fully complied with Paragraphs II.A., II.E., II.I. and III.A of this Order, Respondent shall submit to the Commission a verified written report setting forth in detail the manner and form in which it intends to comply, is complying, and has complied with this Order. Respondent shall submit at the same time a copy of its report concerning compliance with this Order to the Interim Monitor, if an Interim Monitor has been appointed. Respondent shall include in its 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.
- B. One (1) year after the Order Date, annually for the next nine (9) years on the anniversary of the Order Date, and at such other times as the Commission may require, Respondent shall file a verified written report with the Commission setting forth in detail the manner and form in which it is complying and has complied with this Order.

Decision and Order

VII.

IT IS FURTHER ORDERED that Respondent shall notify the Commission at least thirty (30) days prior to:

- A. any proposed dissolution of Respondent;
- B. any proposed acquisition, merger or consolidation of Respondent; or
- C. any other change in Respondent including, without limitation, assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of the Order.

VIII.

IT IS FURTHER ORDERED that, for purposes 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 Respondent made to its principal United States offices, registered office of its United States subsidiary, or its headquarters address, Respondent shall, without restraint or interference, permit any duly authorized representative of the Commission:

- A. access, during business 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 such Respondent related to compliance with this Order, which copying services shall be provided by such Respondent at the request of the authorized representative(s) of the Commission and at the expense of the Respondent; and

Decision and Order

- B. to interview officers, directors, or employees of such Respondent, who may have counsel present, regarding such matters.

IX.

IT IS FURTHER ORDERED that this Order shall terminate on the earlier of the following dates:

- A. January 23, 2019; or
- B. the date on which the last of the May-Davis Patents to expire expires.

By the Commission, Commissioner Harbour recused.

CONFIDENTIAL APPENDIX A**Digital Consumer Pregnancy Test Product Core Employees**

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

Analysis to Aid Public Comment

CONFIDENTIAL APPENDIX B

Water-Soluble Consumer Pregnancy Test Product Core Employees

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

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 Inverness Medical Innovations, Inc. (“Inverness”).

The proposed Consent Agreement is designed to remedy the harm to competition from Inverness’ conduct in acquiring certain assets of ACON Laboratories, Inc. (“ACON”). It would settle charges that Inverness engaged in an unlawful course of conduct to maintain its monopoly power in the lateral flow consumer pregnancy test market and hamper the development of future competition in that market, by restricting ACON’s digital consumer pregnancy test supply and development joint venture with Church & Dwight Co., Inc. (“Church & Dwight”), and by acquiring ACON’s competing water-soluble dye consumer pregnancy test technology.

Analysis to Aid Public Comment

Under the terms of the proposed Decision and Order, Inverness will divest ACON's water-soluble dye consumer pregnancy test product assets. In addition, Inverness will remove barriers to ACON's continued supply of digital tests to Church & Dwight during the remaining term of their joint venture. The proposed Decision and Order also limits Inverness' ability to interfere with the unwinding of the ACON/Church & Dwight joint venture by, among other things, requiring Inverness to disclaim ownership of intellectual property developed by ACON and Church & Dwight during their joint venture.

II. Background

Inverness is a leader in the research, development, manufacture, and sale of consumer pregnancy tests in the United States. Nearly all retail consumer pregnancy tests use immunoassay-based "lateral flow" technology, which tests a urine sample for the presence of the human chorionic gonadotropin ("hCG") hormone produced by pregnant women. Consumer pregnancy tests consist of a plastic handheld stick device, which contains a test strip embedded beneath an indicator window. The test strip contains chemical agents that react to the presence of hCG in the urine sample. If the test is positive for hCG, a colored line will develop within the indicator window.

Lateral flow consumer pregnancy tests are more accurate, easier to use, and less costly than other pregnancy tests, which resemble laboratory test kits. There are no viable substitutes for consumer pregnancy tests based on lateral flow technology.

"Digital" consumer pregnancy tests use and improve upon lateral flow technology. Rather than a colored line indicator, a digital pregnancy test indicates results through a digital display of words, such as "PREGNANT" or "NOT PREGNANT." Digital consumer pregnancy tests are more difficult to develop and manufacture than standard consumer pregnancy tests, because they require more extensive know-how and more exacting manufacturing tolerances.

Analysis to Aid Public Comment

Digital consumer pregnancy tests are a growing segment of the consumer pregnancy test market.

Inverness is the dominant firm in the market for consumer pregnancy tests. Inverness maintains an approximately 70% share of the U.S. consumer pregnancy test market. At the time of Inverness' acquisition of ACON, Inverness was one of only three independent companies marketing or manufacturing digital consumer pregnancy tests. The other firms exited the market in 2006.

ACON developed, manufactured, and sold consumer pregnancy tests in competition with Inverness. Before Inverness' acquisition of the ACON assets, ACON was developing digital consumer pregnancy tests in a joint venture with Church & Dwight, Inverness' leading competitor. The collaboration with Church & Dwight envisioned that ACON would manufacture and supply the resulting digital consumer pregnancy test products on Church & Dwight's behalf.

ACON also had invested in the development of new lateral flow tests that used water-soluble dyes, rather than colored particles, as the reactive agents in the test strip. ACON was one of the only, if not the only, firm involved in the development of consumer pregnancy tests that used water-soluble dye technology. Before the acquisition, ACON had completed prototypes of the product, and supplied sample quantities to U.S. customers.

In 2006, Inverness acquired certain assets from ACON, which included assets relating to ACON's water-soluble dye technology and assets relating to ACON's digital consumer pregnancy test joint venture with Church & Dwight.

III. The Proposed Complaint

The proposed complaint alleges that relevant market in which to analyze Inverness' conduct is the research, development, manufacture, and sale of consumer pregnancy tests in the United States. Inverness is the dominant player in the market for consumer

Analysis to Aid Public Comment

pregnancy tests. Barriers to entry into the consumer pregnancy test market include intellectual property, know-how, and advertising.

The proposed complaint alleges that Inverness engaged in a course of conduct to maintain its monopoly power in this market by threatening to hamper or stifle future competition from two emerging alternative consumer pregnancy test technologies.

First, the proposed complaint alleges that Inverness' acquisition of the ACON assets weakened future competition from digital consumer pregnancy test products. The proposed complaint alleges that, through its acquisition of the ACON assets, Inverness: (a) imposed a covenant not to compete on ACON, which limited the scope and duration of the ACON's digital consumer pregnancy test joint venture with Church & Dwight; (b) required ACON to surrender to Inverness any profits from ACON's joint venture with Church & Dwight; and (c) acquired rights to the intellectual property developed by ACON and Church & Dwight in their joint venture. Through these actions, Inverness interfered with ACON's ability and incentive to develop and manufacture digital consumer pregnancy tests in its joint venture with Church & Dwight. Inverness' conduct also injured competition that might arise after the unwinding of the joint venture between ACON and Church & Dwight, by interfering with ACON's ability and incentive to serve as an independent developer and supplier of digital consumer pregnancy tests, and by hampering Church & Dwight's ability and incentive to introduce competing digital consumer pregnancy test products manufactured by another developer.

Second, the proposed complaint alleges that Inverness' acquisition of the ACON assets eliminated future competition from water-soluble dye lateral flow consumer pregnancy tests. After Inverness acquired the rights to ACON's water-soluble dye consumer pregnancy test product, Inverness made no use of the test, and ceased development and marketing efforts for it. Inverness' acquisition of the ACON assets further entrenched Inverness' monopoly power in consumer pregnancy tests by preventing future

Analysis to Aid Public Comment

competition from competing water-soluble dye consumer pregnancy tests.

IV. The Proposed Order

The proposed order will remedy the Commission's competitive concerns about Inverness' conduct in maintaining its consumer pregnancy test product monopoly power.

First, the proposed order contains provisions to prevent Inverness from interfering with the digital consumer pregnancy test product joint venture between ACON and Church & Dwight, and to enable ACON and Church & Dwight to maintain their competitive viability after the joint venture ends. These provisions include a requirement that Inverness disclaim any ownership rights on intellectual property developed during the joint venture. The proposed order further requires that Inverness will not interfere with ACON's transfer or licensing of digital consumer pregnancy test technology to Church & Dwight, and that Inverness not interfere with ACON's ability to manufacture digital consumer pregnancy tests for Church & Dwight during their collaboration.

Second, to prevent Inverness from harming emerging competition from water-soluble dye consumer pregnancy test products, the proposed order requires Inverness to divest, to Aemoh Products, LLC, a fully-paid perpetual exclusive sublicense to Inverness' water-soluble dye intellectual property. The proposed order seeks to ensure that water-soluble dye products can be developed without risk of infringing Inverness' intellectual property, by requiring Inverness to covenant not to assert intellectual property infringement claims against certain lateral flow products that use Inverness' water-soluble dye technology. These provisions, among others, will give Aemoh – a start-up run by a successful and experienced health products entrepreneur – the ability to complete the commercialization of water-soluble dye based consumer pregnancy tests.

Analysis to Aid Public Comment

V. Opportunity for Public Comment

The proposed consent order has been placed on the public record for 30 days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will again review the proposed consent order and the comments received and will decide whether it should withdraw from the agreement or make the proposed consent order final.

By accepting the proposed Consent Agreement subject to final approval, the Commission anticipates that the competitive problems alleged in the complaint will be resolved. The purpose of this analysis is to invite public comment on the proposed Consent Agreement, in order to aid the Commission in its determination of whether to make the proposed order final. This analysis is not intended to constitute an official interpretation of the proposed order nor is it intended to modify the terms of the proposed order in any way.

Complaint

IN THE MATTER OF

**INDEPENDENT PHYSICIAN ASSOCIATES
MEDICAL GROUP, INC.,
DBA ALLCARE IPA**

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS
OF SEC. 5 OF THE FEDERAL TRADE COMMISSION ACT

Docket C-4245; File No. 061 0258

Complaint, February 2, 2009 – Decision, February 2, 2009

This consent order addresses horizontal agreements among competing physicians, acting through Independent Physician Associates Medical Group, Inc., dba AllCare IPA, to fix prices charged to those offering coverage for health care services (“payors”) and to refuse to deal with payors. The order prohibits the respondent from entering into or facilitating agreements between or among any health care providers (1) to negotiate on behalf of any physician with any payor, (2) to refuse to deal, or threaten to refuse to deal with any payor, (3) regarding any term, condition, or requirement upon which any physician deals, or is willing to deal, with any payor, including, but not limited to price terms or (4) not to deal individually with any payor, or not to deal with any payor except through AllCare. The order does not preclude AllCare from engaging in conduct reasonably necessary to form or participate in legitimate “qualified risk-sharing” or “qualified clinically integrated” joint arrangements, and does not bar agreements that only involve physicians who are part of the same medical group practice. AllCare is required to notify the Commission before it initiates any arrangement to act as an agent or messenger with respect to physician contracting with payors. The order further requires AllCare to send a copy of the complaint and consent order to its physician members, its management and staff, and any payors who communicated with AllCare, or with whom AllCare communicated, with regard to any interest in contracting for physician services, as well as to each physician who begins participating in each group; each payor who contacts each group regarding the provision of physician services; and each person who becomes an officer, director, manager, or employee for three years after the date on which the order becomes final. AllCare must also publish a copy of the complaint and consent order, for three years, in any official publication that it sends to its participating physicians. In addition, the order requires AllCare to terminate preexisting payor contracts held by physicians who were AllCare participants since January 1, 2005, upon receipt by AllCare of a written request for termination by relevant payors, or the termination date, renewal date, or anniversary date of the contract, whichever is earlier. AllCare is also required to send a copy of any payor’s request for termination to every physician who participates in each group. Additional

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provisions require the respondent to provide to the Commission information to assist in the monitoring of its compliance with the order.

Participants

For the *Commission*: *Kerry O'Brien and John Wiegand.*

For the *Respondent*: *Richard A. Feinstein, Boies, Schiller & Flexner LLP.*

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act, as amended, 15 U.S.C. § 41 *et seq.* (“FTC Act”), and by virtue of the authority vested in it by said Act, the Federal Trade Commission (“Commission”), having reason to believe that Independent Physician Associates Medical Group, Inc., dba AllCare IPA (“AllCare”), herein sometimes referred to as “Respondent,” has violated Section 5 of the FTC Act, 15 U.S.C. § 45, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, hereby issues this Complaint stating its charges in that respect as follows:

NATURE OF THE CASE

1. This matter concerns horizontal agreements among competing physicians, acting through Respondent, to fix prices charged to those offering coverage for health care services (“payors”) in the Modesto, California, area and to refuse to deal with payors.

RESPONDENT

2. AllCare, an independent practice association (“IPA”), is a for-profit corporation, organized, existing, and doing business under and by virtue of the laws of the State of California, with its principal place of business located at 3340 Tully Rd., Suite B-4, Modesto, CA 95350. AllCare consists of multiple, independent medical practices

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with a total of approximately 500 physician members, of which approximately 200 are devoted to primary care.

THE FTC HAS JURISDICTION OVER RESPONDENT

3. At all times relevant to this Complaint, Respondent has been engaged in the business of negotiating or attempting to negotiate contracts with payors for the provision of physician services on behalf, and for the pecuniary benefit, of its members.

4. Except to the extent that competition has been restrained as alleged herein, AllCare's physician members have been, and are now, in competition with each other for the provision of physician services in the Modesto area.

5. Respondent is a "person," "partnership," or "corporation" within the meaning of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 44.

6. Respondent's general business practices, including the acts and practices herein alleged, are in or affecting "commerce" as defined in the Federal Trade Commission Act, as amended, 15 U.S.C. § 44.

OVERVIEW OF PHYSICIAN CONTRACTING WITH PAYORS

7. Individual physicians and physician group practices contract with payors of healthcare services and benefits, health maintenance organizations (HMOs), preferred provider organizations (PPOs), self-insured employers, and others, to establish the terms and conditions, including price terms, under which the physicians will render their professional medical services to the payors' subscribers or covered employees and dependents. Physicians and physician group practices entering into such contracts often agree to accept lower compensation from payors in order to obtain access to additional patients made available by the payors' relationship with the covered individuals. These contracts may reduce payors' costs

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and enable them to lower the price of insurance or of providing health benefits, thereby resulting in lower medical costs for covered individuals.

8. Physicians and physician group practices sometimes form or participate in financially integrated joint ventures to provide physician services under agreements with payors willingly seeking such arrangements. Under such arrangements, the physicians and physician group practices may share financial risks and rewards in several ways. For example, the physicians may provide services at a “capitated” rate or share rewards/penalties based on their collective success in achieving pre-established targets or goals regarding aggregate utilization and costs of the services provided to covered individuals. Physicians may also participate in clinically integrated joint ventures implementing an active and ongoing program to evaluate and modify practice patterns by the network’s physician participants and create a high degree of interdependence and cooperation among the physicians to control costs and ensure quality.

9. Other than through their participation in integrated joint ventures, and absent anticompetitive agreements among them, otherwise competing physicians and physician group practices unilaterally decide whether to enter into contracts with payors to provide services to individuals covered by a payor’s programs, and what prices they will accept as payment for their services pursuant to such contracts.

RESPONDENT’S OPERATION

10. Since its formation, AllCare has entered into contracts with payors for and on behalf of its respective physician members, under which AllCare received capitated payments from the payors in exchange for the medical practices’ agreement to provide their professional medical services to patients covered by the contracting payors. The capitated contracts provided to payors, in addition to the physician services, an insurance guarantee component that all covered physician services needed by patients covered under a

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payor's program would be provided by AllCare's physician members for the predetermined capitation charge, regardless of the actual quantity or type of services needed and provided.

11. The member physicians participation in AllCare, and their offering of services through AllCare's capitated contracts, was not, however, the member physicians' exclusive or even primary method of selling their professional medical services. Rather, the member physicians also continued to sell their medical services individually, on a fee-for-service basis, outside of AllCare, to individual patients and through contracts individually and directly entered into with payors.

ANTICOMPETITIVE CONDUCT

12. Since at least 2005, AllCare, acting as a combination of its physician members, and in conspiracy with its members, has acted to restrain competition on fee-for-service contracts by, among other things, facilitating, entering into, and implementing agreements, express or implied, to fix the prices and other terms at which they would contract with payors; to engage in collective negotiations over terms and conditions of dealing with payors; and to have AllCare members refrain from negotiating individually with payors or contracting on terms other than those approved by AllCare.

13. Since at least 2005, AllCare has engaged in contract talks with payors regarding the payors' offers of fee-for-service contracts. Those talks included negotiations over price and other terms that AllCare would present to its physician members.

14. To enforce these joint negotiation efforts, a significant number of AllCare physicians sent at least one payor the same form termination letter. In those letters, the physicians terminated their individual agreements with the payor "with the exception of [their] participation through the agreement with AllCare IPA." Each letter stressed that "I enjoy my relationship with [the payor's] members and wish to continue that relationship, but only through AllCare IPA."

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**RESPONDENT'S CONDUCT IS NOT LEGALLY
JUSTIFIED**

15. Respondent's joint refusal to deal and negotiation of fees and other competitively significant terms, and the agreements, acts, and practices described above, have not been, and are not, reasonably related to any efficiency-enhancing integration among the physician members of AllCare.

**RESPONDENT'S ACTIONS HAVE HAD, OR COULD BE
EXPECTED TO HAVE, SUBSTANTIAL
ANTICOMPETITIVE EFFECTS**

16. Respondent's actions described in Paragraphs 12 through 14 of this Complaint have had, have tended to have, or if successful would have had, the effect of restraining trade unreasonably and hindering competition in the provision of physician services in the Modesto area in the following ways, among others:

- a. unreasonably restraining price and other forms of competition among physicians who are members of AllCare;
- b. increasing prices for physician services;
- c. depriving payors, including insurers and employers, and individual consumers, of the benefits of competition among physicians; and
- d. depriving consumers of the benefits of competition among payors.

17. The combination, conspiracy, acts, and practices described above constitute unfair methods of competition in violation of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45. Such combination, conspiracy, acts, and practices, or the effects thereof, are continuing and will continue or recur in the absence of the relief herein requested.

Decision and Order

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

By the Commission.

DECISION AND ORDER

The Federal Trade Commission (“Commission”), having initiated an investigation of certain acts and practices of Independent Physician Associates Medical Group, Inc., dba AllCare IPA (“AllCare”), herein sometimes referred to as “Respondent,” and Respondent having been furnished thereafter with a copy of the draft Complaint that counsel for the Commission proposed to present to the Commission for its consideration and which, if issued, would charge Respondent with violations of Section 5 of the Federal Trade Commission Act (“Act”), as amended, 15 U.S.C. § 45; and

Respondent, its attorney, and counsel for the Commission having thereafter executed an Agreement Containing Consent Order to Cease and Desist (“Consent Agreement”), containing an admission by Respondent 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 Respondent 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 Respondent has violated the Act, and that a Complaint should issue stating its charges in that respect, and having accepted the executed Consent

Decision and Order

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 issues its Complaint, makes the following jurisdictional findings and issues the following Order:

1. Respondent AllCare is a for-profit corporation, organized, existing, and doing business under and by virtue of the laws of the State of California, with its principal place of business located at 3340 Tully Rd., Suite B-4, Modesto, CA 95350.
2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of Respondent, and this proceeding is in the public interest.

ORDER**I.**

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

- A. “Respondent” means Independent Physician Associates Medical Group, Inc., dba AllCare IPA, its officers, directors, employees, agents, attorneys, representatives, successors, and assigns; and the subsidiaries, divisions, groups, and affiliates controlled by it, and the respective officers, directors, employees, agents, attorneys, representatives, successors, and assigns of each.
- B. “Medical Group Practice” means a bona fide, integrated firm in which physicians practice medicine together as partners, shareholders, owners, members, or employees, or in which only one Physician practices medicine.
- C. “Participate” in an entity means (1) to be a partner, shareholder, owner, member, or employee of such entity, or

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(2) to provide services, agree to provide services, or offer to provide services, to a payor through such entity. This definition also applies to all tenses and forms of the word “participate,” including, but not limited to, “participating,” “participated,” and “participation.”

- D. “Payor” means any Person that pays, or arranges for the payment, for all or any part of any Physician services for itself or for any other Person, as well as any Person that develops, leases, or sells access to networks of Physicians.
- E. “Person” means both natural Persons and artificial Persons, including, but not limited to, corporations, unincorporated entities, and governments.
- F. “Physician” means a doctor of allopathic medicine (“M.D.”) or a doctor of osteopathic medicine (“D.O.”).
- G. “Preexisting Contract” means a contract for the provision of Physician services that was in effect on the date of the receipt by a payor that is a party to such contract of notice sent by Respondent AllCare pursuant to Paragraph V.A.2 of this Order of such payor’s right to terminate such contract.
- H. “Principal Address” means either (1) the primary business address, if there is a business address, or (2) the primary residential address, if there is no business address.
- I. “Qualified Clinically-integrated Joint Arrangement” means an arrangement to provide Physician services in which:
 - 1. all Physicians who Participate in the arrangement Participate in active and ongoing programs of the arrangement to evaluate and modify the practice patterns of, and create a high degree of interdependence and cooperation among, the Physicians who Participate in the arrangement, in order to control costs and ensure the

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quality of services provided through the arrangement;
and

2. any agreement concerning price or other terms or conditions of dealing entered into by or within the arrangement is reasonably necessary to obtain significant efficiencies that result from such integration through the arrangement.
- J. “Qualified Risk-sharing Joint Arrangement” means an arrangement to provide Physician services in which:
1. all Physicians who Participate in the arrangement share substantial financial risk through their Participation in the arrangement and thereby create incentives for the Physicians who Participate jointly to control costs and improve quality by managing the provision of Physician services such as risk-sharing involving:
 - a. the provision of Physician services at a capitated rate,
 - b. the provision of Physician services for a pre-determined percentage of premium or revenue from payors,
 - c. the use of significant financial incentives (e.g., substantial withholds) for Physicians who Participate to achieve, as a group, specified cost-containment goals, or
 - d. the provision of a complex or extended course of treatment that requires the substantial coordination of care by Physicians in different specialties offering a complementary mix of services, for a fixed, predetermined price, when the costs of that course of treatment for any individual patient can vary greatly due to the individual patient’s condition, the choice,

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complexity, or length of treatment, or other factors;
and

2. any agreement concerning price or other terms or conditions of dealing entered into by or within the arrangement is reasonably necessary to obtain significant efficiencies that result from such integration through the arrangement.

K. “Qualified Arrangement” means a Qualified Clinically-integrated Joint Arrangement or a Qualified Risk-sharing Joint Arrangement.

II.

IT IS FURTHER ORDERED that Respondents, directly or indirectly, or through any corporate or other device, in connection with the provision of Physician services in or affecting commerce, as “commerce” is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44, cease and desist from:

- A. Entering into, adhering to, Participating in, maintaining, organizing, implementing, enforcing, or otherwise facilitating any combination, conspiracy, agreement, or understanding between or among any Physicians with respect to their provision of Physician services:
 1. To negotiate on behalf of any Physician with any Payor;
 2. To deal, refuse to deal, or threaten to refuse to deal with any Payor;
 3. Regarding any term, condition, or requirement upon which any Physician deals, or is willing to deal, with any Payor, including, but not limited to, price terms; or
 4. Not to deal individually with any Payor, or not to deal with any Payor other than through Respondent;

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- B. Exchanging or facilitating in any manner the exchange or transfer of information among Physicians concerning any Physician's willingness to deal with a Payor, or the terms or conditions, including price terms, on which the Physician is willing to deal with a Payor;
- C. Attempting to engage in any action prohibited by Paragraphs II.A or II.B above; and
- D. Encouraging, suggesting, advising, pressuring, inducing, or attempting to induce any Person to engage in any action that would be prohibited by Paragraphs II.A through II.C above.

Provided, however, that nothing in this Paragraph II shall prohibit any agreement or conduct involving Respondent that, subject to the requirements of Paragraph IV of this Order, is reasonably necessary to form, Participate in, or take any action in furtherance of, a Qualified Risk-sharing Joint Arrangement or a Qualified Clinically-integrated Joint Arrangement.

III.

IT IS FURTHER ORDERED that, for three (3) years after the date this Order becomes final, for any arrangement under which Respondent would act as an agent, or as a messenger, on behalf of any Physician or any Medical Group Practice with any Payor regarding contracts, except for those contracts under which Respondent is, or will be, paid on a capitated (per member per month) rate by the Payor, Respondent shall notify the Commission in writing ("Paragraph III Notification") at least sixty (60) days prior to entering into the arrangement for which Paragraph III Notification is required. The Paragraph III Notification shall include the number of proposed Physician Participants in the proposed arrangement; the proposed geographic area in which the proposed arrangement would operate; a copy of any proposed Physician Participation agreement; a description of the proposed arrangement's purpose and function; a description of any resulting efficiencies expected to be obtained through the proposed arrangement; and a description of procedures

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to be implemented to limit possible anticompetitive effects of the proposed arrangement, such as those prohibited by this Order.

Provided however, that:

- (a) if, within fifteen (15) days from the date of the Commission's receipt of the Paragraph Notification, a representative of the Commission makes a written request for additional information, then Respondent shall not enter into the arrangement described in the Paragraph III Notification prior to the expiration of thirty (30) days after substantially complying with such request, or such shorter waiting period as may be granted in writing from the Bureau of Competition;
- (b) the expiration of any waiting period described herein without a request for additional information, or without the initiation of an enforcement proceeding, shall not be construed as a determination by the Commission, or its staff, that the proposed arrangement does or does not violate this Order or any law enforced by the Commission;
- (c) the absence of notice that the proposed arrangement has been rejected, regardless of a request for additional information, shall not be construed as a determination by the Commission, or its staff, that the proposed arrangement has been approved;
- (d) receipt by the Commission of any Paragraph III Notification is not to be construed as a determination by the Commission, or its staff, that the proposed arrangement does or does not violate this Order or any law enforced by the Commission; and
- (e) Paragraph III Notification shall not be required prior to Participating in any arrangement for which Paragraph III Notification has previously been given.

Decision and Order

IV.

IT IS FURTHER ORDERED that for three (3) years from the date this Order becomes final, pursuant to each Qualified Arrangement in which Respondent is a Participant, except for those contracts under which Respondent is, or will be, paid on a capitated (per member per month) rate by the Payor, (“Paragraph IV Arrangement”), Respondent shall notify the Commission in writing (“Paragraph IV Notification”) at least sixty (60) days prior to:

- A. Participating in, organizing, or facilitating any discussion or understanding with or among any Physicians or Medical Group Practices in such Arrangement relating to price terms or conditions of dealing with any Payor; or
- B. Contacting a payor, pursuant to an Arrangement to negotiate or enter into any agreement concerning price or other terms or conditions of dealing with any Payor, on behalf of any Physician or Medical Group Practice in such Arrangement.

Provided further Paragraph IV Notification shall include the following information regarding the Arrangement pursuant to which Respondent intends to engage in the above identified conduct:

- a. the total number of Physicians and the number of Physicians in each specialty Participating in the Arrangement;
- b. a description of the Arrangement, including its purpose and geographic area of operation;
- c. a description of the nature and extent of the integration and the efficiencies resulting from the Arrangement;
- d. an explanation of the relationship of any agreement on prices, or contract terms related to price, to furthering the integration and achieving the efficiencies of the Arrangement;

Decision and Order

- e. a description of any procedures proposed to be implemented to limit possible anticompetitive effects resulting from the Arrangement or its activities; and
- f. All studies, analyses, and reports that were prepared for the purpose of evaluating or analyzing competition for Physician services in any relevant market, including, but not limited to, the market share of Physician services in any relevant market.

Provided further that:

- (a) if, within sixty (60) days from the Commission's receipt of the Paragraph IV Notification, a representative of the Commission makes a written request to Respondent for additional information, then Respondent shall not Participate in any arrangement described in Paragraph IV.A or Paragraph IV.B of this Order prior to the expiration of thirty (30) days after substantially complying with such request for additional information, or such shorter waiting period as may be granted in writing from the Bureau of Competition;
- (b) the expiration of any waiting period described herein without a request for additional information, or without the initiation of an enforcement proceeding, shall not be construed as a determination by the Commission, or its staff, that the proposed Arrangement does or does not violate this Order or any law enforced by the Commission;
- (c) the absence of notice that the proposed arrangement has been rejected, regardless of a request for additional information, shall not be construed as a determination by the Commission, or its staff, that the proposed Arrangement has been approved;

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- (d) receipt by the Commission of any Paragraph IV Notification regarding Participation pursuant to a proposed Arrangement is not to be construed as a determination by the Commission that any such proposed Arrangement does or does not violate this Order or any law enforced by the Commission; and
- (e) Paragraph IV Notification shall not be required prior to Participating in any Arrangement for which Paragraph IV Notification has previously been given.

V.

IT IS FURTHER ORDERED that Respondent shall:

- A. Within thirty (30) days after the date on which this Order becomes final:
 - 1. send by first-class mail with delivery confirmation or return receipt requested, or electronic mail with return confirmation, a copy of this Order and the Complaint to:
 - a. every Physician who Participates, or has Participated, in Respondent at any time since January 1, 2005; and
 - b. each current officer, director, manager, and employee of Respondent; and
 - 2. send by first-class mail, return receipt requested, a copy of this Order, the Complaint, and the letter attached as Appendix A to this Order to the chief executive officer of each payor that has contracted with Respondent for the provision of Physician services at any time since January 1, 2005 regarding contracting for the provision of Physician services, except for those contracts under which Respondent is, or will be, paid a capitated (per member per month) rate by the Payor;

Decision and Order

- B. Terminate, without penalty or charge, and in compliance with any applicable laws, any Preexisting Contract with any Payor who is sent the letter required by Paragraph V.A.2 of this Order, at the earlier of: (1) receipt by Respondent AllCare of a written request to terminate such contract from any Payor that is a party to the contract, or (2) the earliest termination date, renewal date (including any automatic renewal date), or the anniversary date of such contract.

Provided, however, a Preexisting Contract for Physician services may extend beyond any such termination or renewal date no later than one (1) year from the date that the Order becomes final if, prior to such termination or renewal date:

- (a) the Payor submits to Respondent AllCare a written request to extend such contract to a specific date no later than one (1) year from the date that this Order becomes final, and
- (b) Respondent AllCare has determined not to exercise any right to terminate.

Provided, further, that any Payor making such request to extend a contract retains the right, pursuant to Paragraph V.B of this Order, to terminate the Preexisting Contract at any time.

- C. Within ten (10) days of receiving a written request to terminate from a Payor, pursuant to Paragraph V.B of this Order, distribute, by first-class mail, return receipt requested, a copy of that request to each Physician Participating in such contract as of the date that Respondent AllCare receives such request to terminate.
- D. For three (3) years from the date this Order becomes final:
1. Distribute by first-class mail, return receipt requested, a copy of this Order and the Complaint to:

Decision and Order

- a. each Physician who begins Participating in Respondent, and who did not previously receive a copy of this Order and the Complaint from Respondent, within thirty (30) days of the time that such Participation begins;
 - b. each payor who contracts with Respondent for the provision of Physician services, except for those payors who contract with Respondent solely for Physician services that are, or will be, paid on a capitated (per member per month) rate by the Payor, and who did not previously receive a copy of this Order and the Complaint from Respondent, within thirty (30) days of the time that such payor enters into such contract; and
 - c. Each Person who becomes an officer, director, manager, or employee of Respondent, and who did not previously receive a copy of this Order and the Complaint from Respondent, within thirty (30) days of the time that he or she assumes such position with Respondent; and
2. Annually publish in an official annual report or newsletter sent to all Physicians who Participate in Respondent, a copy of this Order and the Complaint with such prominence as is given to regularly featured articles.
- E. File verified written reports within sixty (60) days from the date this Order becomes final, annually thereafter for three (3) years on the anniversary of the date this Order becomes final, and at such other times as the Commission may by written notice require. Each report shall include:
1. a detailed description of the manner and form in which the Respondent has complied and is complying with this Order;

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2. the name, address, and telephone number of each payor with which the Respondent has had any contact, except for payors whose sole contacts with Respondent relate to contracts under which Respondent is, or will be, paid a capitated (per member per month) rate by the Payor; and
3. copies of the delivery confirmations, signed return receipts, or electronic mail with return confirmations required by Paragraph V.A.1, and copies of the signed return receipts required by Paragraphs V.A.2 and V.C.

VI.

IT IS FURTHER ORDERED that 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: (1) dissolution of Respondent; (2) acquisition, merger, or consolidation of Respondent; or (3) 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.

VII.

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 Respondent, Respondent shall, without restraint or interference, permit any duly authorized representative of the Commission:

- 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,

Decision and Order

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.

VIII.

IT IS FURTHER ORDERED that this Order shall terminate on February 2, 2029.

By the Commission.

Decision and Order

Appendix A

Appendix A

[Respondent's letterhead]

[name of payor's CEO]
[address]

Dear _____:

Enclosed is a copy of a complaint and a consent order ("Order") issued by the Federal Trade Commission against Independent Physician Associates Medical Group, Inc., dba AllCare IPA ("AllCare").

Pursuant to Paragraph V.B of the Order, AllCare must allow you to terminate, upon your written request without any penalty or charge, any contracts with AllCare for the provision of physician services that were in effect prior to your receipt of this letter.

Paragraph V.B of the Order also provides that, if you do not terminate your contract, the contract will terminate at the earlier of [date one year from the date the Order becomes final] or its earliest termination or renewal date (including any automatic renewal date). If the termination or renewal date occurs prior to [date one year from the date the Order becomes final], you may request AllCare to extend that date to a date no later than [date one year from the date the Order becomes final]. If you choose to extend the term of the contract, you may later terminate the contract at any time.

Sincerely,

[AllCare to fill in information in brackets]

Analysis to Aid Public Comment

**ANALYSIS OF CONSENT ORDER TO AID PUBLIC
COMMENT**

The Federal Trade Commission has accepted, subject to final approval, an agreement containing a proposed Consent Order with Independent Practice Associates Medical Group, Inc., dba AllCare IPA (“AllCare” or “Respondent”). The agreement settles charges that AllCare violated Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45, by fixing prices charged to those offering coverage for health care services (“payors”) in the Modesto, California, area and refusing to deal with payors. The proposed Consent Order has been placed on the public record for 30 days to receive comments from interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will review the agreement and the comments received, and will decide whether it should withdraw from the agreement or make the proposed Consent Order final.

The purpose of this analysis is to facilitate public comment on the proposed Consent Order. The analysis is not intended to constitute an official interpretation of the agreement and proposed Consent Order or to modify their terms in any way. Further, the proposed Consent Order has been entered into for settlement purposes only and does not constitute an admission by Respondent that it violated the law or that the facts alleged in the Complaint (other than jurisdictional facts) are true.

The Complaint’s Allegations

AllCare is a multi-specialty independent practice association consisting of multiple, independent medical practices with a total of approximately 500 physician members, of which approximately 200 are devoted to primary care, in the Modesto, California, area. Since its formation, AllCare has negotiated contracts with payors under which it has received capitated (per member per month) payments. These contracts shift the risk of patient illness to the IPA by specifying that the health plan will pay the IPA a flat monthly fee for each enrollee, with almost no regard for patient utilization. This type

Analysis to Aid Public Comment

of contracting is a form of financial integration. The Complaint does not challenge AllCare's activities concerning these contracts.

AllCare and its physicians also contract with Preferred Provider Organizations ("PPOs") to provide fee-for-service medical care. In PPO arrangements, the payor compensates physicians or group practices for services actually rendered pursuant to agreed-upon fee schedules. PPO contracts may or may not entail financial risk-sharing or clinical integration on the part of providers. It is AllCare's negotiation of certain PPO contracts that is the subject of the Commission's Complaint.

The Complaint alleges that AllCare, since at least 2005, has acted to restrain competition on fee-for-service contracts by facilitating, entering into, and implementing agreements to fix the prices and other terms in contracts with PPO payors; to engage in collective negotiations over terms and conditions of dealing with such payors; and to have AllCare members refrain from negotiating individually with such payors or contracting on terms other than those approved by AllCare. The Complaint further alleges that AllCare, to enforce the joint negotiation efforts, caused a significant number of AllCare physicians to send to at least one payor the same form termination letter. These letters terminated the physicians' individual agreements with the payor and affirmed that the physicians would contract with the payor only through an agreement with AllCare.

AllCare did not engage in any activity that might justify collective agreements on the prices its members would accept for their services. The physicians in AllCare, with respect to PPO contracts, do not share any financial risk in providing medical services, do not collaborate in programs to monitor and modify clinical practice patterns to control members' costs and ensure quality, or otherwise integrate their delivery of health care services. The Respondent's actions have restrained price and other forms of competition among physicians in the Modesto, California, area and thereby harmed consumers (including health plans, employers, and individual consumers) by increasing the prices for physician services

Analysis to Aid Public Comment

The Proposed Consent Order

The proposed Consent Order is designed to prevent the continuance and recurrence of the unlawful conduct alleged in the Complaint while allowing AllCare to engage in legitimate, joint conduct. The proposed Consent Order does not affect AllCare's activities in contracting with the payors on a capitated basis.

Paragraph II.A prohibits Respondent from entering into or facilitating agreements between or among any health care providers (1) to negotiate on behalf of any physician with any payor, (2) to refuse to deal, or threaten to refuse to deal with any payor, (3) regarding any term, condition, or requirement upon which any physician deals, or is willing to deal, with any payor, including, but not limited to price terms or (4) not to deal individually with any payor, or not to deal with any payor except through AllCare.

The other parts of Paragraph II reinforce these general prohibitions. Paragraph II.B prohibits the Respondent from facilitating exchanges of information between health care providers concerning whether, or on what terms, to contract with a payor. Paragraph II.C bars attempts to engage in any action prohibited by Paragraph II.A or II.B, and Paragraph II.D proscribes encouraging, suggesting, advising, pressuring, inducing, or attempting to induce any person to engage in any action that would be prohibited by Paragraphs II.A through II.C.

As in other Commission orders addressing health care providers' collective bargaining with health care purchasers, certain kinds of agreements are excluded from the general bar on joint negotiations. Paragraph II does not preclude AllCare from engaging in conduct that is reasonably necessary to form or participate in legitimate "qualified risk-sharing" or "qualified clinically-integrated" joint arrangements, as defined in the proposed Consent Order. Also, Paragraph II would not bar agreements that only involve physicians who are part of the same medical group practice, defined in Paragraph I.B, because it is intended to reach agreements between and among independent competitors.

Analysis to Aid Public Comment

Paragraphs III and IV require AllCare to notify the Commission before it initiates any arrangement to act as an agent or messenger with respect to physician contracting with payors. The Order also would require AllCare to provide to the Commission key details of the arrangement and to delay the implementation of that arrangement to permit further factual discovery by the Commission at its option. Paragraph III applies such requirements to arrangements under which AllCare would be acting as a messenger, and Paragraph IV applies them to arrangements under which AllCare plans to achieve financial or clinical integration.

Paragraph V.A requires AllCare to send a copy of the Complaint and Consent Order to its physician members, its management and staff, and any payors who communicated with AllCare, or with whom AllCare communicated, with regard to any interest in contracting for physician services.

Part V.B. of the Order requires AllCare to terminate preexisting payor contracts held by physicians who were AllCare participants since January 1, 2005, upon (1) receipt by AllCare of a written request for termination by relevant payors, or (2) the termination date, renewal date, or anniversary date of the contract, whichever is earlier. This termination can be delayed for up to one year after the effective date of the Order, upon the written request of the payor. This provision is intended to eliminate the effects of AllCare's joint price setting behavior.

Paragraph V.C requires that AllCare send a copy of any payor's request for termination to every physician who participates in each group. Paragraph V.D contains further notification provisions relating to future contact with physicians, payors, management, and staff. This provision requires AllCare to distribute a copy of the Complaint and Consent Order to each physician who begins participating in each group; each payor who contacts each group regarding the provision of physician services; and each person who becomes an officer, director, manager, or employee for three years after the date on which the Consent Order becomes final. In addition, Paragraph V.D requires AllCare to publish a copy of the

Analysis to Aid Public Comment

Complaint and Consent Order, for three years, in any official publication that it sends to its participating physicians.

Paragraphs V.E and VI-VII impose various obligations on AllCare to provide to the Commission information that would assist in the monitoring of Respondent's compliance with the Consent Order.

Pursuant to Paragraph VIII, the proposed Consent Order will expire in 20 years from the date it is issued.

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.*

Complaint

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.

Complaint

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.

Complaint

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

Decision and Order

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 Alharma Inc. (“Alharma”), 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

Decision and Order

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 ANTTITRUST 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.

Analysis to Aid Public Comment

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.

Analysis to Aid Public Comment

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 Alparma is consummated. Headquartered in Iceland, Actavis is one of the world's largest generic pharmaceutical companies. Currently, Actavis manufactures Kadian for Alparma 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 Alparma, 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.

Analysis to Aid Public Comment

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.