

Complaint

IN THE MATTER OF

**ACTAVIS GROUP, HF. AND ABRIKA
PHARMACEUTICALS, INC.**

CONSENT ORDER, ETC. , IN REGARD TO ALLEGED VIOLATIONS OF
SEC. 7 OF THE CLAYTON ACT AND SEC. 5 OF THE FEDERAL TRADE
COMMISSION ACT

Docket C-4190; File No. 071 0063
Complaint, May 18, 2007 — Decision, May 18, 2007

This consent order seeks to remedy the anticompetitive effects of the acquisition of Abrika Pharmaceuticals, Inc., by Actavis Group, hf. Both respondents are engaged in the research, development, manufacture, and sale of generic pharmaceutical products, and they are the only two companies selling generic isradipine capsules in the United States. The order requires the respondents to assign and divest the Abrika rights and assets necessary to manufacture and market generic isradipine capsules to Cobalt Laboratories, Inc., the U.S. subsidiary of Arrow Group, or to another Commission-approved acquirer. As part of the divestiture, Abrika will transfer its supply arrangement to Cobalt. Actavis and Abrika will transfer all confidential business information related to Abrika's isradipine product to Cobalt. Finally, Actavis and Abrika will provide technical assistance to Cobalt to allow it to manufacture isradipine in substantially the same manner and quality employed or achieved by Abrika. The order also requires Actavis and Abrika to file reports with the Commission periodically until the divestitures and transfers are accomplished.

Participants

For the *Commission*: Amy S. Posner and Kari A. Wallace.

For the *Respondents*: John F. Collins, Dewey Ballantine LLP;
and Cecil S. Chung and Shirley Z. Johnson, Greenberg Traurig
LLP.

COMPLAINT

Pursuant to the Clayton Act and the Federal Trade Commission Act, and its authority thereunder, the Federal Trade

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Commission (“Commission”), having reason to believe that Respondent Actavis Group, hf. (“Actavis”), a corporation subject to the jurisdiction of the Commission, has agreed to acquire Abrika Pharmaceuticals, Inc., including the voting securities of Abrika Pharmaceuticals, Inc. owned by Alan P. Cohen (known collectively as “Abrika”), 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. “Commission” means the Federal Trade Commission.
2. “FDA” means the United States Food and Drug Administration.
3. “Respondents” means Actavis and Abrika, individually and collectively.

II. RESPONDENTS

4. Respondent Actavis is a corporation organized, existing, and doing business under and by virtue of the laws of Iceland, with its headquarters address at Dalshraun 1, 220 Hafnarfjordur, Iceland. Actavis’s principal subsidiary in the United States, Actavis U.S., is located at 14 Commerce Drive, Suite 301, Cranford, New Jersey 07016. Actavis is engaged in the research, development, manufacture, and sale of generic pharmaceutical products.

5. Respondent Abrika 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 13800 N.W. 2nd Street, Suite 190, Sunrise, Florida 33325. Abrika is engaged in the

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research, development, manufacture, and sale of generic pharmaceutical products.

6. 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

7. On November 20, 2006, Actavis and Abrika entered into an Agreement and Plan of Merger (the “Merger Agreement”) whereby Actavis proposes to acquire 100 percent of the issued and outstanding voting securities of Abrika in a transaction valued at approximately \$235 million (the “Acquisition”).

IV. THE RELEVANT MARKET

8. For the purposes of this Complaint, the relevant line of commerce in which to analyze the effects of the Acquisition is the manufacture and sale of generic isradipine capsules.

9. 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

10. The market for the manufacture and sale of generic isradipine capsules is highly concentrated with a pre-acquisition Herfindahl-Hirschman Index (“HHI”) of 8,872 points. Isradipine capsules are calcium channel blockers that relax blood vessels and reduce the workload on the heart. Currently, Actavis and Abrika are the only suppliers of generic isradipine in the United States with market shares of 6 percent and 94 percent, respectively. The

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Acquisition would create a monopoly in this market and increase the HHI concentration by 1,128 points, resulting in a post-acquisition HHI of 10,000 points.

VI. ENTRY CONDITIONS

11. Entry into the relevant product market described in Paragraph 8 would not be timely, likely, or sufficient in its magnitude, character, and scope to deter or counteract the anticompetitive effects of the Acquisition. Entry would not take place in a timely manner because the combination of generic drug development times and FDA drug approval requirements takes at least two years. Entry would not be likely because the relevant market is relatively small and in decline, limiting sales opportunities for any potential new entrant.

VII. EFFECTS OF THE ACQUISITION

12. The effects of the Acquisition, if consummated, may be to substantially lessen competition and 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 Actavis and Abrika. The merger of Actavis and Abrika eliminates price competition between these two generic drug companies, thereby: (1) increasing the likelihood that Actavis will be able to unilaterally exercise market power in this market and (2) increasing the likelihood that customers would be forced to pay higher prices.

VIII. VIOLATIONS CHARGED

13. The Merger Agreement described in Paragraph 7 constitutes a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

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14. The Acquisition described in Paragraph 7, 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 eighteenth day of May, 2007, issues its Complaint against said Respondents.

By the Commission.

DECISION AND ORDER

The Federal Trade Commission (“Commission”), having initiated an investigation of the proposed acquisition by Respondent Actavis Group hf. (“Actavis”) of Respondent Abrika Pharmaceuticals, Inc. (“Abrika”), hereinafter referred to as “Respondents,” and Respondents having been furnished thereafter with a copy of a draft of Complaint (“Complaint”) that the Bureau of Competition proposed to present to the Commission for its consideration and that, if issued by the Commission, would charge Respondents with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondents, their attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Orders (“Consent Agreement”), containing an admission by Respondents of all the jurisdictional facts set forth in the aforesaid draft of 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

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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 Actavis is a corporation, organized, existing and doing business under and by virtue of the laws of Iceland, with its headquarters address at Dalshraun 1, 220 Hafnarfjordur, Iceland.
2. Respondent Abrika 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 13800 N.W. 2nd Street, Suite 190, Sunrise, Florida 33325.
3. The Commission has jurisdiction of the subject matter of this proceeding and of Respondents, and the proceeding is in the public interest.

ORDER**I.**

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

- A. "Actavis" means Actavis Group hf., its directors, officers, employees, agents, representatives, successors, and

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assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Actavis (including, but not limited to, Actavis Inc. and Panthers Acquisition Corp.), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. After the Acquisition, Actavis shall include Abrika.

- B. “Abrika” means Abrika Pharmaceuticals, Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Abrika, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- C. “Respondents” means Actavis and Abrika, individually and collectively.
- D. “Commission” means the Federal Trade Commission.
- E. “Abrika-Cobalt Agreement” means the Asset Purchase Agreement by and among Abrika Pharmaceuticals, Inc., Actavis Inc., and Cobalt Laboratories Inc., dated April 2, 2007, and all amendments, exhibits, attachments, agreements, and schedules related thereto. The Abrika-Cobalt Agreement is attached to this Order and contained in non-public Appendix I.
- F. “Abrika-PMRS Supply Agreement” means the Commercial Supply Agreement by and between Pharmaceutical Manufacturing Research Services, Inc., and Abrika Pharmaceuticals, dated December 31, 2005, and all amendments, exhibits, attachments, agreements, and schedules related thereto. The Abrika-PMRS Supply Agreement is attached to this Order and contained in non-public Appendix II.

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G. “Acquirer” means:

1. Cobalt; or
2. An entity that receives the prior approval of the Commission to acquire the Isradipine Assets that Respondents are required to assign, grant, license, divest, transfer, deliver, terminate, or otherwise convey pursuant to this Order.

H. “Acquirer Employees” means any of an Acquirer’s employees with any amount of responsibility related to the Isradipine Product.

I. “Acquisition” means the acquisition contemplated by The Agreement and Plan of Merger dated November 20, 2006, by and among Actavis Inc., Panthers Acquisition Corp., Abrika Pharmaceuticals, Inc., and Alan P. Cohen, and all amendments, exhibits, attachments, agreements, and schedules thereto.

J. “Acquisition Date” means the earlier of the following dates:

1. The date Respondents close on the Acquisition; or
2. The date the merger contemplated by the Acquisition is consummated by filing the certificate of merger related to the Acquisition with the Secretary of State of the State of Delaware.

K. “Agency(ies)” means any government regulatory authority or authorities in the world responsible for granting approvals, clearances, qualifications, licenses, or permits for any aspect of the research, Development, manufacture, marketing, distribution, or sale of a Product. This term includes, but is not limited to, the United States Food and Drug Administration (“FDA”).

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- L. “Applications” means the applications for a Product filed or to be filed with the FDA pursuant to 21 C.F.R. Parts 312 and 314, and all supplements, amendments, and revisions thereto, any preparatory work, drafts and data necessary for the preparation thereof, and all related correspondence between Respondents and the FDA. This term includes, but is not limited to, Investigational New Drug Application (“IND”), New Drug Application (“NDA”), Abbreviated New Drug Application (“ANDA”), Supplemental New Drug Application (“SNDAs”), and Marketing Authorization Application (“MAA”) for a Product filed or to be filed with the FDA and all supplements, amendments, and revisions thereto, any preparatory work, drafts, and data necessary for the preparation thereof, and all related correspondence between Respondents and the FDA.
- M. “Assumed Contracts” means any and all of the following contracts or agreements:
1. That make specific reference to the Isradipine Product and pursuant to which any Third Party is obligated to purchase, or has the option to purchase with no further negotiation on price, the Isradipine Product from Respondents unless such contracts apply generally to the divesting Respondents’ sales of generic Products to that Third Party;
 2. Pursuant to which Respondents purchase the active pharmaceutical ingredients or had planned to purchase the active pharmaceutical ingredients from any Third Party for use in connection with the manufacture of the Isradipine Product;
 3. Relating to any clinical trial involving the Isradipine Product;

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4. With universities or other research institutions for the use of the Isradipine Product in scientific research;
5. Relating to the particularized marketing of the Isradipine Product or educational matters relating solely to the Isradipine Product;
6. Pursuant to which a Third Party manufactures the Isradipine Product on behalf of the Respondents;
7. Pursuant to which a Third Party provides the Manufacturing Technology or related equipment to the Respondents;
8. Constituting confidentiality agreements involving the Isradipine Product;
9. Involving any royalty, licensing, or similar arrangement involving the Isradipine Product to which Respondents are party;
10. Pursuant to which a Third Party provides any specialized services necessary to the research, Development, or manufacture of the Isradipine Product to Respondents, including consultation arrangements; and
11. Pursuant to which any Third Party collaborates with the Respondents in the performance of research, Development, marketing, distribution or selling of the Isradipine Product or the Isradipine Product business;

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Provided, however, that where any such contract or agreement also relates to Retained Products, Respondents shall assign to an Acquirer all such rights under the contract or agreement as are related to the Isradipine Product, but concurrently may retain similar rights for the purposes of the Retained Products;

Provided further, however, that Respondents shall provide copies of each contract or agreement to an Acquirer on or before the related Closing Date and segregated in a manner that clearly identifies the purpose of each contract or agreement.

- N. “Categorized Assets” means the following assets related to the Isradipine Product:
1. All Intellectual Property;
 2. A perpetual, fully paid-up and royalty-free license with rights to sublicense to all Licensed Intellectual Property solely within the field of use to use, make, distribute, offer for sale, promote, advertise, sell, import, export, or have used, made, distributed, offered for sale, promoted, advertised, sold, imported, or exported the Isradipine Product within the specified Geographic Territory;
 3. All Product Registrations;
 4. All Manufacturing Technology;
 5. All Marketing Materials;
 6. A list of all NDC Numbers and rights, to the extent permitted by Law, related to the Isradipine Product:

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- a. To require Respondents to discontinue the use of those NDC Numbers in the sale or marketing of Products other than with respect to returns, rebates, allowances, and adjustment for Isradipine Product sold prior to the Acquisition Date;
- b. To prohibit Respondents from seeking from any customer any type of cross-referencing of those NDC Numbers with any Retained Products;
- c. To seek to change any cross-referencing by a customer of those NDC Numbers with the Retained Products (including the right to receive notification from Respondents of any such cross-referencing that is discovered by Respondents);
- d. To seek cross-referencing from a customer of those NDC Numbers with the relevant Acquirer's NDC Numbers related to the Isradipine Product;
- e. To approve the timing of Respondents' discontinued use of those NDC Numbers in the sale or marketing of Products other than with respect to returns, rebates, allowances, and adjustments for Isradipine Product sold prior to the Acquisition Date, provided that Respondents may provide the minimum notice required by contract or law;
- f. To approve any notification from Respondents to any customer regarding the use or discontinued use of such numbers by Respondents prior to such notification being disseminated to the customer, provided that Respondents may provide the minimum notice required by contract or law;

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7. All rights to all of Respondents' relevant Applications;
8. Rights of Reference or Use to the Drug Master Files related to the Applications including, but not limited to, the pharmacology and toxicology data contained in all Applications;
9. All Development Reports;
10. At an Acquirer's option, all Assumed Contracts;
11. All strategic safety programs submitted to the FDA that are designed to decrease product risk by using one or more interventions or tools beyond the package insert;
12. All patient registries, and any other systematic active post-marketing surveillance program to collect patient data, laboratory data and identification information required to be maintained by the FDA to facilitate the investigation of adverse effects;
13. Lists of all customers and/or targeted customers, net sales (in either units or dollars) to such customers on either an annual, quarterly, or monthly basis including, but not limited to, a separate list specifying the above-described information for the High Volume Accounts and including the names of employees for the High Volume Accounts that are or have been responsible for the purchase of the Isradipine Product on behalf of the High Volume Accounts and their business contact information;
14. At an Acquirer's option, all inventory in existence as of the Closing Date including, but not limited to, raw materials, packaging materials, work-in-process and finished goods;

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15. Copies of all unfulfilled customer purchase orders as of the Closing Date, to be provided to the relevant Acquirer not later than two (2) days after the Closing Date;
16. At an Acquirer's option, subject to any rights of the customer, all unfulfilled customer purchase orders; and
17. All of the Respondents' books, records, and files directly related to the foregoing or to the Isradipine Product;

Provided, however, that this term shall not include (1) documents relating to Respondents' general business strategies or practices relating to research, development, manufacture, marketing or sale of generic pharmaceutical Products, where such documents do not discuss with particularity the Isradipine Product, and (2) administrative, financial and accounting records;

Provided further, however, Respondents may exclude from this term quality control records that are determined by the Interim Monitor or the Acquirer not to be material to the manufacture of the Isradipine Product;

Provided further, however, that in cases in which documents or other materials included in the relevant assets to be divested contain information: (1) that relate to both the Isradipine Product and other Products or businesses of Respondents and cannot be segregated in a manner that preserves the usefulness of the information related to the Isradipine Product; or (2) for which the Respondents have a legal obligation to retain the original copies, the 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 an Acquirer, the Respondents shall

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provide such 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 the Respondents provide an Acquirer with the above-described information without requiring the Respondents to completely divest themselves of information that, in content, also relates to Products and businesses other than the Isradipine Product.

- O. “cGMP” means current Good Manufacturing Practice as set forth in the United States Federal, Food, Drug, and Cosmetic Act, as amended, and includes all rules and regulations promulgated by the FDA thereunder.
- P. “Closing Date” means the date on which the Respondents (or a Divestiture Trustee) consummate a transaction to assign, grant, license, divest, transfer, deliver, or otherwise convey assets or rights related to the Isradipine Product to an Acquirer pursuant to this Order.
- Q. “Cobalt” means Cobalt Laboratories 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 24840 S. Tamiami Trail, Suite 1, Bonita Springs, Florida 34134.
- R. “Confidential Business Information” means all information owned by, or in the possession or control of, Respondents 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 Isradipine Product; *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:

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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 Respondents;
 2. Information related to the Isradipine Product that Respondent Actavis can demonstrate it obtained without the assistance of Respondent Abrika prior to the Acquisition;
 3. Information that is required by law to be publicly disclosed;
 4. Information that does not directly relate to the Isradipine Product;
 5. Information relating to Respondents' general business strategies or practices relating to research, Development, manufacture, marketing or sale of generic pharmaceutical Products that does not discuss with particularity the Isradipine Product; and
 6. Information specifically excluded from the Categorized Assets.
- S. "Copyrights" means rights to all original works of authorship of any kind directly related to the Isradipine Product and any registrations and applications for registrations thereof within the Geographic Territory, including, but not limited to, all the following:
1. Promotional materials for healthcare providers;
 2. Promotional materials for patients;
 3. Educational materials for the sales force;

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4. Copyrights in all preclinical, clinical and process development data and reports relating to research and Development, including raw data relating to clinical trials, case report forms relating thereto, statistical programs developed (or modified in a manner material to use or function thereof) to analyze clinical data, market research data, market intelligence reports and statistical programs (if any) used for marketing and sales research;
5. Customer information, promotional and marketing materials, sales forecasting models, medical education materials, sales training materials, and advertising and display materials;
6. Records relating to employees who accept employment with an Acquirer (excluding any personnel records transfer of which is prohibited by law);
7. Records, including customer lists, sales force call activity reports, vendor lists, sales data, reimbursement data, speaker lists, manufacturing records, manufacturing processes, and supplier lists;
8. Data contained in laboratory notebooks;
9. Adverse experience reports and files related thereto (including source documentation), periodic adverse experience reports, and data contained in electronic databases relating thereto;
10. Analytical and quality control data; and
11. All correspondence with the FDA.

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- T. “Development” means all preclinical and clinical drug development activities, including formulation, test method development and stability testing, toxicology, process development, manufacturing scale-up, development-stage manufacturing, quality assurance/quality control development, statistical analysis and report writing, conducting clinical trials for the purpose of obtaining any and all approvals, licenses, registrations or authorizations from any Agency necessary for the manufacture, use, storage, import, export, transport, promotion, marketing, and sale of a Product (including any government price or reimbursement approvals), Product approval and registration, and regulatory affairs related to the foregoing.
- U. “Development Reports” means the following documents related to the Isradipine Product in Respondents’ possession or in which Respondents have a right to access:
1. Pharmacokinetic study reports;
 2. Bioavailability study reports (including reference listed drug information);
 3. Bioequivalence study reports (including reference listed drug information);
 4. All correspondence between Respondents and the FDA relating to the Applications submitted by, on behalf of, or acquired by Respondents;
 5. Annual and periodic reports related to the Applications, including any safety update reports;
 6. FDA approved Product labeling;
 7. Currently used product package inserts (including historical change of controls summaries);

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8. FDA approved patient circulars and information;
 9. Adverse event/serious adverse event summaries;
 10. Summary of Product complaints from physicians;
 11. Summary of Product complaints from customers; and
 12. Product recall reports filed with the FDA.
- V. “Direct Cost” means a cost not to exceed the cost of labor, material, travel and other expenditures to the extent they are directly incurred to provide the relevant assistance or service; *provided, however*, that Direct Cost shall not exceed the average hourly wage rate of Respondents’ employees used by an Acquirer.
- W. “Divestiture Trustee” means the trustee appointed by the Commission pursuant to Paragraph IV. of this Order.
- X. “Domain Name” means the domain names (universe resource locators), and registrations thereof, issued by any entity or authority that issues and maintains the domain name registration; *provided, however*, this term shall not include any trademark or service mark rights to such domain names other than the rights to the Trademarks required to be divested.
- Y. “Drug Master Files” means the information submitted to the FDA as described in 21 C.F.R. Part 314.420 related to a Product.
- Z. “Employee Information” means, as related to the Isradipine Core Employees, and to the extent permitted by law:

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1. A complete and accurate list containing the name of each relevant employee (including former employees who were employed by Respondents within ninety (90) days of the execution of any Remedial Agreement);
2. The following information for each such employee:
 - a. The date of hire and effective service date;
 - b. Job title or position held;
 - c. A specific job description of the employee's responsibilities related to the Isradipine Product; *provided, however*, in lieu of this description, Respondents may provide the employee's most recent performance appraisal;
 - d. The base salary and current wages;
 - e. The most recent bonus paid, aggregate annual compensation for the Respondents' last fiscal year and current target or guaranteed bonus, if any;
 - f. Employment status (*i.e.*, active, on leave, on disability, and full or part time);
 - g. Any other material terms and conditions of employment in regard to such employee that are not otherwise generally available to similarly situated employees; and
3. At the Acquirer's option, copies of all applicable employee benefit plans and summary plan descriptions.

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AA. “Geographic Territory” means the United States of America, including all of the territories within its jurisdiction or control unless otherwise specified.

BB. “High Volume Accounts” means any of Respondents’ customers whose annual and/or projected annual aggregate purchase amounts, in units or in dollars, on a company-wide level of the Isradipine Product in the United States was, is, or is projected to be among the top twenty highest of such purchase amounts by Respondents’ U.S. customers on any of the following dates: (1) the end of the last quarter that immediately preceded the date of the public announcement of the proposed Acquisition; (2) the end of the last quarter that immediately preceded the Acquisition Date; (3) the end of the last quarter that immediately preceded the Closing Date for the relevant assets; or (4) the end of the last quarter following the Acquisition Date and/or the Closing Date.

CC. “Intellectual Property” means all of the following related to the Isradipine Product:

1. Patents;
2. Copyrights;
3. Trademarks, Trade Dress, trade secrets, know-how, techniques, data, inventions, practices, methods, and other confidential or proprietary technical, business, research, Development and other information; and
4. Rights to obtain and file for patents and copyrights and registrations thereof;

Provided, however, this term does not include the names or trade dress of “Actavis,” “Abrika,” or the names or trade dress of any other corporation, companies, or brands

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owned or sold by Respondents or related logos to the extent used on Respondents' Retained Products.

DD. "Interim Monitor" means any monitor appointed pursuant to Paragraph III. of this Order.

EE. "Isradipine Assets" means, within the Geographic Territory and to the extent legally transferrable, all of Respondent Abrika's rights, title and interest in all assets related to:

1. The Isradipine Product;
2. Respondent Abrika's business related to the Isradipine Product;
3. The research, Development, manufacture, distribution, marketing and sale of the Isradipine Product; and
4. The Categorized Assets related to the Isradipine Product.

FF. "Isradipine Core Employees" means the Research and Development Employees and the Manufacturing Employees.

GG. "Isradipine Divestiture Agreement" means:

1. The Abrika-Cobalt Agreement; or
2. Any agreement that receives the prior approval of the Commission between Respondents and an Acquirer for the divestiture of the Isradipine Assets entered into pursuant to Paragraph II.A. of this Order, and any attachments, agreements, and schedules related thereto.

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HH. “Isradipine Product” means all Products in Development, manufactured, marketed or sold by Respondent Abrika pursuant to Respondent Abrika’s ANDA No. 77-317 (isradipine instant release capsules 2.5 mg/5.0 mg) and any supplements, amendments, or revisions thereto.

II. “Licensed Intellectual Property” means:

1. Patents that are related to the Isradipine Product that Respondents can demonstrate have been routinely used, prior to the Acquisition Date, for Retained Products:
 - a. That have been marketed or sold on an extensive basis by the Respondents within the two-year period immediately preceding the Acquisition; or
 - b. For which, prior to the announcement of the Acquisition, there was an approved marketing plan to market or sell Retained Products on an extensive basis by Respondents; and
2. 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 the Isradipine Product and that Respondents can demonstrate have been routinely used, prior to the Acquisition Date, by Respondents for Retained Products:
 - a. That have been marketed or sold on an extensive basis by the Respondents within the two-year period immediately preceding the Acquisition; or

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- b. For which, prior to the announcement of the Acquisition, there was an approved marketing plan to market or sell Retained Products on an extensive basis by Respondents;

Provided, however, that, Respondents may take a paid-up, royalty-free, irrevocable, non-exclusive, with a right to sublicense, license back from the Acquirer for such intellectual property for use in connection with Retained Products;

Provided further, however, that, in cases where the aggregate retail sales in dollars within the two-year period immediately preceding the Acquisition of the Retained Products collectively are less than the aggregate retail sales in dollars within the same period of the Isradipine Product collectively, the above described intellectual property shall be considered, at the Acquirer's option, to be Intellectual Property and, thereby, subject to assignment to the Acquirer.

- JJ. "Manufacturing Employees" means all Respondents' salaried employees who have directly participated in the planning, design, implementation or use of the Manufacturing Technology of the Isradipine Product (irrespective of the portion of working time involved unless such participation consisted solely of oversight of legal, accounting, tax or financial compliance) within the eighteen (18) month period immediately prior to the Closing Date;

Provided, however, Respondents may exclude from this term those employees that are determined by the Interim Monitor or an Acquirer, in consultation with Commission staff, not to be material to the planning, design, implementation or use of the Manufacturing Technology of the Isradipine Product.

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KK. “Manufacturing Technology” means all technology, trade secrets, know-how, and proprietary information (whether patented, patentable or otherwise) related to the manufacture of the Isradipine Product (including, for those instances in which the manufacturing equipment is not readily available from a Third Party, at the Acquirer’s option, all such equipment used to manufacture the Isradipine Product), including, but not limited to, all product specifications, processes, product designs, plans, trade secrets, ideas, concepts, manufacturing, 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 FDA Applications conformance and cGMP compliance, labeling, all other information related to the manufacturing process, and supplier lists.

LL. “Marketing Materials” means all marketing materials used specifically in the marketing or sale of the Isradipine Product in the Geographic Territory as of the Closing Date, including, without limitation, all advertising materials, training materials, product data, mailing lists, sales materials (*e.g.*, detailing reports, vendor lists, sales 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 net purchases information to be provided on the basis of either dollars and/or units for each month, quarter or year), sales forecasting models, educational materials, advertising and display materials, speaker lists, promotional and marketing materials, Website content and advertising and display materials, artwork for the production of packaging components, television masters and other similar materials

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related to the Isradipine Product; *provided, however*, this term excludes the pricing information of the Isradipine Product.

- MM. “NDC Numbers” means the National Drug Codes numbers, including both the labeler codes assigned by the FDA and the additional numbers assigned by the Application holder as a product code for a specific Product.
- NN. “Patents” means all patents, patent applications, including provisional patent applications, and statutory invention registrations, in each case existing as of the Closing 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, and all rights therein provided by international treaties and conventions, related to any Product of or owned by Respondents as of the Closing Date (except where this Order specifies a different time).
- OO. “PMRS” means Pharmaceutical Manufacturing Research Services, Inc., a corporation organized, existing and doing business under and by virtue of the laws of the State of Pennsylvania, with its headquarters address at 423 Sargon Way, Horsham, Pennsylvania 19044.
- PP. “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.
- QQ. “Product Registrations” means all registrations, permits, licenses, consents, authorizations, and other approvals, and pending applications and requests therefor, required by applicable Agencies related to the research, Development,

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manufacture, distribution, finishing, packaging, marketing, or sale of the Product within the Geographic Territory, including all Applications in existence for the Product as of the Closing Date.

RR. “Remedial Agreements” means:

1. Any agreement related to the Isradipine Assets entered into pursuant to Paragraph II. of this Order; and
2. Any agreement entered into by a Divestiture Trustee pursuant to Paragraph IV. of this Order.

SS. “Research and Development Employees” means all Respondents’ salaried employees who directly have participated in the research, Development, or regulatory approval process, or clinical studies of the Isradipine Product (irrespective of the portion of working time involved, unless such participation consisted primarily of oversight of legal, accounting, tax or financial compliance) within the eighteen (18) month period immediately prior to the Closing Date;

Provided, however, Respondents may exclude from this term those employees who are determined by the Interim Monitor or an Acquirer, in consultation with Commission staff, not to be material to the research, Development, or regulatory approval process, or clinical studies of the Isradipine Product.

TT. “Retained Products” means any Product other than the Isradipine Product.

UU. “Rights of Reference or Use” means the authority to rely upon, and otherwise use, an investigation for the purpose of obtaining approval of Applications, including the ability

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to make available the underlying raw data from the investigation for FDA audit.

VV. “Third Party” means any private entity other than the following: (1) Respondents; or (2) an Acquirer.

WW. “Trade Dress” means the current trade dress of the Isradipine Product, including but not limited to, Product packaging, and the lettering of the Product trade name or brand name.

XX. “Trademarks” means all proprietary names or designations, trademarks, service marks, trade names, and brand names, including registrations and applications for registration therefor (and all renewals, modifications, and extensions thereof) and all common law rights, and the goodwill symbolized thereby and associated therewith, for the Product.

YY. “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*, this term shall not include the following: (1) content owned by Third Parties and other 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 the Isradipine Product.

II.

IT IS FURTHER ORDERED that:

A. Not later than ten (10) days after the Acquisition Date, Respondents shall divest the Isradipine Assets, absolutely and in good faith, to Cobalt pursuant to, and in accordance with, the Isradipine Divestiture Agreement (which

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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 Cobalt or to reduce any obligations of Respondents under such agreement);

Provided, however, that if Respondents have divested the Isradipine Assets to Cobalt 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 Cobalt is not an acceptable purchaser of the Isradipine Assets then Respondents shall immediately rescind the transaction with Cobalt and shall divest the Isradipine Assets within one hundred eighty (180) days from the date the Order becomes final, absolutely and in good faith, at no minimum price, to an Acquirer and only in a manner that receives the prior approval of the Commission;

Provided further, however, that if Respondents have divested the Isradipine Assets to Cobalt 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 the manner in which the divestiture was accomplished is not acceptable, the Commission may direct Respondents, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the Isradipine Assets to Cobalt (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. Not later than thirty (30) days after the Acquisition Date, Respondents shall assign the Abrika-PMRS Supply Agreement to the Acquirer of the Isradipine Assets.

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- C. For a period of eight (8) months after the Closing Date, or December 31, 2007, whichever is later, Respondents shall not solicit any current customer of the Isradipine Product for the supply of Products similar to the Isradipine Product.
- D. At an Acquirer's option, and upon reasonable notice, Respondents shall provide, for a period of four (4) years after the Closing Date, the following technical assistance:
 - 1. An organized, comprehensive, complete, useful, timely, and meaningful transfer of information related to the Product Manufacturing Technology, and, as a part of such transfer, shall designate employees of Respondents knowledgeable with respect to such Product Manufacturing Technology and experienced in such transfers to a committee for the purposes of communicating directly with an Acquirer and the Interim Monitor for the purposes of effecting such transfer; and
 - 2. In a timely manner and at Direct Cost:
 - a. Assistance and advice to enable an Acquirer, or its designated Third Party manufacturer including, but not limited to, PMRS, to obtain all necessary permits and approvals from any Agency to manufacture and sell the Isradipine Product;
 - b. Assistance to an Acquirer to manufacture the Isradipine Product in substantially the same manner, quality, and quantity(ies) employed or achieved by Respondent Abrika for the Isradipine Product;
 - c. Consultation with Respondents' employees with relevant knowledge, and training at a facility chosen by an Acquirer, sufficient to satisfy

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management of an Acquirer that its personnel are adequately trained in the manufacture of the Isradipine Product; and

- d. Personnel, assistance and training as an Acquirer might reasonably need to transfer the assets related to the Isradipine Product.

E. Respondents shall:

1. At an Acquirer's option and upon reasonable notice, provide, in a timely manner and at no greater than Direct Cost, assistance of Respondents' employees with knowledge to assist an Acquirer to defend against, respond to, or otherwise participate in any litigation related to the Intellectual Property related to the Isradipine Product;
2. For any patent infringement suit in which Respondents are parties or are preparing to be parties to prior to the Closing Date, and where such a suit would have the potential to interfere with an Acquirer's freedom to practice in the research, Development, manufacture, use, import, export, distribution or sale of the Isradipine Product:
 - a. Cooperate with an Acquirer and provide any and all necessary technical and legal assistance, documentation and witnesses from Respondents in connection with obtaining resolution of any pending patent litigation involving the Isradipine Product;
 - b. Waive conflicts of interest, if any, to allow Respondents' outside legal counsel to represent an Acquirer in any ongoing patent litigation involving the Isradipine Product; and

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- c. Permit the transfer to an Acquirer of all of the litigation files and any related attorney work-product in the possession of Respondents' outside counsel relating to the Isradipine Product; and
3. Not join, file, prosecute or maintain any suit, in law or equity against an Acquirer for the research, Development, manufacture, use, import, export, distribution, or sale of the Isradipine Product, if such suit would have the potential to interfere with an Acquirer's freedom to practice the research, Development, manufacture, use, import, export, distribution, or sale of the relevant Isradipine Product, under:
 - a. Any Patent owned or licensed by Respondents as of the Acquisition Date that claims a method of making, using, or administering, or a composition of matter, relating to the Isradipine Product, or that claims a device relating to the use thereof; and
 - b. Any Patents owned or licensed at any time after the Acquisition Date by Respondents that claim any aspect of the research, Development, manufacture, use, import, export, distribution, or sale of the respective Isradipine Product, other than such Patents that claim inventions conceived by and reduced to practice after the Acquisition Date;

Provided, however, Respondents shall also covenant to an Acquirer that, as a condition of any assignment, transfer, or license to a Third Party of the above-described Patents, the Third Party shall agree to covenant not to sue an Acquirer under such Patents if Respondents were prohibited from bringing such suit.

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F. As related to the Isradipine Product, Respondents shall:

1. Submit and deliver to an Acquirer, at Respondents' expense, in good faith and as soon as practicable, in a manner that ensures its completeness and accuracy, all Confidential Business Information;
2. Provide an Acquirer and the Interim Monitor with access to all Confidential Business Information and to employees who possess or are able to locate or identify the books, records, and files that contain Confidential Business Information pending complete delivery of all the Confidential Business Information;
3. Not use, directly or indirectly, any Confidential Business Information related to the research, Development, manufacturing, marketing, or sale of the Isradipine Product other than to comply with the requirements of this Order;
4. Not disclose or convey any Confidential Business Information, directly or indirectly, to any person except an Acquirer; and
5. Not provide, disclose or otherwise make available, directly or indirectly, any Confidential Business Information related to the marketing or sales of the Isradipine Product to the employees associated with business related to those Retained Products that are approved by the FDA for the same or similar indications.

G. Not later than thirty (30) days after the Acquisition Date, Respondents shall provide written notification of the restrictions on the use of the Confidential Business Information by Respondents' personnel to all of Respondents' employees who:

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1. Are, or were, directly involved in the research, Development, manufacturing, distribution, sale or marketing of the Isradipine Product;
2. Are directly involved in the research, Development, manufacturing, distribution, sale or marketing of Retained Products that are approved by the FDA for the same or similar indications as the Isradipine Product prior to the Acquisition; and/or
3. May have Confidential Business Information.

Provided, however, 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 relevant Closing Date. Respondents shall maintain complete records of all such agreements at Respondents' corporate headquarters, and provide an officer's certification to the Commission stating that such acknowledgment program has been implemented and is being complied with. Respondents shall provide an Acquirer with copies of all certifications, notifications and reminders sent to Respondents' personnel.

- H. Respondents shall require, as a condition of continued employment post-divestiture of the assets required to be divested pursuant to this Order, that each Isradipine Core Employee retained by Respondents, the direct supervisor of any such employee, and any other employee retained by Respondents and designated by the Interim Monitor, sign a confidentiality agreement pursuant to which such employee shall be required to maintain all Confidential Business Information as strictly confidential, including the non-disclosure 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).

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I. Respondents shall:

1. For a period of at least six (6) months after the Closing Date (“Employee Access Period”), provide an Acquirer with the opportunity to enter into employment contracts with the Isradipine Core Employees; and
2. Provide an Acquirer with the Employee Information no later than the earlier of the following dates:
 - a. Ten (10) days after notice by staff of the Commission to Respondents to provide the Employee Information; or
 - b. Ten (10) days after the Closing Date.

Provided, however, failure by Respondents to provide the Employee Information within the time provided herein shall extend the Employee Access Period with respect to any such employee in an amount equal to the delay.

J. Respondents shall:

1. During the Employee Access Period, not interfere with the hiring or employing of the Isradipine Core Employees by an Acquirer, and remove any impediments within the control of Respondents that may deter these employees from accepting employment with an Acquirer, including, but not limited to, any non-compete or non-disclosure provision of employment that would affect the ability or incentive of those individuals to be employed by an Acquirer. In addition, Respondents shall not make any counteroffer to such an Isradipine Core Employee who

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has received a written offer of employment from an Acquirer;

Provided, however, that this paragraph shall not prohibit Respondents from continuing to employ any Isradipine Core Employee during the Employee Access Period (subject to the condition of continued employment prescribed in this Order);

2. Until the Closing Date, provide all Isradipine Core Employees with reasonable financial incentives to continue in their positions and to research, develop, and manufacture the Isradipine Product consistent with past practices and/or as may be necessary to preserve the marketability, viability and competitiveness of the Isradipine Product and to ensure successful execution of the pre-Acquisition plans for such Isradipine Product. Such incentives shall include a continuation of all employee compensation and benefits offered by Respondents until the Closing Date for the divestiture of the Isradipine Product has occurred, including regularly scheduled raises, bonuses, and vesting of pension benefits (as permitted by Law);

Provided, however, that nothing in this Order requires or shall be construed to require Respondents to terminate the employment of any employee or prevents Respondents from continuing the employment of the Isradipine Core Employees (other than those conditions of continued employment prescribed in this Order) in connection with the Acquisition; and

3. For a period of one (1) year from the Closing Date, not:
 - a. Directly or indirectly, solicit or otherwise attempt to induce any Acquirer Employee to terminate his

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or her employment relationship with an Acquirer;
or

- b. Hire any Acquirer Employees; *provided, however*, Respondents may hire any Acquirer Employee whose employment has been terminated by an Acquirer, or who independently applies for employment with Respondents, as long as such employee was not solicited in violation of the non-solicitation requirements contained herein;

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

- K. Prior to the Closing Date, Respondents shall secure all consents and waivers from all Third Parties that are necessary to permit Respondents to divest the assets required to be divested pursuant to this Order to an Acquirer, and/or to permit an Acquirer to continue the research, Development, manufacture, sale, marketing or distribution of the Isradipine Product; *provided, however*, Respondents may satisfy this requirement by certifying that an Acquirer has executed all such agreements directly with each of the relevant Third Parties.
- L. Respondents shall not enforce any agreement against a Third Party or an Acquirer to the extent that such agreement may limit or otherwise impair the ability of an Acquirer to acquire the Product Manufacturing Technology related to the Isradipine Product, the related equipment, or the use of such equipment, from the Third Party. Such agreements include, but are not limited to,

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agreements with respect to the disclosure of Confidential Business Information related to such Product Manufacturing Technology.

M. Not later than ten (10) days after the Closing Date, Respondents shall grant a release to each Third Party that is subject to an agreement as described in Paragraph II.L. that allows the Third Party to provide the relevant Product Manufacturing Technology and/or the related equipment or use thereof, to an Acquirer. Within five (5) days of the execution of each such release, Respondents shall provide a copy of the release to an Acquirer for the relevant assets.

N. Respondents shall not, in the Geographic Territory:

1. Use the Trademarks related to the Isradipine Product or any mark confusingly similar to such Trademarks, as a trademark, trade name, or service mark;
2. Attempt to register Trademarks related to the Isradipine Product;
3. Attempt to register any mark confusingly similar to Trademarks related to the Isradipine Product;
4. Challenge or interfere with an Acquirer's use and registration of Trademarks related to the Isradipine Product; or
5. Challenge or interfere with an Acquirer's efforts to enforce its trademark registrations for and trademark rights in Trademarks related to the Isradipine Product against Third Parties;

provided, however, that nothing in this Order shall preclude Respondents from continuing to use those trademarks, tradenames, or service marks related to the Retained Products as of the Acquisition Date.

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- O. The Remedial Agreements shall be deemed incorporated into this Order, and any failure by Respondents to comply with any term of the Remedial Agreements shall constitute a failure to comply with this Order. Respondents shall include in each Remedial Agreement a specific reference to this Order and the remedial purpose thereof. The Remedial Agreements entered into pursuant to Paragraph II. are attached to this Order and contained in non-public Appendices I. and II.
- P. Pending divestiture of the Isradipine Assets required to be divested pursuant to this Order, Respondents shall take such actions as are necessary to maintain the full economic viability and marketability of the business associated with such 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 these assets until after their respective transfer to an Acquirer in a manner that ensures that there is no disruption, delay, or impairment of the regulatory approval processes related to such assets. Respondents shall not sell, transfer, encumber or otherwise impair such assets (other than in the manner prescribed in this Order) nor take any action that lessens the full economic viability, marketability, or competitiveness of the above-described businesses.
- Q. The purpose of Paragraphs II. is: (1) to ensure the continued use of such assets in the research, Development, manufacture, distribution, sale and marketing of the Isradipine Product; (2) to create a viable and effective competitor in the relevant market alleged in the Complaint who is independent of Respondents; and, (3) to remedy the lessening of competition resulting from the Acquisition as alleged in the Commission's Complaint in a timely and sufficient manner.

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

- A. Denise F. Smart of Smart Consulting Group, LLC, shall serve as the monitor (“Interim Monitor”) to assure that Respondents expeditiously comply with all of their obligations and perform all of their responsibilities as required by this Order and the Remedial Agreements.
- B. If Ms. Smart fails to serve, or if a new Interim Monitor must be selected, the Commission shall select the Interim Monitor, subject to the consent of Respondent Actavis, which consent shall not be unreasonably withheld. If Respondent Actavis 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 Actavis 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 purposes of the Order.
- D. Respondents shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Interim Monitor:

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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 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 by Respondents of:
 - (1) The divestiture of all Isradipine Assets in a manner that fully satisfies the requirements of this Order; and
 - (2) Notification by each Acquirer to the Interim Monitor that such Acquirer is: (1) approved by the FDA to manufacture each of the Isradipine Product, and (2) able to manufacture such Isradipine Product in commercial quantities, in a manner consistent with cGMP, independently of Respondent; or
 - b. The completion by Respondents of the last obligation under the Order pertaining to the Interim Monitor's service;

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

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4. Subject to any demonstrated legally recognized privilege, the Interim Monitor shall have full and complete access to Respondents' personnel, books, documents, records kept in the normal course of business, facilities and technical information, and such other relevant information as the Interim Monitor may reasonably request, related to Respondents' compliance with their obligations under the Order, including, but not limited to, their obligations related to the Isradipine 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;
5. The Interim Monitor shall serve, without bond or other security, at the expense of Respondents on such reasonable and customary terms and conditions as the Commission may set. The Interim Monitor shall have authority to employ, at the expense of Respondents, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Interim Monitor's duties and responsibilities;
6. Respondents shall indemnify the Interim Monitor and hold the Interim Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Interim Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from misfeasance, gross negligence, willful or wanton acts, or bad faith by the Interim Monitor;

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7. Respondents shall report to the Interim Monitor in accordance with the requirements of this Order and/or as otherwise provided in any agreement approved by the Commission. The Interim Monitor shall evaluate the reports submitted to the Interim Monitor by Respondents, and any reports submitted by the Acquirer with respect to the performance of Respondents' obligations under the Order or the Remedial Agreements. 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 Respondents of their obligations under the Order; and
 8. Respondents may require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, that such agreement shall not restrict the Interim Monitor from providing any information to the Commission.
- E. The Commission may, among other things, require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Interim Monitor's duties.
- F. If the Commission determines that the Interim Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Interim Monitor in the same manner as provided in this Paragraph.

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- 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.
- H. 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 their obligations under Paragraph II. of this Order, the Commission may appoint a trustee (“Divestiture Trustee”) 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 Paragraph II. in a manner that satisfies the requirements of such Paragraph. In the event that the Commission or the Attorney General brings an action pursuant to § 5(l) of the Federal Trade Commission Act, 15 U.S.C. § 45(l), or any other statute enforced by the Commission, Respondents shall consent to the appointment of a Divestiture Trustee in such action to assign, grant, license, divest, transfer, deliver or otherwise convey the relevant assets. Neither the appointment of a Divestiture Trustee nor a decision not to appoint a Divestiture Trustee under this Paragraph shall preclude the Commission or the Attorney General from seeking civil penalties or any other relief available to it, including a court-appointed Divestiture Trustee, pursuant to § 5(l) of the Federal Trade Commission Act, or any other statute enforced by the Commission, for any failure by Respondents to comply with this Order.

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- B. The Commission shall select the Divestiture Trustee, subject to the consent of Respondent Actavis, which consent shall not be unreasonably withheld. The Divestiture Trustee shall be a person with experience and expertise in acquisitions and divestitures. If Respondent Actavis has 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 Respondent Actavis 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 this Order.
- D. If a Divestiture Trustee is appointed by the Commission or a court pursuant to this Paragraph, Respondents shall consent to the following terms and conditions regarding the Divestiture Trustee's powers, duties, authority, and responsibilities:
 - 1. Subject to the prior approval of the Commission, the Divestiture Trustee shall have the exclusive power and authority to assign, grant, license, divest, transfer, deliver or otherwise convey the assets that are required by this Order to be assigned, granted, licensed, divested, transferred, delivered or otherwise conveyed;
 - 2. The Divestiture Trustee shall have one (1) year after the date the Commission approves the trust agreement described herein to accomplish the divestiture, which shall be subject to the prior approval of the

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Commission. If, however, at the end of the one (1) year 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; *provided, however*, the Commission may extend the divestiture period only two (2) times;

3. Subject to any demonstrated legally recognized privilege, the Divestiture Trustee shall have full and complete access to the personnel, books, records and facilities related to the relevant assets that are required to be assigned, granted, licensed, divested, delivered or otherwise conveyed by this Order and to any other relevant information, as the Divestiture Trustee may request. Respondents shall develop such financial or other information as the Divestiture Trustee may request and shall cooperate with the Divestiture Trustee. Respondents shall take no action to interfere with or impede the Divestiture Trustee's accomplishment of the divestiture. Any delays in divestiture caused by Respondents shall extend the time for divestiture under this Paragraph in an amount equal to the delay, as determined by the Commission or, for a court-appointed Divestiture Trustee, by the court;
4. The Divestiture Trustee shall use commercially reasonable efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission, subject to Respondents' absolute and unconditional obligation to divest expeditiously and at no minimum price. 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

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Divestiture Trustee shall divest to the acquiring entity selected by Respondents from among those approved by the Commission; and, *provided further, however*, 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 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 Respondents, and the Divestiture Trustee's power shall be terminated. The compensation of the Divestiture Trustee shall be based at least in significant part on a commission arrangement contingent on the divestiture of all of the relevant assets that are required to be divested by this Order;
6. Respondents shall indemnify the Divestiture Trustee and hold the Divestiture Trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Divestiture Trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of, any

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claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from misfeasance, gross negligence, willful or wanton acts, or bad faith by the Divestiture Trustee;

7. The Divestiture Trustee shall have no obligation or authority to operate or maintain the relevant assets required to be divested by this Order; *provided, however*, that 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;
 8. 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; and
 9. 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.

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V.

IT IS FURTHER ORDERED that, in any instance wherein Respondents' counsel (including in-house counsel under appropriate confidentiality arrangements) either retain unredacted copies of documents or other materials provided to an Acquirer or obtain access to original documents (under circumstances where copies of documents are insufficient or otherwise unavailable) provided to an Acquirer, Respondents shall assure that Respondents' counsel do so only in order to do the following:

- A. Comply with the Remedial Agreements, this Order, any law (including, without limitation, any requirement to obtain regulatory licenses or approvals), any data retention requirement of any applicable government entity, or any taxation requirements; or
- B. Defend against, respond to, or otherwise participate in any litigation, investigation, audit, process, subpoena or other proceeding relating to the divestiture, the Isradipine Assets, and businesses associated with the Isradipine Assets;

Provided, however, that Respondents may disclose such information as necessary for the purposes set forth in this Paragraph pursuant to an appropriate confidentiality order, agreement or arrangement; and

Provided further, however, that pursuant to this Paragraph V., Respondents shall: (1) require those who view such unredacted documents or other materials to enter into confidentiality agreements with an Acquirer (but shall not be deemed to have violated this requirement if an Acquirer 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.

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

- A. Within five (5) days of the Acquisition, Respondents shall submit to the Commission a letter certifying the date on which the Acquisition occurred.
- B. Within thirty (30) days after the date this Order becomes final, and every sixty (60) days thereafter until Respondents have fully complied with Paragraph II. of this Order (*i.e.*, have assigned, licensed, divested, transferred, delivered, or otherwise conveyed all relevant assets or rights to an Acquirer in a manner that fully satisfies the requirements of the Order), Respondents shall:
 - 1. 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;
 - 2. At the same time, submit a copy of their verified report concerning compliance with this Order to the Interim Monitor, if any Interim Monitor has been appointed; and
 - 3. In their verified reports, include, among other things, a full description of the efforts being made to comply with the relevant Paragraphs of the Order, all substantive contacts or negotiations related to the divestiture of the relevant assets and the identity of all persons contacted, copies of all written communications to and from such persons, all internal memoranda, and all reports and recommendations concerning completing the obligations.

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- C. One (1) year after the date this Order becomes final, annually for the next nine years on the anniversary of the date this Order becomes final, and at other times as the Commission may require, Respondents shall file a verified written report with the Commission that includes information regarding any modifications or amendments to the Isradipine Divestiture Agreement or the Actavis Isradipine Product Supply Agreement, if applicable, that Respondents entered without the prior approval of the Commission, and sets forth in detail the manner and form in which they have complied and are complying with the Order.

VII.

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

- A. Any proposed dissolution of Respondent Actavis;
- B. Any proposed acquisition, merger or consolidation of Respondent Actavis; or
- C. Any other change in Respondent Actavis including, but not limited to, 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 Respondents made to their principal United States offices or headquarters address, Respondents shall, without restraint or interference, permit any duly authorized representative of the Commission:

Decision and Order

- A. Access, during business office hours of Respondents and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda and all other records and documents in the possession or under the control of Respondents related to compliance with this Order, which copying services shall be provided by Respondents at the request of authorized representative(s) of the Commission; and
- B. To interview officers, directors, or employees of Respondents, who may have counsel present, regarding such matters.

IX.

IT IS FURTHER ORDERED that this Order shall terminate on May 18, 2017.

By the Commission.

**NON-PUBLIC APPENDIX I
ISRADIPINE DIVESTITURE AGREEMENT
ABRIKA-COBALT AGREEMENT
[Redacted From the Public Record But Incorporated By
Reference]**

Analysis to Aid Public Comment

NON-PUBLIC APPENDIX II
ABRIKA-PMRS SUPPLY AGREEMENT
[Redacted From the Public Record But Incorporated By
Reference]

ANALYSIS OF AGREEMENT CONTAINING CONSENT
ORDER TO AID PUBLIC COMMENT

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an Agreement Containing Consent Order (“Consent Agreement”) from Actavis Group hf. (“Actavis”), which is designed to remedy the anticompetitive effects of the acquisition of Abrika Pharmaceuticals, Inc. (“Abrika”) by Actavis. Under the terms of the proposed Consent Agreement, the company would be required to assign and divest the Abrika rights and assets necessary to manufacture and market generic isradipine capsules to Cobalt Laboratories, Inc. (“Cobalt”), the U.S. subsidiary of Arrow Group.

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 an Agreement and Plan of Merger executed on November 20, 2006, Actavis proposes to acquire all of the voting securities of Abrika for \$235 million. The Commission’s Complaint alleges that the proposed acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15

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U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, by lessening competition in the U.S. markets for the manufacture and sale of generic isradipine capsules. The proposed Consent Agreement will remedy the alleged violation by replacing the lost competition that would result from the acquisition in this market.

Actavis is a leading developer, manufacturer, marketer, and distributor of generic pharmaceutical drugs. Headquartered in Iceland, Actavis sells generic pharmaceuticals in over 30 countries and has manufacturing facilities in Europe, the United States, and Asia. Abrika is a Sunrise, Florida based specialty generic pharmaceutical company engaged in the formulation and commercialization of both controlled release and immediate release products.

Generic Isradipine Capsules

Isradipine belongs to a group of drugs known as calcium channel blockers. Calcium is involved in blood vessel contraction, and by blocking calcium, isradipine relaxes and widens the blood vessels, thereby lowering blood pressure, preventing spasms of the blood vessels of the heart and reducing the oxygen needs of the heart muscle. Isradipine is typically prescribed to patients as a blood pressure lowering medication, and is also used to treat hypertension, ischemia and depression. Generic isradipine was first introduced in the United States in 2006. Sales in that year totaled approximately \$3 million.

Actavis and Abrika are the only two companies selling generic isradipine capsules in the United States. The number of generic suppliers has a direct and substantial effect on generic pricing as each additional generic supplier can have a competitive impact on the market. Because there are multiple generic equivalents for isradipine capsules, the branded version no longer significantly constrains the generic's pricing.

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Entry into the market for the manufacture and sale of generic isradipine capsules would not be timely, likely, or sufficient in its magnitude, character, and scope to deter or counteract the anticompetitive effects of the acquisition. Entry would not take place in a timely manner because the combination of generic drug development times and FDA drug approval requirements takes at least two years. Entry would not be likely because the relevant market is relatively small and in decline, limiting sales opportunities for any new entrant.

The proposed acquisition would cause significant anticompetitive harm to consumers in the U.S. market for the manufacture and sale of generic isradipine capsules. The acquisition would eliminate Abrika as a competitor and create a monopoly in the market for the manufacture and sale of generic isradipine capsules. The evidence indicates that the presence of more than one competitor allows customers to negotiate lower prices and that the reduction in the number of competitors in this market would allow the merged entity to unilaterally exercise market power with a resulting increase in prices.

The Consent Agreement

The proposed Consent Agreement effectively remedies the proposed acquisition's anticompetitive effects in the relevant product market. Pursuant to the Consent Agreement, Actavis and Abrika are required to divest certain rights and assets related to the generic isradipine capsules to a Commission-approved acquirer no later than ten (10) days after the acquisition. Specifically, the proposed Consent Agreement requires that Abrika divest its rights and assets relating to generic isradipine capsules to Cobalt.

The acquirer of the divested assets must receive the prior approval of the Commission. The Commission's goal in evaluating a possible purchaser of divested assets is to maintain the competitive environment that existed prior to the acquisition.

Analysis to Aid Public Comment

A proposed acquirer of divested assets must not itself present competitive problems.

Cobalt, which specializes in the sale and marketing of generic pharmaceuticals, is the United States arm of the Arrow Group, a private multinational that employs over 700 individuals. The Arrow Group has experience in the development, manufacturing, and sale of pharmaceuticals and has production facilities in Canada, Malta, Australia and Brazil. Cobalt is an acceptable acquirer of generic isradipine because it has experience in distributing and marketing generic pharmaceutical products in the United States. Currently, the company has received FDA approval for the sale of nine generic products. The acquisition by Cobalt does not present a competitive problem in the generic isradipine market because Cobalt currently does not participate in the market and has no independent plans to enter. With its resources, sales and marketing capabilities, and experience with generic products, Cobalt should be successful in restoring the competition that would be lost if the proposed Actavis/Abrika transaction were to proceed unremedied.

If the Commission determines that Cobalt is not an acceptable acquirer of the assets to be divested, or that the manner of the divestitures to Cobalt is not acceptable, the parties must unwind the sale and divest the assets within six (6) months of the date the Order becomes final to another Commission-approved acquirer. If the parties fail to divest within six (6) months, the Commission may appoint a trustee to divest the generic isradipine capsule assets.

The proposed remedy contains provisions to ensure that the divestitures are successful. Abrika's isradipine product is manufactured for Abrika by a third-party manufacturer. As part of the divestiture, Abrika will transfer its supply arrangement to Cobalt. Actavis and Abrika will transfer all confidential business information related to Abrika's isradipine product to Cobalt. Finally, Actavis and Abrika will provide technical assistance to

Analysis to Aid Public Comment

Cobalt to allow it to manufacture isradipine in substantially the same manner and quality employed or achieved by Abrika.

The Commission has appointed Denise F. Smart of Smart Consulting Group, LLC as the Interim Monitor to oversee the asset transfer and to ensure Actavis and Abrika's compliance with all of the provisions of the proposed Consent Agreement. Ms. Smart has over twenty years of experience in the pharmaceutical industry. Her experience includes providing consulting services in healthcare business development and regulatory compliance to major pharmaceutical companies, biotechnology companies and medical device companies. In order to ensure that the Commission remains informed about the status of the proposed divestitures and the transfers of assets, the proposed Consent Agreement requires Actavis and Abrika to file reports with the Commission periodically until the divestitures and transfers are accomplished.

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 Order or to modify its terms in any way.

Complaint

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

*Docket C-4192; File No. 062 3066
Complaint, June 4, 2007 — Decision, June 4, 2007*

This consent order addresses allegedly deceptive and unfair practices regarding respondent InPhonic's advertised mail-in rebates on wireless telephone packages marketed online. The order prohibits InPhonic from making a claim about the amount of any rebate, unless it discloses, clearly and conspicuously, on its website and on any rebate coupon or form, all terms, conditions, or other limitations of the rebate offer. In addition, the order prohibits InPhonic from misrepresenting what documentation consumers must submit and any material terms of any rebate program. It prohibits InPhonic from representing that consumers will have the opportunity to resubmit deficient rebate requests, unless it gives consumers a reasonable period of time in which to resubmit such requests and notifies them precisely how to correct any deficiencies. The order requires InPhonic to provide to consumers all required rebate documentation. It prohibits InPhonic from making any representation about the time in which any rebate will be provided, unless it has a reasonable basis for the representation at the time it is made, and it prohibits InPhonic from failing to provide any rebate within the time specified or, if no time is specified, within 30 days. The order also requires InPhonic to send rebates to eligible purchasers, including consumers whose rebate requests were previously denied on the basis of certain reasons. In addition, the order includes reporting and compliance provisions.

Participants

For the *Commission*: *Matthew D. Gold, Linda K. Badger, and Kerry O'Brien.*

For the *Respondent*: *Dana Frix, Chadbourne & Parke LLP; and F. Martin Dajani, DLA Piper Rudnick Gray Cary.*