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UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

COMMISSIONERS: Deborah Platt Majoras, Chairman
Pamela Jones Harbour
Jon Leibowitz
William E. Kovacic
J. Thomas Rosch

In the Matter of)
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)

ACTAVIS GROUP hf.)
a corporation;)

and)
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ABRIKA PHARMACEUTICALS, INC.)
a corporation.)
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)
)

Docket No. C-

DECISION AND ORDER

The Federal Trade Commission (“Commission”), having initiated an investigation0 T0 413.2800 TD(AB

- 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.
- 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”).

- 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 (“SNDA”), 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;
 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.

- 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;
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;
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 s

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 provide such Acquirer a

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;
 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.
- 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);

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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- 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.

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 IsrBT14OU0.0000 60 TD0000 ment statu

3. Trademarks, Trade Dress, trade secrets, know-how, techniques, data, inventions, practices, methods, and other confidential or proprietary technical, business, research, Development a

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
 - 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

dollars within the same period of the Isradipine Product collectively, the above described intellectual property

production of packaging components, television masters and other similar materials 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, 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 te

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 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.
- 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 0 0.00144.0000 144.2400 TD (At an Acquirer's option 0 0.00144.0000 144

- 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:
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).

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 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,

- 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, 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.

- 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.

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:
 - 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 product in commerce

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

7. Respondents shall report to the Interim Monitor in accordance with the requirements of this Order and/or as otherwise provided in any agreement approved by the Commission. The Interim Monitor shall evaluate the reports submitted to the Interim Monitor by Respondents, and any reports submitted by the 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 In

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.
- 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 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

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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 claim, whether51.087uth, the

agreement unreasonably); and (2) use its best efforts to obtain a protective order to protect the confidentiality

IX.

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

By the Commission.

Donald S. Clark
Secretary

SEAL
ISSUED:

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

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