1310152

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

COMMISSIONERS: **Edith Ramirez, Chairwoman**
Julie Brill
Maureen K. Ohlhausen
Joshua D. Wright

In the Matter of	)	
ACTAVIS, INC., a corporation;	)	**Docket No. C-**
and	)	
WARNER CHILCOTT PLC, a public limited company.	)	

DECISION AND ORDER
[Public Record Version]

E. AAcquirer(s)@ means the following:

1. a Person specified by name in this Order to acquire particular assets or rights that a Respondent(s) is required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to this Order and that has been approved by the Commission to accomplish the requirements of this Order in connection with the Commission=s determination to make this Order final and effective; or

2. a Person approved by the Commission to acquire particular assets or rights that a Respondent(s) is required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to this Order.

F. AAcquisition@ means Respondent Actavis=s acquisition of the voting securities of Respondent Warner Chilcott. The acquisition is contemplated pursuant to a *Transaction Agreement* by and among Warner Chilcott, Actavis Limited, Actavis Ireland Holding Limited, Actavis W.C. Holding LLC, and Actavis W.C. Holding 2 LLC, dated as of May 19, 2013, submitted to the Commission.

G. AAcquisition Date@ means the date on which the Acquisition is consummated.

H. AAgency(ies)@ means any government regulatory authority or authorities in the world responsible for granting approval(s), clearance(s), qualification(s), license(s), or permit(s) for any aspect of the research, Development, manufacture, marketing, distribution, or sale of a Product. The term AAgency@ includes, without limitation, the United States Food and Drug Administration (AFDA@).

I. "Amneal" means Amneal Pharmaceuticals L.L.C., a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its headquarters address located at 440 U.S. Highway 22 East, Suite 104, Bridgewater, New Jersey 08807.

J. "Atelvia Patents" means the following United States patents: US 5,583,122, US 5,622,721, US 7,645,459, US 7,645,460, US 8,246,989, and any re-examinations and re-issues of the foregoing patents, and any patents claiming priority thereto.

K. AApplication(s)@ means all of the following: ANew Drug Application@ (ANDA@), AAbbreviated New Drug Application@ (AANDA@), ASupplemental New Drug Application@ (ASNDA@), or AMarketing Authorization Application@ (AMAA@), the applications for a Product filed or to be filed with the FDA pursuant to 21 C.F.R. Part 314 et seq., and all supplements, amendments, and revisions thereto, any preparatory work, registration dossier, drafts and data necessary for the preparation thereof, and all correspondence between a Respondent and the FDA related thereto. The term AApplication@ also includes includes an AInvestigational New Drug Application@ (AIND@) filed or to be filed with the FDA pursuant to 21 C.F.R. Part 312, and all supplements, amendments, and revisions thereto, any preparatory work, registration dossier, drafts and data necessary for the preparation thereof, and all correspondence between a Respondent and the FDA related thereto.

provided, however, that A

directly related to the conduct of the Business related to a Divestiture Product(s). The term "Confidential Business Information" *excludes* the following:

1. information relating to any Respondent=s general business strategies or practices that does not discuss with particularity the Divestiture Products;

2. information specifically excluded from the Divestiture Product Assets conveyed to the Acquirer of the related Divestiture Product(s);

3. information that is contained in documents, records or books of any Respondent that is provided to an Acquirer by a Respondent that is unrelated to the Divestiture Products acquired by that Acquirer or that is exclusively related to Retained Product(s); and

4. information that is protected by the attorney work product, attorney-client, joint

2. waivers of any conflicts of interest to allow Respondent Actavis's outside legal counsel to represent the Acquirer in any ongoing patent litigation related to the Risedronate Products and the Estradiol Group Two Products.

Y. "Divestiture Product Core Employees" means the Product Research and Development Employees and the Product Manufacturing Employees related to each Divestiture Product.

Z. ADivestiture Product License@ means a perpetual, non-exclusive, fully paid-up and royalty-free license(s) with rights to sublicense to all Product Licensed Intellectual Property and all Product Manufacturing Technology related to general manufacturing know-how that was owned, licensed, or controlled by Respondent Actavis exclusively for the purposes of:

1. researching and Developing the specified Divestiture Products for marketing, distribution or sale within the Geographic Territory;

2. using, making, having made, distributing, offering for sale, promoting, advertising, or selling the specified Divestiture Products within the Geographic Territory;

3. importing or exporting the specified Divestiture Products to or from the Geographic Territory to the extent related to the marketing, distribution or sale of the specified Divestiture Products in the Geographic Territory; and

4. having the specified Divestiture Products made anywhere in the World for distribution or sale within, or import into the Geographic Territory;

*provided however,*or c 03952i-1.6(oduTJf)4(rld7(r)]TJ5.6(uct7(icense)Tjse(s)5(uct7(lle)42i-1.by c2i-1.6(

active pharmaceutical ingredient(s) or other necessary ingredient(s) or component(s) from any Third Party for use in connection with the manufacture of the specified Divestiture Product;

3. relating to any Clinical Trials involving the specified Divestiture Product;

4. with universities or other research institutions for the use of the specified Divestiture Product in scientific research;

5. relating to the particulari

raw data relating to Clinical Trials of that Product, all case report forms relating thereto and all statistical programs developed (or modified in a manner material to the use or function thereof (other than through user references)) to analyze clinical data, all market research data, market intelligence reports and statistical programs (if any) used for marketing and sales research; all copyrights in customer information, promotional and marketing materials, that Product's sales forecasting models, medical education materials, sales training materials, and advertising and display materials; all records relating to employees of a Respondent who accept employment with an Acquirer (excluding any personnel records the transfer of which is prohibited by applicable Law); all copyrights in records, including customer lists, sales force call activity reports, vendor lists, sales data, reimbursement data, speaker lists, manufacturing records, manufacturing processes, and supplier lists; all copyrights in data contained in laboratory notebooks relating to that Product or relating to its biology; all copyrights in adverse experience reports and files related thereto (including source documentation) and all copyrights in periodic adverse experience reports and all data contained in electronic databases relating to adverse experience reports and periodic adverse experience reports; all copyrights in analytical and quality control data; and all correspondence with the FDA or any other Agency.

WW. AProduct Development Reports@ means:

1. Pharmacokinetic study reports related to the specified Divestiture Product;
2. Bioavailability study reports (including reference listed drug information) related to the specified Divestiture Product;
3. Bioequivalence study reports (including reference listed drug information) related to the specified Divestiture Product;
4.

11. summary of Product complaints from customers related to the specified Divestiture Product;

12. Product recall reports filed with the FDA related to the specified Divestiture Product, and all reports, studies and other documents related to such recalls;

13. investigation reports and other documents related to any out of specification results for any impurities found in the specified Divestiture Product;

14. reports related to the specified Divestiture Product from any consultant or outside contractor engaged to investigate or perform testing for the purposes of resolving any product or process issues, including without limitation, identification and sources of impurities;

15. reports of vendors of the active pharmaceutical ingredients, excipients, packaging components and detergents used to produce the specified Divestiture Product that relate to the specifications, degradation, chemical interactions, testing and historical trends of the production of the specified Divestiture Product;

16. analytical methods development records related to the specified Divestiture Product;

17. manufacturing batch records related to the specified Divestiture Product;

18. stability testing records related to the specified Divestiture Product;

19. change in control history related to the specified Divestiture Product; and

20. executed validation and qualification protocols and reports related to the specified Divestiture Product.

XX. AProduct Employee Information@ means the following, for each Divestiture Product Core Employee, as and to the extent permitted by Law:

1. a complete and accurate list containing the name of each Divestiture Product Core Employee (including former employees who were employed by the specified Respondent within ninety (90) days of the execution date of any Remedial Agreement);

2. with respect to each such employee, the following information:

   a. the date of hire and effective service date;

   b. job title or position held;

   c. a specific description of the employee=s responsibilities related to the relevant Divestiture Product; *provided*, *however*, in lieu of this description, the specified Respondent may provide the employee=s most recent performance appraisal;

   d. the base salary or current wages;

   e. the most recent bonus paid, aggregate annual compensation for the relevant

Respondent=s last fiscal year and current target or guaranteed bonus, if any;

f. employment status (*i.e.*, active or on leave or disability; full-time or part-time);

g. and any other material terms and conditions of employment in regard to such employee that are not otherwise generally available to similarly situated employees;

3. at the Acquirer=s option or the Proposed Acquirer=s option (as applicable), copies of all employee benefit plans and summary plan descriptions (if any) applicable to the relevant employees.

YY. AProduct Intellectual Property@ means all of the following related to a Divestiture Product (other than Product Licensed Intellectual Property):

1. Patents;

2. Product Copyrights;

3. Product Trademarks, Product 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, trademarks, and copyrights and registrations thereof and to bring suit against a Third Party for the past, present or future infringement, misappropriation, dilution, misuse or other violations of any of the foregoing;

provided, however, AProduct Intellectual Property@ does not include the corporate names or corporate trade dress of AActavis@, “Warner Chilcott”, or the related corporate logos thereof, or the corporate names or corporate trade dress of any other corporations or companies owned or controlled by the Respondents or the related corporate logos thereof, or general registered images or symbols by which Actavis or Warner Chilcott can be identified or defined;

provided, *further*, *however*, Product Intellectual Property does not include the Zenchant® trademark and related copyrights.

ZZ. AProduct Licensed Intellectual Property@ means the following:

1. Patents that are related to the specified Divestiture Product that a Respondent can demonstrate have been routinely used, prior to the Acquisition Date,

thereof, that are related to the specified Divestiture Product and that a Respondent can demonstrate have been routinely used, prior to the Acquisition Date, for Retained Product(s) of a Respondent that has been marketed or sold on an extensive basis by a Respondent within the two-year period immediately preceding the Acquisition.

AAA. "Product Manufacturing Employees" means all salaried employees of a Respondent who have directly participated in the planning, design, implementation or operational management of the Product Manufacturing Technology of the specified Divestiture 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.

BBB. AProduct Manufacturing Technology@ means all of the following related to a Divestiture Product:

1. all technology, trade secrets, know-how, formulas, and proprietary information (whether patented, patentable or otherwise) related to the manufacture of that Product, including, but not limited to, the following: all product specifications, processes, analytical methods, 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 Application(s) conformance and cGMP compliance, and labeling and all other information related to the manufacturing process, and supplier lists;

2. all ingredients, materials, or components used in the manufacture of that Product including the active pharmaceutical ingredient, excipients or packaging materials; and,

3. 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 that Product.

CCC. AProduct Marketing Materials@ means all marketing materials used specifically in the marketing or sale of the specified Divestiture Product in the Geographic Territory as of the Closing Date, including, without limitation, all advertising materials, training materials, product data, mailing lists, sales materials (*sprktinat pl*

DDD. “Product Research and Development Employees” means all salaried employees of a Respondent who have directly participated in the research, Development, regulatory approval process, or clinical studied of the specified Divestiture Product (irrespective of the portion of working time involved, unless such participation consisted solely of oversight of legal, accounting, tax or financial compliance) with the eighteen (18) month period immediately prior to the Closing Date.

EEE. “Product Scientific and Regulatory Material” means all technological, scientific, chemical, biological, pharmacological, toxicological, regulatory and Clinical Trial materials and information related to a Product.

AProduct Trade Dress@ means the current trade dress @

assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed, including without limitation, any agreem

other materials, and projected time lines for the delivery of all such Product Manufacturing Technology (including all related intellectual property) to the Acquirer or its Manufacturing Designee; and

4. providing, in a timely manner, assistance and advice to enable the Acquirer or its Manufacturing Designee to:

    a. manufacture the specified Divestiture Product in the qual

provided, however, that if Respondent Actavis has divested the Divestiture Product Assets and granted the related Divestiture Product License to Amneal prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondent Actavis that Amneal is not an acceptable purchaser of the Divestiture Product Assets, then Respondent Actavis shall immediately rescind the transaction with Amneal, in whole or in part, as directed by the Commission, and shall divest the Divestiture Product Assets and grant the related Divestiture Product License within one hundred eighty (180) days from the Order Date, absolutely and in good faith, at no minimum price, to an Acquirer that receives the prior approval of the Commission, and only in a manner that receives the prior approval of the Commission;

provided further that if Respondent Actavis has divested the Divestiture Product Assets and granted the related Divestiture Product License to Amneal prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondent Actavis that the manner in which the divestiture was accomplished is not acceptable, the Commission may direct Respondent Actavis, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the Divestiture Product Assets or grant of the related Divestiture Product License, as applicable, to Amneal (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. Prior to the Closing Date, Respondent Actavis shall secure all consents and waivers from all Third Parties that are necessary to permit Respondent Actavis to divest the assets required to be divested pursuant to this Order to an Acquirer, and to permit the relevant Acquirer to continue the Business of the Divestiture Product(s) being acquired by that Acquirer;

provided, however, Respondent Actavis may satisfy this requirement by certifying that the relevant Acquirer for the Divestiture Product has executed all such agreements directly with each of the relevant Third Parties.

C. Respondent Actavis shall:

1. submit to each Acquirer, at Respondent Actavis's expense, all Confidential Business Information related to the Divestiture Products being acquired by that Acquirer;

2. deliver all Confidential Business Information related to the Divestiture Product(s) being acquired by that Acquirer to that Acquirer:

    a. in good faith;

    b. in a timely manner, *i.e.*, as soon as practicable, avoiding any delays in transmission of the respective information; and

c. in a manner that ensures its completeness and accuracy and that fully preserves its usefulness;

3. pending complete delivery of all such Confidential Business Information to the relevant Acquirer, provide that Acquirer and the Interim Monitor (if any has been appointed) with access to all such Confidential Business Information and employees who possess or are able to locate such information for the purposes of identifying the books, records, and files directly related to the Divestiture Product(s) being acquired by that Acquirer that contain such Confidential Business Information and facilitating the delivery in a manner consistent with this Order;

4. not use, directly or indirectly, any such Confidential Business Information related to the Business of the Divestiture Products other than as necessary to comply with the following:

   a. the requirements of this Order;

   b. Respondent Actavis's obligations to each respective Acquirer under the terms of any related Remedial Agreement; or

   c. applicable Law;

5. not disclose or convey any such Confidential Business Information, directly or indirectly, to any Person *except* (i) the Acquirer of the particular Divestiture Products, (ii) other Persons specifically authorized by that Acquirer to receive such information, (iii) the Commission or (iv)the Interim Monitor (if any has been appointed);

6. not provide, disclose or otherwise make available, directly or indirectly, any such Confidential Business Information related to the marketing or sales of the Divestiture Products to Respondents' employees responsible for making pricing decisions related to those Retained Products that are the therapeutic equivalent (as that term is defined by the FDA) as the Divestiture Products; and

7. not provide, disclose or otherwise make available, directly or indirectly, any such Confidential Business Information that was in the ownership or possession of Respondent Actavis prior to the Acquisition that is related to any patent infringement suit filed by Respondent Warner Chilcott against Respondent Actavis (and other prospective ANDA holder(s)) related to the Risedronate Products or the Estradiol Group Two Products to any of the Respondents' employees who: (i) was an employee of Respondent Warner Chilcott prior to the Acquisition; or (ii) is involved in the prosecution of any such law suit on behalf Respondents against any other prospective ANDA holder(s).

D. For each Acquirer of a Divestiture Product, Respondent Actavis shall provide, or cause to be provided to that Acquirer in a manner consistent with the Technology Transfer Standards the following:

1. all Product Manufacturing Technology (including all related intellectual property) related to the Divestiture Product(s) being acquired by that Acquirer; and

2. all rights to all Product Manufacturing Technology (including all related intellectual property) that is owned by a Third Party and licensed to Respondent Actavis related to the Divestiture Products being acquired by that Acquirer.

   Respondent Actavis shall obtain any consents from Third Parties required to comply with this provision. No Respondent shall enforce any agreement against a Third Party or an Acquirer to the extent that such agreement may limit or otherwise impair the ability of that Acquirer to use or to acquire from the Third Party the Product Manufacturing Technology (including all related intellectual property) related to the Divestiture Products acquired by that Acquirer. Such agreements include, but are not limited to, agreements with respect to the disclosure of Confidential Business Information related to such Product Manufacturing Technology. Not later than ten (10) days after the Closing Date, Respondents shall grant a release to each Third Party that is subject to such agreements that allows the Third Party to provide the relevant Product Manufacturing Technology to that Acquirer. Within five (5) days of the execution of each such release, Respondents shall provide a copy of the release to that Acquirer.

E. For each Acquirer of a Divestiture Product that is a Contract Manufacture Product, Respondent Actavis shall:

1. upon reasonable written notice and request from that Acquirer to Respondent Actavis, Contract Manufacture and deliver, or cause to be manufactured and delivered, to the requesting Acquirer, in a timely manner and under reasonable terms and conditions, a supply of each of the Contract Manufacture Products related to the Divestiture Products acquired by that Acquirer at Supply Cost, for a period of time sufficient to allow that Acquirer (or the Manufacturing Designee of the Acquirer) to obtain all of the relevant Product Approvals necessary to manufacture in commercial quantities, and in a manner consistent with cGMP, the finished drug product independently of Respondents, and to secure sources of supply of the active pharmaceutical ingredients, excipients, other ingredients, materials, and necessary components listed in Application(s) of the Respondents for the Divestiture Product(s) acquired by that Acquirer from Persons other than Respondents;

2. make representations and warranties to such Acquirer that the Contract Manufacture Product(s) supplied to the Acquirer pursuant to a Remedial Agreement meet the relevant Agency-approved specifications. For the Contract Manufacture Product(s) to be marketed or sold in the Geographic Territory, the supplying Respondent shall agree to indemnify, defend and hold the Acquirer harmless from any and all suits, claims, actions, demands, liabilities, expenses or losses alleged to result from the failure of the Contract Manufacture Product(s)

supplied to the Acquirer pursuant to a Remedial Agreement by that Respondent to meet cGMP. This obligation may be made contingent upon the Acquirer giving that Respondent prompt written notice of such claim and cooperating fully in the defense of such claim;

provided, however, that the supplying Respondent may reserve the right to control the defense of any such claim, including the right to settle the claim, so long as such settlement is consistent with that Respondent's responsibilities to supply the Contract Manufacture Products in the manner required by this Order;

provided further, however, that this obligation shall not require the supplying Respondent to be liable for any negligen

6. during the term of any agreement to Contract Manufacture, the supplying Respondent shall take all actions as are reasonably necessary to ensure an uninterrupted supply of the Contract Manufacture Product(s);

7. in the event that the supplying Respondent becomes unable to supply or produce a Contract Manufacture Product from the facility or facilities originally contemplated under a Remedial Agreement with an Acquirer, then Respondents shall provide a therapeutically equivalent (as that term is defined by the FDA) Product from another of Respondents' facility or facilities in those instances where such facilities are being used or have previously been used, and are able to be used, by Respondents to manufacture such Product(s);

8. during the term of any agreement to Contract Manufacture, provide access to all information and facilities, and make such arrangements with Third Parties, as are necessary to allow the Interim Monitor to monitor compliance with the obligations to Contract Manufacture;

however, nothing in this Order shall be interpreted to require Respondents to waive or relinquish their rights in the Atlevia® trademark and related copyrights.

G. Prior to the Closing Date, and at such time(s) as may be provided for under any applicable FDA rules or procedures, Respondents shall:

1. relinquish any and all claims that Respondent Actavis was the first applicant to submit an ANDA that references or is based on Atelvia (*i.e.*, Application Number N022560) pursuant to 21 C.F.R. § 314.107;

2. relinquish any and all claims to any rights pursuant to ANDA No. 203090 that Respondents or any subsequent holder of this ANDA may have to market on an

J. Respondents shall require, as a condition of continued employment post-divestiture of the assets required to be divested pursuant to this Order, that each employee that has had access to Confidential Business Information within the one (1) year period prior to the Closing Date sign a confidentiality agreement pursuant to which that employee shall be required to maintain all Confidential Business Information related to the Divestiture Products as strictly confidential, including the nondisclosure of that information to all other employees, executives or other personnel of Respondents (other than as necessary to comply with the requirements of this Order).

K. Not later than thirty (30) days after the Closing Date, Respondents shall provide written notification of the restrictions on the use and disclosure of the Confidential Business Information related to the Divestiture Products by Respondents' personnel to all of its employees who:

1. are covered by Paragraph II.C.6;

2. were directly involved in the research and Development of any of the Divestiture Products; and/or

3. are or were directly involved any patent infringement suit filed by Respondent Warner Chilcott against Respondent Actavis (and other prospective ANDA holder(s)) related to the Risedronate Products or the Estradiol Group Two Products;

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

For each Acquirer of aearch a

Divestiture Product Core Employees. Failure by Respondents to provide the Product Employee Information for any Divestiture Product Core Employee within the time provided herein shall extend the Divestiture Product Core Employee Access Period(s) with respect to that employee in an amount equal to the delay;

3. during the Divestiture Product Core Employee Access Period(s), not interfere with the hiring or employing by that Acquirer or its Manufacturing Designee of the Divestiture Product Core Employees, and remove any impediments within the control of any Respondent that may deter these employees from accepting employment with that Acquirer or its Manufacturing Designee, including, but not limited to, any noncompete or nondisclosure provision of employment with respect to a Divestiture Product or other contracts with any Respondent that would affect the ability or incentive of those individuals to be employed by that Acquirer or its Manufacturing Designee. In addition, Respondents shall not make any counteroffer to such a Divestiture Product Core Employee who has received a written offer of employment from that Acquirer or its Manufacturing Designee;

   provided, however, that, subject to the conditions of continued employment prescribed in this Order, this Paragraph shall not prohibit Respondents from continuing to employ any Divestiture Product Core Employee under the terms of that employee=s employment with Respondents prior to the date of the written offer of employment from the Acquirer or its Manufacturing Designee to that employee;

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

   provided, however, that this Paragraph does not require nor shall be construed to require a Respondent to terminate the employment of any employee or to prevent a Respondent from continuing to employ the Divestiture Product Core Employees in connection with the Acquisition; and

5. for a period of one (1) year from the Closing Date, not, directly or indirectly, solicit or otherwise attempt to induce any employee of the Acquirer or its Manufacturing Designee with any amount of responsibility related to a Divestiture Product (ADivestiture Product Employee@) to terminate his or her employment relationship with the Acquirer or its Manufacturing Designee; or hire any Divestiture Product Employee;

provided, however, Respondents may hire any former Divestiture Product Employee whose employment has been terminated by the Acquirer or its Manufacturing Designee or who independently applies for employment with Respondents, as long as that employee was not solicited in violation of the nonsolicitation requirements contained herein;

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

M. Until Respondent Actavis completes the divestitures required by this Order and fully provide, or causes to be provided, the Product Manufacturing Technology related to a particular Divestiture Product to the relevant Acquirer,

1. Respondent Actavis shall take actions as are necessary to:

   a. maintain the full economic viability and marketability of the Businesses associated with that Divestiture Product;

   b. minimize any risk of loss of competitive potential for that Business;

   c. prevent the destruction, removal, wasting, deterioration, or impairment of any of the assets related to that Divestiture Product;

   d. ensure the assets related to each Divestiture Product are provided to the relevant Acquirer in a manner without disruption, delay, or impairment of the regulatory approval processes related to the Business associated with each Divestiture Product;

   e. ensure the completeness of the transfer and delivery of the Product Manufacturing Technology; and

2. Respondent Actavis shall not sell, transfer, encumber or otherwise impair the assets required to be divested (other than in the manner prescribed in this Order) nor take any action that lessens the full economic viability, marketability, or competitiveness of the Businesses associated with that Divestiture Product.

N. Respondents shall not join, file, prosecute or maintain any suit, in law or equity, against an Acquirer or the Divestiture Product Releasee(s) of that Acquirer under the following:

1. any Patent owned by or licensed to the Respondents as of the day after the Acquisition Date that claims a method of making, using, or administering, or a composition of matter of a Product, or that claims a device relating to the use thereof;

2. any Patent that was filed or in existence prior to the Acquisition Date that is acquired by or licensed to the Respondents at any time after the Acquisition Date

that claims a method of making, using, or administering, or a composition of matter of a Product, or that claims a device relating to the use thereof;

if such suit would have the potential directly to limit or interfere with that Acquirer=s freedom to practice the following: (i) the research, Development, or manufacture anywhere in the World of the Divestiture Product(s) acquired by that Acquirer for the purposes of marketing or sale in the United States of America of such Divestiture Product(s); or (ii) the use within, import into, export from, or the supply, distribution, sale or offer for sale within the United States of America of the Divestiture Product(s) acquired by that Acquirer. Respondents shall also covenant to that Acquirer that as a condition of any assignment or license to a Third Party of the above-described Patents by the Respondents, the Third Party shall agree to provide a covenant whereby the Third Party covenants not to sue that Acquirer or the related Divestiture Product Releasee(s) under such Patents, if the suit would have the potential to interfere with that Acquirer=s freedom to practice the following: (i) the research, Development, or manufacture anywhere in the World of the Divestiture Product(s) acquired by that Acquirer for the purposes of the marketing, sale or offer for sale of such Divestiture Product(s) in the United States of America; or (ii) the use within, import into, export from, or the supply, distribution, or sale or offer for sale within, the United States of America of the Divestiture Product(s) acquired by that Acquirer. The provisions of this Paragraph do not apply to: (i) any Patent owned by, acquired by, or licensed to or from the Respondents that claims inventions conceived by and reduced to practice after the Acquisition Date, or (ii) any dosage forms, strengths or indications not described in the ANDAs related to the Divestiture Product as of the Closing Date;

provided however, that, for the purposes of this Paragraph II.N. only, and only with respect to any suit filed by Respondent Warner Chilcott prior to May 19, 2013 involving the Risedronate Products, the term "Patent" shall exclude the Atelvia Patents;

provided further, however, that, for the purposes of this Paragraph II.M. only, and only with respect to any suit filed by Respondent Warner Chilcott prior to May 19, 2013 involving the Estadiol Group Two Products, the term "Patent" shall exclude the Lo Loestrin Patents.

O. Upon reasonable written notice and request from an Acquirer to Respondent Actavis, Respondent Actavis shall provide, in a timely manner, at no greater than Direct Cost, assistance of knowledgeable employees of Respondent Actavis to assist that Acquirer to defend against, respond to, or otherwise participate in any litigation brought by a Third Party related to the Product Intellectual Property related to any of the Divestiture Product(s) acquired by that Acquirer, if such litigation would have the potential directly to limit or interfere with that Acquirer=s freedom to practice the following: (i) the research, Development, or manufacture anywhere in the World of the Divestiture Product(s) acquired by that Acquirer for the purposes of marketing, sale or offer for sale within the United States of America of such Divestiture Product(s); or (ii) the use within,

import into, export from, or the supply, distribution, or sale or offer for sale within, the United States of America of the Divestiture Product(s) acquired by that Acquirer.

P. For any patent infringement suit related to a Divestiture Product filed prior to the Closing Date in which Respondent Actavis is alleged to have infringed a Patent of a Third Party or for any potential patent infringement suit from a Third Party that Respondent Actavis has prepared or is preparing as of the Closing Date to defend against, and where such a suit would have the potential directly to limit or interfere with the an Acquirer=s freedom to practice the following: (i) the research, Development, or manufacture anywhere in the World of the Divestiture Product(s) acquired by that Acquirer for the purposes of marketing, sale or offer for sale within the United States of America of such Divestiture Product(s); or (ii) the use within, import into, export from, or the supply, distribution, sale or offer for sale within, the United States of America of the Divestiture Product(s) acquired by that Acquirer, Respondent Actavis shall:

1. cooperate with that Acquirer and provide any and all necessary technical and legal assistance, documentation and witnesses from Respondent Actavis in connection with obtaining resolution of any pending patent litigation related to that Divestiture Product;

2. waive conflicts of interest, if any, to allow the Respondent Actavis=s outside legal counsel to represent that Acquirer in any ongoing patent litigation related to that Divestiture Product; and

3. permit the transfer to that Acquirer of all of the litigation files and any related attorney work-product in the possession of the Respondent Actavis's outside counsel related to that Divestiture Product.

Q. The purpose of the divestiture of the Divestiture Product Assets and the provision of the related Product Manufacturing Technology and the related obligations imposed on the Respondents by this Order is:

1. to ensure the continued use of such assets for the purposes of the Business associated with each Divestiture Product within the Geographic Territory; and

2. to create a viable and effective competitor, that is independent of Respondents in the Business of each Divestiture Product within the Geographic Territory; 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. At any time after the Respondents sign the Consent Agreement in this matter, the Commission may appoint a monitor (AInterim Monitor@) to assure that the Respondents expeditiously comply with all of their obligations and performs all of their responsibilities as required by this Order, the Order to Maintain Assets and the Remedial Agreements.

B. The Commission shall select the Interim Monitor, subject to the consent of Respondents, which consent shall not be unreasonably withheld. If Respondents have not opposed, in writing, including the reasons for opposing, the selection of a proposed Interim Monitor within ten (10) days after notice by the staff of the Commission to 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. If an Interim Monitor is appointed, 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.7(li Tc-.00di Tce.005 TwC7

a. the date the Acquirer of that Divestiture Product (or that Acquirer's

H. Respondents shall report to the Interim Monitor in accordance with the requirements of this Order and 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 Respondent's obligations under the Order

seeking civil penalties or any other relief available to it, including a court-appointed Divestiture Trustee, pursuant to '

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 Respondent Actavis=s absolute and unconditional obligation to divest expeditiously and at no minimum price. The divestiture shall

9. Respondent Actavis 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. The Commission may, among other things, require the Divestiture Trustee and each of the Divestiture Trustee=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 Divestiture Trustee=s duties.

F. 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.

G. Respondent Actavis 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,* that such agreement shall not restrict the Divestiture Trustee from providing any information to the Commission.

H. 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.

V.

IT IS FURTHER ORDERED that, in addition to any other requirements and prohibitions relating to Confidential Business Information in this Order, the Respondents shall assure that their own counsel (including its own in-house counsel under appropriate confidentiality arrangements) shall not retain unredacted copies of documents or other materials provided to an Acquirer or access original documents provided to an Acquirer, except under circumstances where copies of documents are insufficient or otherwise unavailable, and for the following purposes:

A. To assure the Respondent=s compliance with any Remedial Agreement, this Order, any Law (including, without limitation, any requirement to obtain regulatory licenses or approvals, and rules promulgated by the Commission), any data retention requirement of any applicable Government Entity, or any taxation requirements; or

B. To defend against, respond to, or otherwise participate in any litigation, investigation, audit, process, subpoena or other proceeding relating to the divestiture or any other aspect of the Divestiture Products or the assets and Businesses associated with those Divestiture Products;

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

provided further, however, that pursuant to this Paragraph V, the Respondent(s) needing such access to original documents shall: (i) require those who view such unredacted documents or other materials to enter into confidentiality agreements with the relevant Acquirer (but shall not be deemed to have violated this requirement if that Acquirer withholds such agreement unreasonably); and (ii) use best efforts to obtain a protective order to protect the confidentiality of such information during any adjudication.

VI.

IT IS FURTHER ORDERED that:

A. Any Remedial Agreement shall be deemed incorporated into this Order.

B. Any failure by the Respondents to comply with any term of such Remedial Agreement shall constitute a failure to comply with this Order.

C. Each Remedial Agreement related to each of the Divestiture Products shall include a specific reference to this Order, the remedial purposes thereof, and provisions to reflect the full scope and breadth of the Respondents' obligation to the Acquirer pursuant to this Order.

D. For each Divestiture Product that is a Contract Manufacture Product, Respondent Actavis shall include in the Remedial Agreement(s) related to that Divestiture Product a representation from the Acquirer that the Acquirer shall use commercially reasonable efforts to secure the FDA approval(s) necessary to manufacture, or to have manufactured by a Third Party, in commercial quantities, each such Divestiture Product, as applicable, and to have any such manufacture to be independent of the Respondents, all as soon as reasonably practicable.

E. No Respondent shall seek, directly or indirectly, pursuant to any dispute resolution mechanism incorporated in any Remedial Agreement, or in any agreement related to any of the Divestiture Products a decision the result of which would be inconsistent with the terms of this Order or the remedial purposes thereof.

F. No Respondent shall modify or amend any of the terms of any Remedial Agreement without the prior approval of the Commission, except as otherwise provided in Rule 2.41(f)(5) of the Commission's Rules of Practice and Procedure, 16 C.F.R. § 2.41(f)(5). Notwithstanding any term of the Remedial Agreement(s), any modification or amendment of any Remedial Agreement made without the prior approval of the Commission, or as otherwise provided in Rule 2.41(f)(5), shall constitute a failure to comply with this Order.

NON-PUBLIC APPENDIX I
DIVESTITURE AGREEMENTS

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