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UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

COMMISSIONERS: **Jon Leibowitz, Chairman**
William E. Kovacic
J. Thomas Rosch
Edith Ramirez
Julie Brill

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In the Matter of

)

DECISION AND ORDER
[Public Record Version]

The Federal Trade Commission ("Commission"), having initiated an investigation of the proposed acquisition by Respondent Novartis AG ("Novartis" or "Respondent") of a majority of the outstanding voting shares of Alcon, Inc., and Respondent having been furnished thereafter with a copy of a draft of Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondent with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondent, its attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Orders ("Consent Agreement"), containing an admission by Respondent of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondent that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission's Rules; and

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1. Respondent Novartis is a corporation organized, existing and doing business under and by virtue of the laws of the Swiss Confederation, with its principal executive offices located at Lichtstrasse 35, CH-4056 Basel, Switzerland, and the address of its United States subsidiary, Novartis Pharmaceuticals Corporation (a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware), located at 59 Route 10, East Hanover, New Jersey 07936.

2. Alcon, Inc., is a corporation organized, existing and doing business under and by virtue of the laws of the Swiss Confederation, with its principal executive offices located at Bösch 69, P.O. Box 62, Hünenberg, Switzerland, and the principal offices of its United States subsidiary, Alcon Laboratories, Inc. (a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware), located at 6201 South Freeway, Fort Worth, Texas 76134-

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

E. "Acquisition" means Respondent Novartis's acquisition of shares of the common stock of Alcon from Nestlé. The "Acqu

L. "Closing Date" means the date on which Respondent (or a Divestiture Trustee) consummates a transaction to assign, grant, license, divest, transfer, deliver, or otherwise convey the Miotics Product Assets.

M. "Component(s)" means any active ingredient, adjuvant, and/or other component of a Product that is intended to affect the efficacy or safety of an active ingredient of such Product; *provided however*, that Respondent may retain the right, concurrently with the Acquirer's rights, to use adjuvants and excipients that are used in both the Miotics Products and Retained Products.

N. "Confidential Business Information" means all information owned by, or in the possession or control of, the Respondent that is not in the public domain and that is directly related to the research, Development, manufacture, marketing, commercialization, importation, exportation, cost, supply, sales, sales support, or use of the Miotics Products;

provided however, that the restrictions contained in this Order regarding the Respondent's use, conveyance, provision, or disclosure of "Confidential Business Information" shall not apply to the following:

1. information that subsequently falls within the public domain through no violation of this Order or breach of confidentiality or non-disclosure agreement with respect to such information by Respondent;

2. information related to the Miotics Products that Alcon obtained without the assistance of Respondent Novartis prior to the Acquisition;

3. information that is required by Law to be publicly disclosed;

4. information that does not directly relate to the Miotics Products;

5. information related to Retained Products

6. information relating to either Respondent's general business strategies or practices relating to research, Development, manufacture, marketing or sales of pharmaceutical Products that does not discuss the Miotics Products with particularity;

7. information specifically excluded from the Miotics Product Assets; or

8. information that is protected by the attorney work product, attorney-client, joint defense or other privilege prepared in connection with the Acquisition and relating to any United States, state, or foreign antitrust or competition Laws.

O. “Contract Manufacture” means:

1. to manufacture a Miotics Product, or ingredient or Component thereof, or

2. to supply or provide any part of the manufacturing process of a Miotics Product including, without limitation, the finish, fill, and/or packaging of a Miotics Product.

P. “Contract Manufacture Products and Services” means:

1. any Miotics Product, ingredient or Component thereof, and

2. any finish, fill, and/or packaging for a Miotics Product,

for which any part of the manufacturing process is performed by the Respondent prior to the Closing Date at a facility that is not subject to divestiture pursuant to this Order.

Q. “Copyrights” means rights to all original works of authorship of any kind directly related to the specified Product(s) and any registrations and applications for registrations thereof within the Geographic Territory, including, but not limited to, the following: all such rights with respect to all promotional materials for healthcare providers, all promotional materials for patients, and educational materials for the sales force; cop

S. “Development” means all preclinical and clinical drug development activities (including formulation), including test method development and stability testing, toxicology, formulation, process development, manufacturing scale-up, development-stage manufacturing, quality assurance/quality control development, statistical analysis and report writing, 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. “Develop” means to engage in Development.

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AA. "High Volume Account(s)" means any retailer, wholesaler or distributor whose annual and/or projected annual aggregate purchase amounts (on a company-wide level), in units or in dollars, of a Miotics Product in the United States from the Respondent was, or is projected to be among the top twenty highest of such purchase amounts by the Respondent's U.S. customers on any of the following dates: (1) the end of the last quarter that immediately preceded the date of the public announcement of the proposed Acquisition; (2) the end of the last quarter that immediately preceded the Acquisition Date; (3) the end of the last quarter that immediately preceded the Closing Date; or (4) the end of the last quarter following the Acquisition and/or the Closing Date.

BB. "Interim Monitor" means any monitor appointed pursuant to Paragraph III of this Order or Paragraph III of the related Order to Maintain Assets.

CC. "Law" means all laws, statutes, rules, regulations, ordinances, and other pronouncements by any Government Entity having the effect of law.

DD. "Miotics Product(s)" means all Products that are intraocular solutions containing the active pharmaceutical ingredient generically known as acetylcholine together with any salts, esters, metabolites, derivatives, isomers, hydrates, solvates, ethers, quaternary amines, polymorphs and prodrugs thereof offered by Respondent Novartis for sale in the United States of America, including without limitation, under the brand name Miochol®-E, during the one (1) year period immediately preceding the Acquisition Date. The term "Miotics Product(s)" excludes any Product offered by Alcon prior to the Acquisition Date.

EE. "Miotics Product Assets" means all of the Respondent's rights, title and interest in and to all assets related to the Respondent's business throughout the World related to the Miotics Products to the extent legally transferable, including the research, Development, manufacture, distribution, marketing, and sale of the Miotics Products, including, without limitation, the following assets related to the Miotics Products:

1. all Product Intellectual Property;

2. all Freedom to Operate Searches;

3. all Product Improvements;

4. all Product Approvals;

5. all Product Manufacturing Technology;

6. all Product Marketing Materials;

7. all Website(s);

8. a list of all of the NDC Numbers used for Miotics Products, and rights, to the extent permitted by Law:

    a. to require Respondent to cease and desist from using the NDC Numbers in the sale or marketing of Products other than with respect to returns, rebates, allowances, and adjustments for Miotics Products sold prior to the Acquisition Date;

    b. to prohibit Respondent from seeking from any customer any type of cross-referencing of such NDC Numbers with any Retained Product(s);

    c. to seek to change any cross-referencing by a customer of such NDC Numbers with the Retained Product(s) (including the right to receive notification from Respondent of any such cross-referencing that is discovered by Respondent);

    d. to seek cross-referencing from a customer of such NDC Numbers with the Acquirer's NDC Numbers;

    e. to approve the timing of Respondent's cessation of use of such NDC Numbers in the sale or marketing of Products other than with respect to returns, rebates, allowances, and adjustments for Miotics Products sold prior to the Acquisition Date; and

    f. to approve any notification(s) from Respondent to any customer(s) regarding the use or cessation of use of such NDC numbers by Respondent prior to such notification(s) being disseminated to the customer(s);

9. all rights to all of Respondent's Applications;

10. Right of Reference or Use to the Drug Master Files related to the above-described Applications including, but not limited to, the pharmacology and toxicology data contained in all Application(s);

11. all Product Development Reports;

12. at the Acquirer's option, all Product Assumed Contracts;

13. 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;

14. 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;

15. a list of all customers and/or targeted customers for the Miotics Product(s) and the net sales (in either units or dollars) of the Miotics Products 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

FF. “Miotics Product Core Employee(s)” means the Product Research and Development Employees and the Product Manufacturing Employees related to the Miotics Products.

GG. “Miotics Product Divestiture Agreement(s)” means the following agreements:

1. “Asset Purchase Agreement” between Novartis Pharmaceuticals Corporation, Novartis Pharma AG and Bausch & Lomb Incorporated, dated as of July 21, 2010, and all amendments, exhibits, attachments, agreements, and schedules thereto;

2. “Supply Agreement” between Novartis Pharma AG and Bausch & Lomb Incorporated in the form attached to the Asset Purchase Agreement, and all amendments, exhibits, attachments, agreements, and schedules thereto;

3. “Quality Agreement” in the form attached to the Supply Agreement, and all amendments, exhibits, attachments, agreements, and schedules thereto;

4. “Transitional Technical Services Agreement” between Novartis Pharm AG and Bausch & Lomb Incorporated in the form attached to the Asset Purchase Agreement, and all amendments, exhibits, attachments, agreements, and schedules thereto;

provided, however, the term “Miotics Product Divestiture Agreements” excludes those provisions of any agreement that relate exclusively to the allocation of the purchase price for the purposes of taxes.

The Miotics Product Divestiture Agreements are attached to this Order and contained in non-public Appendix II.A.

HH. “Miotics Product Licenses” means a perpetual, non-exclusive, fully paid-up and royalty-free license(s) with rights to sublicense to: (1) all Product Licensed Intellectual Property and (2) all Product Manufacturing Technology that relates to both the Miotics Products and the Retained Products including, without limitation, general manufacturing know-how, for all of the following purposes:

1. to research and Develop the Miotics Products for marketing, distribution or sale within the United States of America;

2. to use, make, have made, distribute, offer for sale, promote, advertise, or sell the Miotics Products within the United States of America;

3. s)” means the Product Research P000 0.0000 TD(tio)Tj12.7200 0.0000 TD(o)Tj15.980 0.00 rgBT9

provided further however, that for any Product Licensed Intellectual Property that is the subject of a license from a Third Party to the Respondent, the scope of the rights granted hereunder shall only be required to be equal to the scope of the rights granted by the Third Party to the Respondent.

II. "Miotics Product Releasee(s)" means the Acquirer or any Person controlled by or under common control with the Acquirer, or any licensees, sublicensees, manufacturers, suppliers, distributors, and customers of the Acquirer, or of Acquirer-affiliated entities.

JJ. "NDC Numbers" means the National Drug Code numbers, including both the labeler code assigned by the FDA and the additional numbers assigned by an Application holder as a product code for a specific Product.

KK. "Nestlé" means Nestlé S.A., a corporation organized, existing and doing business under and by virtue of the laws of the Swiss Confederation, with its principal executive offices located at Avenue Nestlé 55, CH-1800 Vevey, Switzerland; its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Nestlé.

LL. "Order Date" means the date on which this Decision and Order becomes final.

MM. "Order to Maintain Assets" means the Order to Maintain Assets incorporated into and made a part of the Agreement Containing Consent Orders.

NN. "Patent(s)" means all patents, patent applications, including provisional patent applications, invention disclosures, certificates of invention and applications for certificates of invention 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, additions, 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 Respondent as of the Closing Date (*except* where this Order specifies a different time).

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the Geographic Territory, and includes, without limitation, all approvals, registrations, licenses or authorizations granted in connection with any Application.

RR. "Product Assumed Contracts" means all of the following contracts or agreements (copies of each such contract to be provided to the Acquirer on or before the Closing Date and segregated in a manner that clearly identifies the purpose(s) of each such contract) that are related to the research, Development, manufacture, distribution, finishing, packaging, marketing, sale, storage or transport of the Miotics Product(s) within the Geographic Territory:

1. that make specific reference to the Miotics Product(s) and pursuant to which any Third Party is obligated to purchase, or has the option to purchase without further negotiation of terms, the Miotics Product(s) from the Respondent unless such contract applies generally to the Respondent's sales of Products to that Third Party;

2. pursuant to which Respondent purchases the active pharmaceutical ingredient(s), Component, or other necessary ingredient(s) or had planned to purchase the active pharmaceutical ingredient(s), Component or other necessary ingredient(s) from any Third Party for use in connection with the manufacture of the Miotics Product(s);

3. relating to any Clinical Trials involving the Miotics Product(s);

4. with universities or other research institutions for the use of the Miotics Product(s) in scientific research;

5. relating to the particularized marketing of the Miotics Product(s) or educational matters relating solely to the Miotics Product(s);

6. pursuant to which a Third Party manufactures or packages the Miotics Product(s) on behalf of the Respondent;

7. pursuant to which a Third Party provides the Product Manufacturing Technology related to the Miotics Product(s) to the Respondent;

8. pursuant to which a Third Party is licensed by Respondent to use the Product Manufacturing Technology related to the Miotics Product(s);

9. constituting confidentiality agreements pertaining to the Miotics Product(s) *except* such agreements that Respondent is specifically required to enforce on behalf of the Acquirer pursuant to a Remedial Agreement;

10. involving any royalty, licensing, or similar arrangement involving the Miotics Product(s);

11. pursuant to which a Third Party provides any specialized services necessary to the research, Development, manufacture or distribution of the Miotics Products to the Respondent including, but not limited to, consultation arrangements; and/or

12. pursuant to which any Third Party collaborates with Respondent in the performance of research, Development, marketing, distribution or selling of the Miotics Product(s) or the Miotics Product(s) business;

provided, however, that where any such contract or agreement also relates to a Retained Product(s), Respondent shall assign the Acquirer all such rights under the contract or agreement as are related to the Miotics Product(s), but concurrently may retain similar rights for the purposes of the Retained Product(s).

SS. "Product Development Reports" means:

1. Pharmacokinetic study reports related to the Miotics Product(s);

2. Bioavailability study reports (including reference listed drug information) related to the Miotics Product(s);

3. Bioequivalence study reports (including reference listed drug information) related to the Miotics Product(s);

4. all correspondence to the Respondent from the FDA and from the Respondent to the FDA relating to the Application(s) submitted by, on behalf of, or acquired by, the Respondent related to the Miotics Product(s);

5. annual and periodic reports related to the above-described Application(s), including any safety update reports;

6. FDA approved Product labeling related to the Miotics Product(s);

7. currently used product package inserts (including historical change of controls summaries) related to the Miotics Product(s);

8. FDA approved patient circulars and information related to the Miotics Product(s);

9. adverse event/serious adverse event summaries related to the Miotics Product(s);

10. summary of Product complaints from physicians related to the Miotics Product(s);

11. summary of Product complaints from customers related to the Miotics Product(s); and

12. Product recall reports filed with the FDA related to the Miotics Product(s).

TT. “Product Employee Information” means the following, for each Miotics Product Core Employee, as and to the extent permitted by Law:

1. a complete and accurate list containing the name of each relevant employee (including former employees who were employed by Respondent within ninety (90) days of the execution date of any Remedial Ag

3. Trademarks (inc

BBB. “Remedial Agreement(s)” means the following:

1. any agreement between Respondent and the Acquirer that is specifically referenced and attached to this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, related to the relevant assets or rights to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed, and that has been approved by the Commission to accomplish the requirements of the Order in connection with the Commission’s determination to make this Order final;

2. a

immediately preceding the Acquisition Date. "Supply Cost" shall expressly exclude any intracompany business transfer profit; *provided, however*, that in each instance where: (1) an agreement to Contract Manufacture is specifically referenced and attached to this Order, and (2) such agreement becomes a Remedial Agreement, "Supply Cost" means the cost as specified in such Remedial Agreement.

GGG. "Technology Transfer Standards" means requirements and standards sufficient to ensure that the information and assets required to be delivered pursuant to this Order are delivered in an organized, comprehensive, complete, useful, error-free, timely (*i.e.*, ensuring no unreasonable delays in transmission), and meaningful manner. Such standards and requirements shall include, *inter alia*,

a. designating employees knowledgeable about the Product Manufacturing Technology (and all related intellectual property) related to the specified Product(s) who will be responsible for communicating directly with the Acquirer and/or its Designee, and the Interim Monitor (if one has been appointed), for the purpose of effecting such delivery;

b. preparing technology transfer protocols and transfer acceptance criteria for both the processes and analytical methods related to the specified Product(s) that are acceptable to the Acquirer;

c. preparing and implementing a detailed technological transfer plan that contains, *inter alia*, the transfer of all relevant information, all appropriate documentation, all other materials, and projected time lines for the delivery of all such Product Manufacturing Technology (including all related intellectual property) to the Acquirer or its Designee; and

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

(1) manufacture the specified Product(s) in the quality and quantities achieved by the Respondent, or the manufacturer and/or developer of such specified Product(s);

(2) obtain any Product Approvals necessary for the Acquirer or its Designee, to manufacture, distribute, market, and sell the specified Product(s) in commercial quantities and to meet all Agency-approved specifications for the specified Product(s); and

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

HHH. "Third Party(ies)" means any non-governmental Person other than the following: Respondent Novartis, Alcon, or the Acquirer.

III. "Trade Dress" means the current trade dress of the specified Product, including but not limited to, Product packaging, and the lettering of the Product trade name or brand name.

JJJ. "Trademark(s)" means all proprietary names or designations, trademarks, service marks, trade names, and brand names, including registrations and applications for registration thereof (and all renewals, modifications, and extensions thereof) and all common law rights, and the goodwill symbolized thereby and associated therewith.

KKK. "Website" means the content of the Website(s) located at the Domain Names, the Domain Names, and all copyrights in such Website(s), to the extent owned by Respondent; *provided, however,* "Website" shall not include the following: (1) content owned by Third Parties and other Product Intellectual Property not owned by Respondent that are incorporated in such Website(s), such as stock photographs used in the Website(s), *except* to the extent that Respondent can convey its rights, if any, therein; or (2) content unrelated to any of the Miotics Product(s).

II.

IT IS FURTHER ORDERED that:

A. Not later than the earlier of: (

was accomplished is not acceptable, the Commission may direct Respondent, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the

claim and cooperating fully in the defense of such claim. The Remedial Agreement shall be consistent with the obligations assumed by Respondent under this Order;

provided, however, that Respondent may reserve the right to control the defense of any such litigation, including the right to settle the litigation, so long as such settlement is consistent with Respondent's responsibilities to supply the ingredients and/or Components in the manner required by this Order; *provided further* that this obligation shall not require Respondent to be liable for any negligent act or omission of the Acquirer or for any representations and warranties, express or implied, made by the Acquirer that exceed the representations and warranties made by Respondent to the Acquirer;

provided further that in each instance where: (1) an agreement to divest relevant assets is specifically referenced and attached to this Order, and (2) such agreement becomes a Remedial Agreement for a Miotics Product, each such agreement may contain limits on Respondent's aggregate liability resulting from the failure of the Products supplied to the Acquirer pursuant to such Remedial Agreement by Respondent to meet cGMP;

3. make representations and warranties to the Acquirer that Respondent shall hold harmless and indemnify the Acquirer for any liabilities or loss of profits resulting from the failure by Respondent to deliver the Contract Manufacture Products and Services in a timely manner as required by the Remedial Agreement(s) unless Respondent can demonstrate that its failure was entirely beyond the control of Respondent and in no part the result of negligence or willful misconduct by Respondent;

provided, however, that in each instance where: (1) an agreement to divest relevant assets is specifically referenced and attached to this Order, and (2) such agreement becomes a Remedial Agreement for a Miotics Product, each such agreement may contain limits on Respondent's aggregate liability for such a breach;

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Acquirer and at a facility chosen by the Acquirer, for the purposes of enabling the Acquirer (or the Designee of the Acquirer) to obtain all Product Approvals to manufacture the Miotics Products in the same quality achieved by, or on behalf of, the Respondent and in commercial quantities, and in a manner consistent with cGMP, independently of Respondent, and sufficient to satisfy management of the Acquirer that its personnel (or the Designee's personnel) are adequately trained in the manufacture of the Miotics Products; and

7. not extend or renew any agreement to Contract Manufacture that becomes a Remedial Agreement, or enter into any subsequent agreement to Contract Manufacture with the Acquirer to succeed an agreement to Contract Manufacture that becomes a Remedial Agreement, without the prior approval of the Commission.

Paragraphs II.D.1. - 6., shall remain in effect until the earliest of: (1) the date the Acquirer (or the Designee(s) of the Acquirer), respectively, is approved by the FDA to manufacture the Miotics Product and able to manufacture the Miotics Products in commercial quantities, in a manner consistent with cGMP, independently of Respondent and Alcon; (2) the date the Acquirer notifies the Commission and the Respondent of its intention to abandon its efforts to manufacture the Miotics Products; (3) the date of written notification from staff of the Commission that the Interim Monitor, in consultation with staff of the Commission, has determined that the Acquirer has abandoned its efforts to manufacture the Miotics Product, or (4) five (5) years from the Closing Date.

E. Respondent shall:

1. submit to the Acquirer, at Respondent's expense, all Confidential Business Information;

2. deliver such Confidential Business Information to the 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 Acquirer, provide the 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 Miotics Products that contain such Confidential Business Information and facilitating the delivery in a manner consistent with this Order;

4. not use, direc

1. are or were directly involved in the research, Development, manufacturing, distribution, sale or marketing of any of the Miotics Products;

2. are directly involved in the research, Development, manufacturing, distribution, sale or marketing of Retained Products that are indicated for the same use as the Miotics Products; and/or

3. may have Confidential Business Information.

Respondent 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 afte

lessens the full economic viability, marketability, or competitiveness of the business associated with the Miotics Products.

K. Respondent shall not join, file, prosecute or maintain any suit, in law or equity, against the Acquirer or the Miotics Product Releasee(s) for the research, Development, manufacture, use, import, export, distribution, or sale of the Miotics Product(s) under the following:

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

2. any Patents owned or licensed at any time after the Acquisition Date by Respondent that claim any aspect of the research, Development, manufacture, use, import, export, distribution, or sale of the Miotics Product(s), other than such Patents that claim inventions conceived by and reduced to practice after the Acquisition Date;

if such suit would have the potential to interfere with the Acquirer's freedom to practice the following: (1) the research, Development, or manufacture of the Miotics Products anywhere in the World for the purposes of marketing, distribution or sale within the Geographic Territory; or (2) the use within, import into, export from, or the supply, distribution, or sale within, the Geographic Territory of the Miotics Product(s). Respondent shall also covenant to the Acquirer that as a condition of any assignment, transfer, or license to a Third Party of the above-described Patents, the Third Party shall agree to provide a covenant whereby the Third Party covenants not to sue the Acquirer or the related Miotics Product Releasee(s) under such Patents, if the suit would have the potential to interfere with that Acquirer's freedom to practice the following: (1) the research, Development, or manufacture of the Miotics Products anywhere in the World for the purposes of marketing, distribution or sale within the Geographic Territory; or (2) the use within, import into, export from, or the supply, distribution, or sale within, the Geographic Territory of the Miotics Product(s).

L. Upon reasonable written notice and request from the Acquirer to Respondent, Respondent shall provide, in a timely manner, at no greater than Direct Cost, assistance of knowledgeable employees of Respondent to assist that Acquirer to defend against, respond to, or otherwise participate in any litigation related to the Product Intellectual Property related to any of the Miotics Products, if such litigation would have the potential to interfere with the Acquirer's freedom to practice the following: (1) the research, Development, or manufacture of the Miotics Product(s); or (2) the use, import, export, supply, distribution, or sale of the Miotics Product(s) within the Geographic Territory.

M. For any patent infringement suit in which either: (1) the Respondent is alleged to have infringed a Patent of another Person prior to the Closing Date, or for such suit as the Respondent has prepared or is preparing as of the Closing Date to defend against such infringement claim(s), and where such a suit would have the potential to interfere with the Acquirer's freedom to practice the following: the research, Development, or manufacture of

the Miotics Product(s); or the use, import, export, supply, distribution, or sale of the Miotics Product(s), or (2) a Person is alleged to have infringed a Patent the rights of which are granted to the Acquirer pursuant to this Order, or for such suit as the Respondent has prepared or is preparing as of the Closing Date to prosecute, Respondent shall:

1. cooperate with the Acquirer and provide any and all necessary technical and legal assistance, documentation and witnesses from Respondent in connection with obtaining resolution of any pending patent litigation involving the Miotics Product(s);

2. waive conflicts of interest, if any, to allow Respondent's outside legal counsel to represent the Acquirer in any ongoing patent litigation involving the Miotics Product(s); and

3. permit the transfer to the Acquirer of all of the litigation files and any related attorney work-product in the possession of Respondent's outside counsel relating to the Miotics Product(s).

N. Respondent shall not, in the Geographic Territory:

1. use the Trademarks related to the Miotics Products or any mark confusingly similar to such Trademarks, as a trademark, trade name, or service mark;

2. attempt to register Trademarks related to the Miotics Produc

III.

IT IS FURTHER ORDERED that:

A. At any time after Respondent signs the Consent Agreement in this matter, the Commission may appoint a monitor ("Interim Monitor") to assure that Respondent expeditiously complies with all of its obligations and perform all of its responsibilities as required by this Order, the Order to Main thatha

b. the date the Acquirer notifies the Commission and the Respondent of its intention to abandon its efforts to manufacture the Miotics Product; or

c. the date of written notification from staff of the Commission that the Interim Monitor, in consultation with staff of the Commission, has determined that the Acquirer has abandoned its efforts to manufacture the Miotics Product;

d. five (5) years from the Closing Date;

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

4. Subject to any demonstrated legally recognized privilege, the Interim Monitor shall have full and complete access to Respondent's personnel, books, documents, records kept in the ordinary course of business, facilities and technical information, and such other relevant information as the Interim Monitor may reasonably request, related to Respondent's compliance with its obligations under the Order, including, but not limited to, its obligations related to the relevant assets. Respondent shall cooperate with any reasonable request of the Interim Monitor and shall take no action to interfere with or impede the Interim Monitor's ability to monitor Respondent's compliance with the Order.

5. The Interim Monitor shall serve, without bond or other security, at the expense of Respondent, on such reasonable and customary terms and conditions as the Commission may set. The Interim Monitor shall have authority to employ, at the expense of Respondent, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Interim Monitor's duties and responsibilities.

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

7. Respondent shall report to the Interim Monitor in accordance with the requirements of this Order and/or as otherwise provided in any agreement approved by the Commission. The Interim Monitor shall evaluate the reports submitted to the Interim Monitor by Respondent, and any reports submitted by the Acquirer with respect to the performance of Respondent's obligations under the Order or the Remedial Agreement(s). Within thirty (30) days from the date the Interim Monitor receives these reports, the Interim Monitor shall report in writing to the Commission concerning performance by Respondent of its obligations under the Order;

provided, however, beginning one hundred twenty (120) days after Respondent has filed its final report pursuant to Paragraph VIII.B., and every one hundred twenty (120) days thereafter, the Interim Monitor shall report in writing to the Commission concerning progress by the Acquirer toward obtaining FDA approval to manufacture the Miotics Products and obtaining the ability to manufacture the Miotics Products in commercial quantities, in a manner consistent with cGMP, independently of Respondent and Alcon.

8. Respondent may require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement; *provided, however,* that such agreement shall not restrict the Interim Monitor from providing any information to the Commission.

E. The Commission may, among other things, require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Interim Monitor's duties.

F. If the Commission determines that the Interim Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Interim Monitor in the same manner as provided in this Paragraph.

G. The Commission may on its own initiative, or at the request of the Interim Monitor, issue such additional orders or directions as may be necessary or appropriate to a

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 Respondent to comply with this Order.

B. The Commission shall select the Divestiture Trustee, subject to the consent of the Respondent, which consent shall not be unreasonably withheld. The Divestiture Trustee shall be a Person with experience and expertise in acquisitions and divestitures. If Respondent 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 of the identity of any

amount equal to the delay, as determined by the Commission or, for a court-appointed Divestiture Trustee, by the court.

4. The Divestiture Trustee shall use commercially reasonable efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission, subject to Respondent's absolute and unconditional obligation to divest expeditiously and at no minimum price. The divestiture shall be made in the manner and to the Acquirer as required by this Order; *provided, however*, if the Divestiture Trustee receives bona fide offers from more than one acquiring Person, and if the Commission determines to approve more than one such acquiring Person, the Divestiture Trustee shall divest to the acquiring Person selected by Respondent from among those approved by the Commission; *provided further, however*, that Respondent shall select such Person 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 Respondent, 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 Respondent, 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 Respondent, 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. Respondent shall indemnify the Divestiture Trustee and hold the Divestiture Trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Divestiture Trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Divestiture Trustee.

7. The Divestiture Trustee shall have no obligation or authority to operate or maintain the relevant assets required to be divested by this Order; *provided, however*, that the Divestiture Trustee appointed pursuant to this Paragraph may be the same Person appointed as Interim Monitor pursuant to the relevant provisions of the Order to Maintain Assets in this matter.

8. The Divestiture Trustee shall report in writing to Respondent and to the Commission every sixty (60) days concerning the Divestiture Trustee's efforts to accomplish the divestiture.

9. Respondent may require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, such agreement shall not restrict the Divestiture Trustee from providing any information to the Commission.

E. If the Commission determines that a Divestiture Trustee has ceased to act or failed to act diligently, the Commission may appoint a substitute Divestiture Trustee in the same manner as provided in this Paragraph.

F. The Commission or, in the case of a court-appointed Divestiture Trustee, the court, may

1. in the research, Development, and manufacture of the Miotics Products for the purposes of the business associated with the Miotics Products within the Geographic Territory; and

2. in the distribution, sale and marketing of the Miotics Products in the Geographic Territory; and,

D. to remedy the lessening of competition resulting from the Acquisition as alleged in the Commission's Complaint in a timely and sufficient manner.

VIII.

IT IS FURTHER ORDERED that:

A. Within five (5) days of the Acquisition, Respondent shall submit to the Commission a letter certifying the date on which the Acquisition occurred.

B. Within thirty (30) days after the Order Date, and every sixty (60) days thereafter until Respondent has fully complied with the following: Paragraphs II.A , II.B., II.C., II.E.1.-3., II.G., II.H.1.-4., II.I., and II.K., Respondent shall submit to the Commission a verified written report setting forth in detail the manner and form in which it intends to comply, is complying, and has complied with this Order. Respondent shall submit at the same time a copy of its report concerning compliance with this Order to the Interim Monitor, if any Interim Monitor has been appointed. Respondent shall include in its reports, among other things that are required from time to time, a full description of the efforts being made to comply with the relevant paragraphs of the Order, including a full description of all substantive contacts or negotiations related to the divestiture of the Miotics Product Assets and the identity of all Persons contacted, including copies of all written communications to and from such Persons, all internal memoranda, and all reports and recommendations concerning completing the obligations.

C. One (1) year after the Order Date, annually for the next nine years on the anniversary of the Order Date, and at other times as the Commission may require, Respondent shall file a verified written report with the Commission setting forth in detail the manner and form in which it has complied and is complying with the Order.

IX.

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

A. any proposed dissolution of Novartis AG;

B. any proposed acquisition, merger or consolidation of Novartis AG; or

C. any other change in Respondent including, but not limited to, assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of this Order.

X.

IT IS FURTHER ORDERED that, for purposes of determining or securing compliance with this Order, and subject to any legally recog

XI.

IT IS FURTHER ORDERED that this Order shall terminate on September 28, 2020.

By the Commission, Commissioner Kovacic recused.

Donald S. Clark
Secretary

SEAL
ISSUED: September 28, 2010

NON-PUBLIC APPENDIX II.A.
MIOTICS PRODUCT DIVESTITURE AGREEMENTS

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