

UNITED STATES OF AMERICA  
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: Edith Ramirez, Chairwoman  
Maureen K. Ohlhausen  
Terrell McSweeney

In the Matter of )  
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)  
Valeant Pharmaceuticals International, Inc., ) Docket No. G4602  
a corporation. )  
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DECISION AND ORDER  
[Public Record Version]

The Federal Trade Commission ("Commission"), having initiated an investigation of the acquisition by Valeant Pharmaceuticals International, Inc. ("Valeant" or "Respondent") of all of the issued and outstanding capital stock of Paragon Holdings, which includes wholly owned subsidiaries Paragon Vision Sciences, and CRT Technology, Inc. ("Paragon"), 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 hereafter executed an Agreement Containing Consent Order ("Consent Agreement") containing an admission by Respondent of all the jurisdictional facts set forth in the aforesaid draft of complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondent that the law has been violated as alleged in such complaint, or that the facts as alleged in such complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondent has violated the said Acts, and that a complaint should issue stating its charges in that respect, and having thereupon accepted the Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30)

issues its complaint, makes the following jurisdictional findings and issues the following Decision and Order ("Order"):

1. Respondent Valeant is a corporation organized, existing, and doing business under and by virtue of the laws of the Province of British Columbia, Canada, with its principal executive offices located at 2150 St. Elzear Blvd. West, Laval Quebec H7L 4A8 Canada and its United States address for service of process and the Complaint and Decision and Order as follows: Corporate Secretary/General Counsel, 400 Somerset Corporate Blvd., Bridgewater, NJ 08807.
2. Paragon Holdings I, Inc. is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Arizona, with its executive offices and principal place of business located at

supplements, amendments, and revisions thereto, any preparatory work, registration dossier, drafts and data necessary for the preparation thereof, and all correspondence between the holder and the FDA related thereto.

F. "Business" means the research, development, manufacture, commercialization, distribution, marketing, promotion, importation, exportation, advertisement and/or sale of a Product.

G. "Business Records" means all books, records, files, databases, printouts, and all other documents of any kind whether stored or maintained in hard copy paper format, by means of electronic, optical, or magnetic media or devices, photographic or video images, or any other format or media including, without limitation customer files, customer lists, customer purchasing histories, supplier and vendor files, vendor lists, correspondence, advertising and marketing materials, marketing analyses, sales materials, price lists, cost information, employee lists and contracts, salary and benefits information, personnel files, financial and accounting records and documents, financial statements, financial plans and forecasts, operating plans, studies, reports, regulatory materials, Applications, Agency filings and submissions, Agency correspondence, operating procedures, technical information, manuals, policies and procedures, service and warranty records, maintenance logs

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3. Information that becomes known to the Respondent from a third party breach of applicable law or a confidentiality obligation with respect to the information.
- J. "Contracts" means all real and personal property leases, software licenses, Intellectual Property licenses, warranties, guaranties, insurance agreements, employment contracts, all contracts of any kind relating to construction, customer contracts, sales contracts, distribution contracts, supply agreements, utility contracts, collective bargaining agreements, confidentiality agreements, disclosure agreements, and other contracts or agreements of any kind.
- K. "Copyrights" means rights to all original works of authorship of any kind directly related to a Product and any registrations and applications for registrations thereon, all copyrightable works, registered and unregistered copyrights in both published works and unpublished works, and all applications, registrations, and renewals in connection therewith,

approved by the Commission to accomplish the divestiture of the Paragon Divestiture Assets and other requirements of this Order.

- N. "Divestiture Date" means the date on which the divestiture required by this Order
- O. "Divestiture Trustee" means the Divestiture Trustee appointed pursuant to Paragraph VI. of this Order.
- P. "Domain Name" means the domain name(s) (universal resource locators), and registration(s) thereof, issued by any Person or authority that issues and maintains the domain name registration.
- Q. "Employee Information" means the following, as and to the extent permitted by law:
  - 1. A complete and accurate list containing the name of each Paragon Employee (including former employees who were employed by the Paragon Business within ninety (90) days of the execution date of any proposed Divestiture Agreement)
  - 2. With respect to each such employee, the following information:
    - a.

any federal, state, and local regulatory registrations, permits, and applications for which transfer is not permitted by law; and

3. All fixtures, equipment, machinery, tools, molds, dies, vehicles, personal property, or tangible property of any kind located at ~~such~~ ~~utili~~ ~~(ies)~~ that are owned or leased by Respondent, or that Respondent has the legal right to use, or over which it has custody or control, that are related to:
  - a. The research, development, production, manufacture, marketing, or sale of any Product related to the Paragon Business
  - b. Compliance with any statute, ordinance, regulation, rule, or other legal requirement (including, but not limited to, environmental laws) of any Government Entity
- S. "FDA" means the U.S. Food and Drug Administration.
- T. "General Vision Correction GP Button Product(s)" means GP Button Products used to manufacture GP Finished Contact Lens Products for general vision correction. FDA approval of General Vision Correction GP Button Products used in GP Finished Contact Lens Products for general vision correction marketed in the United States (designated as Class II medical devices) requires submission of a premarket notification pursuant to 21 C.F.R. Part 807.( a Section 510(k) submission).
- U. "GP Button Product(s)" means ~~semi~~ finished optical material blanks made of oxygen permeable plastic polymers containing silicone/~~and~~ fluorine. FDA approval of GP Button Products used in GP Finished Contact Lens Products to be marketed in the United States for: (1) daily wear (designated as Class II medical devices) requires submission of a premarket notification pursuant to 21 C.F.R. Part 807 & Section 510(k) submission); and for (2) Ortho-k and extended wear (designated as Class III medical devices) requires submission of a premarket approval (PMA) Application pursuant to 21 C.F.R. Part 814.
- V. "GP Finished Contact Lens Product(s)" means finished rigid gas permeable contact lenses manufactured from GP Button Products and prescribed by licensed eye care practitioners (e.g., ophthalmologists, optometrists) for daily, extended, and overnight wear, and for therapeutic uses, to correct or address vision and corneal conditions such as myopia (nearsightedness), hyperopia (farsightedness), presbyopia (need for bifocals), keratoconus (degenerative corneal disorder), and irregular corneas.
- W. "Government Entity" means any Federal, state, local, or U.S.-government, or any court, legislature, government agency, or government commission, or any judicial or regulatory authority of any government.
- X. "Intellectual Property" means all intellectual property owned or licensed (as licensor or licensee) by any Person, and all associated rights thereto, including all of the following in any jurisdiction t8(y)22( j()-11(( t8u2( j)-2(e)42)-1(8((is)t2( j()(s)1 w2(m)j()-11(l6(ti:(a)-d)2)-25)-2

trademarks, and copyrights and registrations thereof and to sue and recover damages or obtain injunctive relief for infringement, dilution, misappropriation, misuse, violation, or breach of any of the foregoing

*provided, however,* that “Intellectual Property” does not include the corporate names or corporate Trade Dress of Valeant 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 Respondent or the related corporate logos thereof (here, Bausch + Lomb; Boston®) or general registered images or symbols by which Valeant can be identified or defined.

Y. “Inventories” means

1. All inventories, stores, and supplies of any finished Products and work in progress; and
2. All inventories, stores, and supplies of raw materials and other materials relating to the research, development, manufacture, finishing, packaging, distribution, marketing, or sale of any Products

Z. “Manufacturing Technology and Equipment” means all technology and equipment to make a Product including, but not limited to:

1. All technology, trade secrets, know-how, formulas, and proprietary information (whether patented, patentable, or otherwise) relating to the manufacture of a Product including, but not limited to, all of the following: product specifications; processes; analytical methods; product designs; plans; trade secrets; ideas; concepts; manufacturing, engineering, and other manuals and drawings; standard operating procedures; flow diagrams; quality assurance and quality control systems; research records; clinical data; compositions; annual product reviews; regulatory communications; control history current and historical information associated with FDA Application(s) conformance and cGMP compliance labeling and all other information related to the manufacturing process; and supplier lists;
2. All ingredients, materials, or components used in the manufacture of the Product and
3. All equipment (including tooling, molds, and dies) and machinery used to manufacture, finish, and package the Product

AA. “Marketing Materials” means all materials used in the marketing or sale of Products of the Divestiture Deal, including, without limitation, all advertising and display materials, promotional and marketing materials, training materials, educational materials, speaker lists, product data, mailing lists, sales materials (

- BB. “Monitor” means any Person(s) appointed by the Commission pursuant to ~~Part~~ V. of this Order.
- CC. “New Paragon” means Paragon Companies LLC, a limited liability company organized, existing, and doing business under and by virtue of the laws of the State of Arizona, with its executive offices and principal place of business located at 947 East Impala Avenue, Mesa, AZ 85204-6619.
- DD. “New Paragon Acquisition Agreement(s)” means
1. The Stock Purchase Agreement by and among Paragon Companies LLC, Valeant Pharmaceuticals International, and solely for purposes of certain Sections as specified herein, Joseph E. Sicari, dated September 30, 2016;
  2. All amendments, exhibits, attachments, agreements, and schedules, thereto each case that have received the prior approval of the Commission
- The New Paragon Acquisition Agreements are contained in ~~Public~~ Appendix I. The New Paragon Acquisition Agreements that have 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 ~~Divestiture Agreements~~.
- EE. “Order Date” means the date on which this Order is issued as final and effective by the Commission.
- FF. “Ortho-K” means orthokeratology, a ~~non~~ surgical process for reshaping the cornea of the eye with specially designed therapeutic rigid gas permeable contact lenses, usually worn overnight and removed during waking hours, in order to correct or reduce myopic refractive error (nearsightedness), and for correction or reduction of other refractive errors such as astigmatism.
- GG. “Ortho-K GP Button Product(s)” means GP Button Products used to manufacture Ortho-K GP Finished Contact Lens Products. FDA approval of Ortho-K GP Button Products used in Ortho-K GP Finished Contact Lens Products to be marketed in the United States (designated as Class II medical devices) requires submission of a premarket approval (PMA) Application pursuant to 21 C.F.R. Part 814.
- HH. “Paragon” means Paragon Holdings I, Inc., a corporation organized, existing, and doing business under and by virtue of the laws of the State of Arizona, with its executive offices and principal place of business located at 947 East Impala Avenue, Mesa, AZ 85204-6619; its joint ventures, subsidiaries, divisions, groups, and affiliates, including, but not limited to, Paragon Vision Sciences, Inc. and CRT Technology, and all assets of Paragon Holdings Inc. acquired by Valeant in connection with the Paragon Acquisition.
- II. “Paragon Acquisition” means the acquisition of Paragon by Valeant pursuant to the Paragon Acquisition Agreement, dated May 8, 2015, and effective May 18, 2015.
- JJ. “Paragon Acquisition Agreement” means the Stock Purchase Agreement by and among Valeant Pharmaceuticals International, Paragon Holdings I, Inc., All Shareholders of Paragon Holdings I, Inc. listed on Exhibit A, and Joseph E. Sicari as the Shareholder Representative, dated May 8, 2015.



- KK. "Paragon Business" means the worldwide Business conducted by Paragon with respect to the Paragon Products, all other GP Button Products, and all GP Finished Contact Lens Products, as of the date of the Paragon Acquisition, and as it has been maintained by Respondent since the Paragon Acquisition, including, without limitation, all business activities relating thereto, and all tangible and intangible assets and property of any kind used for or relating thereto, all improvements and additions thereto, including, but not limited to, the Pelican Business; and the respective entities through which Paragon conducts its Business and/or pursuant to which it is organized as of the Divestiture Date
- LL. "Paragon Divestiture Assets" means all of Respondent's rights, title, and interests and to all tangible and intangible assets and property of any kind used for or relating to the Paragon Business, wherever located, and any improvements or additions thereto, including, but not limited to:
1. All Intellectual Property;
  2. All Manufacturing Technology and Equipment;
  3. All Applications and all rights to such Applications;
  4. All Scientific and Regulatory Material;
  5. All Product Approvals
  6. All Marketing Materials
  7. All Websites and Domain Names
  8. All Contracts;
  9. All Facility Assets, including, but not limited to, the facility located at 947 East Impala Avenue, Mesa, AZ 85206-1919;
  10. All Inventories; and
  11. All Business Records related to the foregoing, provided, however, that where Respondent's Business Records contain information: (i) that relates both to the Paragon Business and its retained Products and/or Business and cannot be segregated in a manner that preserves the usefulness of the information as it relates to the Paragon Business; or (ii) for which the Respondent has a legal obligation to retain the original copies, Respondent shall be required to provide only copies or relevant excerpts of the relevant Business Records containing this information. In instances where such copies are provided to the Acquirer, Respondent shall provide that Acquirer access to original documents under circumstances where copies of documents are insufficient for evidentiary or regulatory purposes. The purpose of this provision is to ensure that the Respondent provides the Acquirer with the above-described information without requiring the Respondent completely to divest itself of information, in a content, also relates to Respondent's retained Product and/or Business. Respondent shall also be permitted to retain copies of Business Records relating to the Paragon Business to the extent necessary or required for the purposes of



1. recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them;
  2. intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals; or
  3. intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.
- UU. "Product Approval(s)" means any approvals, registrations, permits, licenses, consents, authorizations, and other approvals, and pending applications and requests therefor, required by applicable Agencies related to the research, development, manufacture, distribution, finishing, packaging, marketing, sale, storage, or transport of a Product, and includes, without limitation, all approvals, registrations, licenses and authorizations granted in connection with an Application related to that Product.
- VV. "Scientific and Regulatory Material" means all technological, scientific, chemical, biological, pharmacological, toxicological, regulatory, and clinical trial materials and information.
- WW. "Scleral GP Button Product(s)" means GP Button Product used to manufacture Scleral GP Finished Contact Lens Products which are larger diameter GP Finished Contact Lens Products designed to cover the entire corneal surface of the eye and rest on the "white," or sclera, of the eye. Scleral GP Finished Contact Lens Products may be prescribed to address vision or corneal conditions such as keratoconus (degenerative corneal disorder), irregular corneas, or dry eyes, and after LASIK or other corneal refractive surgery. FDA approval of Scleral GP Button Products used in Scleral GP Finished Contact Lens Products to be marketed in the United States (

- AAA. "Transition Agreement(s)" means any agreement(s) between the Respondent and the Acquirer, in each case for a period not to exceed (1) one year except as otherwise approved by the Commission, entered into at the option of the Acquirer that receive the prior approval of the Commission for any services (or training for the Acquirer to provide services for itself) or for the supply of any materials or products reasonably necessary to transfer the Paragon Divestiture Assets and the Paragon Business to the Acquirer in a manner consistent with the purposes of this Order. Services may include, but are not limited to, payroll, employee benefits, accounting, IT systems, distribution, warehousing, or other logistical and administrative support. Respondent shall provide any services to the Acquirer at no more than Respondent's Direct Costs. Any agreements for the supply of materials or products shall be at commercially reasonable prices.
- BBB. "Websites and Domain Names" 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 the Respondent

## II.

IT IS FURTHER ORDERED that:

- A. No later than ten (10) days after the Order Date, Respondent shall divest the Paragon Divestiture Assets, absolutely and in good faith, to New Paragon pursuant to, and in accordance with, the New Paragon Acquisition Agreement (which agreement shall not limit or contradict, or be construed to limit or contradict, the terms of this Order, it being understood that this Order shall not be construed to reduce any rights or benefits of New Paragon or to reduce any obligations of Respondent under such agreement), and such agreement, if it is approved by the Commission as a Divestiture Agreement related to the Paragon Divestiture Assets, is incorporated by reference into this Order and made a part hereof

*provided, however,* that if Respondent has divested the Paragon Divestiture Assets to New Paragon prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondent that New Paragon is not an acceptable purchaser of the Paragon Divestiture Assets, Respondent shall immediately rescind the transaction with New Paragon whole or in part, as directed by the Commission, and shall divest Paragon Divestiture Assets within one hundred eighty (180) days after 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 has divested the Paragon Divestiture Assets to New Paragon prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondent that the manner in which the divestiture was accomplished is not acceptable, the Commission may direct Respondent to appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the Paragon Divestiture Assets to New Paragon (including, but not



III.

IT IS FURTHER ORDERED that:

- A. Respondent shall cooperate with and assist the Acquirer of the Paragon Divestiture Assets to evaluate independently and retain

permitted to use and to disclose confidential information to or within Paragon (but not to third parties) prior to the Divestiture Date; and

- c. Provide ~~a~~ Paragon Employees with reasonable financial incentives to continue in their positions until the Divestiture Date, including, but not limited to, a continuation of all employee benefits, including regularly scheduled or merit raises and bonuses, and ~~the~~ regularly scheduled vesting of all pension benefits (as permitted by law and for those Paragon Employees covered by a pension plan)

- B. For a period of two (2) years following the Divestiture Date, Respondent shall not directly or indirectly, solicit, hire or enter into any arrangement for the services of any Paragon Employee who has accepted an offer of employment with, or who is employed by, the Acquirer; *provided, however*, that a violation of this provision will not occur if:
  1. The Paragon Employee's employment has been terminated by the Acquirer;
  2. Respondent advertises for employees in newspapers, trade publications, or other media or engages recruiters to conduct general employee search activities, in either case not targeted specifically at any one or more of the employees of the Acquirer; or
  3. Respondent hires a Paragon Employee who has applied for employment with Respondent, provided that such application was not solicited or induced in violation of this Order

#### IV.

IT IS FURTHER ORDERED that:

- A. After the Divestiture Date, Respondent shall not use, solicit, or access, directly or indirectly, any Confidential Business Information and shall not disclose, provide, discuss, exchange, circulate, convey, or otherwise furnish such Confidential Business Information, directly or indirectly, to any Person except
  1. As required or permitted by this Order;
  2. For the purpose of performing its obligations under the Divestiture Agreement
  3. To prosecute or defend against any dispute or in a legal proceeding
  4. To comply with applicable law, regulations, and other legal governmental requirements (including in connection with tax returns, reports required by securities laws, payroll, benefits, personnel reports, ongoing legal proceedings, litigation, disputes, investigations, inquiries, subpoenas, reviews, audits, or regulatory proceedings)

B. No later than five (5) days after the Divestiture Date, Respondent shall provide written notification of the restrictions, prohibitions, and requirements of this Paragraph IV. to all of its employees, agents, and representatives with responsibilities relating to the Paragon







VI.

IT IS FURTHER ORDERED that:

- A. If the Responder has not fully complied with the obligations of

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monies derived from the divestitures 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 any 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, malfeasance, 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.
8. The Divestiture Trustee shall report in writing to Respondent and to the Commission every thirty (30) days concerning the Divestiture Trustee's efforts to (i) 2(v) 4(s)-1  
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IX.

IT IS FURTHER ORDERED that for purposes of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request and upon five (5) days' notice to Respondent made to either Respondent's principal United States offices, registered office of its United States subsidiary or its headquarters address, Respondent shall, without restraint or interference, permit any duly authorized representative of the Commission:

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

X.

IT IS FURTHER ORDERED that this Order shall terminate on January 25, 2027.

By the Commission.

Donald S. Clark  
Secretary

SEAL:  
ISSUED: January 25, 2017

NON-PUBLIC APPENDIX I  
NEW PARAGON DIVESTITURE AGREEMENT

[Redacted from the PublicRecord Version of the Order, But Incorporated by Reference]