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UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

COMMISSIONERS: **Timothy J. Muris, Chairman**
Mozelle W. Thompson
Orson Swindle
Thomas B. Leary
Pamela Jones Harbour

In the Matter of	)	
	)	
CEPHALON, INC.,	)	
a corporation;	)	
	)	
and	)	
	)	**Docket No.**
CIMA LABS INC.,	)	**DECISION AND ORDER**
a corporation.	)	**[Public Record Version]**
	)	

The Federal Trade Commission ("Commission") having initiated an investigation of the proposed merger of Respondent Cephalon, Inc. ("Cephalon") and Respondent CIMA LABS INC. ("CIMA"), hereinafter referred to as "Respondents," and Respondents 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 Respondents with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

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

The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondents have violated the said Acts, and that a Complaint should issue stating its charges in that respect, and having accepted the executed Consent Agreement

and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby makes the following jurisdictional findings and issues the following Decision and Order ("Order"):

1. Respondent Cephalon is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its offices and principal place of business located at 145 Brandywine Parkway, West Chester, Pennsylvania 19380.

2. Respondent CIMA is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its offices and principal place of business located at 10000 Valley View Road, Eden Prairie, Minnesota 55344.

3. The Federal Trade Commission has jurisdiction over the subject matter of this proceeding and of Respondents, and the proceeding is in the public interest.

ORDER

I.

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

A. "Cephalon" means Cephalon, Inc., its directors, officers, employees, agents, representatives, predecessors, successors, and assigns; its joint ventures, subsidiaries, divisions, groups and affiliates controlled by Cephalon, Inc. (including, but not limited to, MergerCo), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. After the Effective Date, the term "Cephalon" shall include CIMA.

B. "CIMA" means CIMA LABS INC., its directors, officers, employees, agents, representatives, predecessors, successors, and assigns; its joint ventures, subsidiaries, divisions, groups and affiliates controlled by CIMA LABS, INC., and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.

C. "Respondents" means Cephalon and CIMA, individually and collectively.

D. "Commission" means the Federal Trade Commission.

E. "Barr" means Barr Laboratories, Inc., a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware, having its principal place of business located at Two Quaker Road, P.O. Box 2900, Pomona, New York 10970.

F. "Acquisition" means the acquisition contemplated by the "Agreement and Plan of Merger" dated as of November 3, 2003, by and among Cephalon, CIMA and MergerCo ("Acquisition Agreement"), whereby Cephalon agreed to acquire CIMA.

G. “Agency(ies)” means any governmental 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 Oral Opioid Fentanyl. The term “Agency” includes, but is not limited to, the United States Food and Drug Administration (“FDA”) and the United States Drug Enforcement Administration (“DEA”).

H. “Application”, “New Drug Application”

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O. “Day(s)” means the period of time prescribed under this Order as computed pursuant to 16 C.F.R. § 4.3 (a).

P. “Designee” means any entity other than the Respondent(s) that will manufacture Oral Opioid Fentanyl for a Commission-approved Acquirer.

Q. “DD5” means the Product in preclinical development by Respondent Cephalon as of the Effective Date that is a buccal patch formulation comprising Fentanyl and is designated “DD5.”

R. “Development” means all preclinical and clinical drug development activities (including formulation), including test method development and stability testing, toxicology, bioequivalency, 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 governmental price or reimbursement approvals), Product approval and registration, and regulatory affairs related to the foregoing. “Develop” means to engage in Development.

S. “Direct Cost” means the cost of direct labor and direct material used to provide the relevant assistance or service.

T. “Divestiture Trustee” means a trustee appointed by the Commission pursuant to the relevant provisions of this Order.

U. “Drug Master Files” means the information submitted to the FDA as described in 21 C.F.R. Part 314.420 related to a Product.

V. “Effective Date” means the earlier of the following dates:

1. the date the Respondents close on the Acquisition Agreement; or

2. the date the merger contemplated by the Acquisition Agreement becomes effective by filing the certificate of merger with the Secretary of State of the State of Delaware.

W. “Fentanyl” means the chemical substance known by the international non-proprietary name fentanyl citrate and/or all pharmaceutically active derivatives thereof including, without limitation, esters, salts, hydrates, solvates, polymorphs, prodrugs, metabolites and isomers thereof and all hydrates, solvates, polymorphs, prodrugs and isomers of such salts.

X. “Field” means the prevention, treatment, diagnosis, or control of a particular medical condition.

Y. "Final FDA Approval" means approval of a Product by the FDA pursuant the Federal Food, Drug, and Cosmetic Act § 505(b), 21 U.S.C. 355(b).

Z. "Final Finished Form" means a Product packaged in final form and ready for sale by the Commission-approved Acquirer to the Commission-approved Acquirer's ultimate customer (other than for the addition of the Commission-approved Acquirer's specific packaging and/or labeling).

AA. "Generic Entrant Forbearance Date" means the earlier of the following dates:

1. August 3, 2007; or

2. one hundred eighty (180) Days after the Marketing Licensing Date.

BB. "Governmental Entity" means any Federal, state, local or non-U.S. government or any court, legislature, governmental agency or governmental commission or any judicial or regulatory authority of any government.

CC. "Interim Monitor" means a monitor appointed by the Commission pursuant to Paragraph III of this Order.

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

EE. "Marketing Licensing Date" means the following dates:

1. with respect to Substantially Sugar-Free Formulations of Oral Opioid Fentanyl, the earliest of the following dates:

   a. the date of Final FDA Approval of OVF;

   b. the date of notice of a withdrawal of approval by the FDA of NDA No. 20-747;or

   c. the date of Final FDA Approval of a Substantially Sugar-Free Formulation of Oral Opioid Fentanyl (*unless*, at least sixty (60) Days prior to the occurrence of the Marketing Licensing Date with respect to all other formulations of Oral Opioid Fentanyl (as determined below), the FDA determines such formulation is therapeutically equivalent to other formulations of Oral Opioid Fentanyl already approved by the FDA, *i.e.*, the FDA determines that any actual or potential bioequivalence problems have been resolved with adequate evidence supporting bioequivalence);

provided, however, that should Marketing Licensing Date with respect to Substantially Sugar-Free Formulations of Oral Opioid Fentanyl (as determined above) occur prior to

the occurrence of the Marketing Licensing Date with respect to all other formulations of Oral Opioid Fentanyl (as determined below), then the Marketing Licensing Date for the Sugar-Free Formulations of Oral Opioid Fentanyl shall instead be defined to be the same date as Marketing Licensing Date with respect to all other formulations of Oral Opioid Fentanyl (as determined below); and

2. with respect to all other formulations of Oral Opioid Fentanyl the earliest of the following dates:

   a. the date of Final FDA Approval of OVF;

   b. September 5, 2006, if Respondents are not granted Pediatric Exclusivity with respect to Oral Opioid Fentanyl; or

   c. February 3, 2007, if Respondents are granted Pediatric Exclusivity with respect to Oral Opioid Fentanyl,

provided, however, if Respondents have not obtained Final FDA Approval of a Substantially Sugar-Free Formulation of Oral Opioid Fentanyl on or before the later of the following dates: (1) July 1, 2005; or (2) one hundred eighty (180) Days from the date of an Approvable Letter for a Substantially Sugar-Free Formulation of Oral Opioid Fentanyl issued to the Respondents (but only if such Approvable Letter is issued on or before July 1, 2005), then the Marketing Licensing Date with respect to Substantially Sugar Free Formulations and all other formulations of Oral Opioid Fentanyl shall be no later than September 5, 2006.

FF. "Not Approvable Letter" means a letter from the FDA that an Application may not be approved, as described in 21 C.F.R. Part 314.120.

GG. "Oral Opioid Fentanyl" means all Products that contain the active pharmaceutical ingredient Fentanyl and any dose form, presentation or line extension thereof existing as of the Effective Date. The term "Oral Opioid Fentanyl" also includes all Products marketed or in Development by Respondent Cephalon on or before the Effective Date that contain active pharmaceutical ingredient Fentanyl and are planned to be marketed for use in the Field of pain management. This includes all sugar-free versions of such Products (*except* where this Order specifically differentiates between Substantially Sugar-Free Formulation(s) and other formulations of the Products); *provided, however*, the term "Oral Opioid Fentanyl" does not include the following: (1) Products that were owned or controlled by Respondent CIMA prior to the Effective Date and that were not owned or controlled by Respondent Cephalon prior to such date; and (2) Respondent Cephalon's Product DD5.

HH. "Oral Opioid Fentanyl Assets" means all of Respondent Cephalon's rights in and to all Product Intellectual Property and Product Manufacturing Technology related to Respondent Cephalon's business in the United States related to the Oral Opioid Fentanyl to the extent

legally transferable, including the research, Development, manufacture, distribution, marketing or sale of Oral Opioid Fentanyl, including, without limitation, the following:

1. license(s) to all Product Intellectual Property;

2. Right of Reference or Use to the Drug Master Files including, but not limited to, the

KK. "Oral Opioid Fentanyl Releasee(s)" means the Commission-approved Acquirer or any entity controlled by or under common control with the Commission-approved Acquirer, or any licensees, sublicensees, manufacturers, suppliers, distributors, and customers of the Commission-approved Acquirer, or of such Commission-approved Acquirer-affiliated entities.

LL. "Oral Opioid Risk Management Program" means a strategic safety program designed to decrease product risk by using one or more interventions or tools beyond the package insert, which program may be modified or amended from time to time and may be a condition of Final FDA Approval.

MM. "OVF" means the Product, OraVescent® Fentanyl, under development by Respondent CIMA that contains Fentanyl and is formulated with an effervescent agent and is the subject of an IND No. 65,447 or any other IND subsequently filed by Respondents.

NN. "Patents" means all patents, patent applications and statutory invention registrations, in each case existing as of the Effective Date (*except* where this Order specifies a different time), and includes all reissues, divisions, continuations, continuations-in-part, substitutions, reexaminations, restorations, and /or patent term extensions thereof, all inventions disclosed therein, all rights therein provided by international treaties and conventions, and all rights to obtain and file for patents and registrations thereto in the United States, related to a Product of or owned by Respondent Cephalon as of the Effective Date.

OO. "Pediatric Exclusivity" means exclusivity obtained in accordance with the requirements of Federal Food, Drug, and Cosmetic Act § 505a, 21 U.S.C. 355a.

PP. "Product" means any pharmaceutical, biological, or genetic composition containing any formulation or dosage of a compound referenced as its pharmaceutically, biologically or genetically active ingredient.

QQ. "Product Employee Information" means the following:

1. a complete and accurate list containing the name of each relevant employee as of the execution date of the related Remedial Agreement. This list shall be organized by the relevant respective employee categories defined in this Order, (*i.e.*, "Product Manufacturing Employees," or "Product Research and Development Employees," as applicable);

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

    a. job title or position held;

    b. a specific description of the employee's responsibilities related to Oral Opioid Fentanyl; *provided, however*, in lieu of this description, Respondents may provide

the employee's most recent performance appraisal.

RR. "Product Intellectual Property" means all of the following related to the Product(s):

1. Patents;

2. Product Trademarks;

3. trade secrets, know-how, techniques, data, inventions, practices, methods and other confidential or proprietary technical, business, research, Development and other information; and

4. rights to obtain and file for Patents and registrations thereof;

provided, however, "Product Intellectual Property" does not include the names "CIMA", "Cephalon," or the names of any other corporations or companies owned by Respondents or related logos to the extent used on other of Respondent CIMA's or Respondent Cephalon's Products;

provided further, however, "Product Intellectual Property" does not include the trade name Actiq®.

SS. "Product Manufacturing Employees" means all salaried employees of Respondent(s) who directly have participated (irrespective of the portion of working time involved) in the manufacture of the Oral Opioid Fentanyl, including, but not limited to, the Senior Director of Commercial Manufacturing, the Associate Director of Production Planning, and the Manager of Commercial Manufacturing, and all those involved in the quality assurance and quality control of the Oral Opioid Fentanyl, within the eighteen (18) month period immediately prior to the Closing Date.

TT. "Product Manufacturing Technology" means all technology, trade secrets, know-how, and proprietary information (whether patented, patentable or otherwise) related to the manufacture (including all equipment used to manufacture a Product in Final Finished Form), validation, packaging, release testing, stability and shelf life of Oral Opioid Fentanyl, including all product formulations, in existence and in the possession of Respondents as of the Closing Date, product specifications, processes, product designs, plans, trade secrets, ideas, concepts, manufacturing, engineering and other manuals and drawings, standard operating procedures, flow diagrams, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, safety, efficacy, bioequivalency, quality assurance, quality control and clinical data, research records, compositions, annual product reviews, process validation reports, analytical method validation reports, specifications for stability trending and process controls, testing and reference standards for impurities in and degradation of products, technical data packages, chemical and physical characterizations, dissolution test methods and results, formulations for administration,

clinical trial reports, regulatory communications and labeling and all other information related to the manufacturing process, and supplier lists.

UU. "Product Research and Development Employees" means all employees of Respondent(s) who directly have participated (irrespective of the portion of working time involved) in the research, Development, regulatory approval process, or clinical studies of Oral Opioid Fentanyl within the eighteen (18) month period immediately prior to the Closing Date.

VV. "Product Scientific and Regulatory Material" means all technological, scientific, chemical, biological, pharmacological, toxicological, regulatory and clinical trial materials and information related to Oral Opioid Fentanyl, and full rights to use such materials, in any and all jurisdictions.

WW. "Product Trademark(s)" means the following as related to Oral Opioid Fentanyl:

1. the U.S. Trademark Registration No. 2,622,734 as needed for a single dose entity of any generic version of Oral Opioid Fentanyl;

2. at the Commission-approved Acquirer's option, any trademark or trade dress covering the size, shape and color of a single dose entity of any generic version of Oral Opioid Fentanyl;

3. the Oral Opioid Risk Management Program; and

4. the appearance, structure, textual or graphical content and/or color scheme of any labeling, dosing information, product inserts, storage containers and/or other materials, to the extent that the FDA or and other Agency requires the Commission-approved Acquirer to duplicate such appearance, structure, textual or graphical content and/or color scheme of any labeling, dosing information, product inserts, storage containers and/or other materials.

XX. "Proposed Acquirer" means an entity proposed by the Respondents (or a Divestiture Trustee) to the Commission and submitted for the approval of the Commission as the acquirer for particular assets required to be granted, licensed, delivered or otherwise conveyed by Respondents pursuant to this Order.

YY. "Remedial Agreement" means the following:

1. the Oral Opioid Fentanyl License and Supply Agreement, if such agreement has not been rejected by the Commission pursuant to Paragraph II.A. of this Order; or

2. any agreement between a Respondent(s) and a Commission-approved Acquirer (or between a Divestiture Trustee and a Commission-approved Acquirer) that has been approved by the Commission to accomplish the requirements of this Order, and all

amendments, exhibits, attachments, agreements, and schedules thereto, related to the relevant assets to be granted, licensed, delivered or otherwise conveyed that have been approved by the Commission to accomplish the requirements of this Order.

ZZ. "Right of Reference or Use" means the authority to rely upon, and otherwise use, an investigation for the purpose of obtaining approval of an Application, including the ability to make available the underlying raw data from the investigation for FDA audit.

AAA. "Substantially Sugar-Free Formulation(s)" means either of the following:

1. a Product containing less than one-half (0.5) grams of Sugar(s) per dosage; or

2. a Product approved by the FDA for labeling as "Sugar-Free."

BBB. "Sugar(s)" means the sum of all free mono- and disaccharides (such as glucose, fructose, lactose, and sucrose) as defined in 21 C.F.R. §101.9(c)(6)(ii).

CCC. "Supply Cost" means the manufacturer's average direct per unit cost of manufacturing the Product plus costs of manufacturing the Product that are directly attributable to FDA regulatory, quality control and compliance. "Supply Cost" shall expressly exclude any intracompany business transfer profit.

DDD. "Third Party(ies)" means any private entity other than the following: (1) the Respondents, or (2) the Commission-approved Acquirer.

II.

IT IS FURTHER ORDERED that:

A. Not later than ten (10) Days after the Effective Date, Respondents shall grant irrevocable, perpetual, fully paid-up and royalty-free license(s) in the United States to the Oral Opioid Fentanyl Assets and shall grant, license, deliver or otherwise convey the Oral Opioid Fentanyl Assets, absolutely and in good faith, on a non-exclusive basis to Barr pursuant to and in accordance with the Oral Opioid Fentanyl License and Supply Agreement (which agreement shall not vary or contradict, or be construed to vary or contradict, the terms of this Order, it being understood that nothing in this Order shall be construed to reduce any rights or benefits of Barr or to reduce any obligations of Respondents under such agreement). Such licenses shall be effective as follows:

1. as of the Closing Date, as to Barr's rights to manufacture and Develop Oral Opioid Fentanyl using the Oral Opioid Fentanyl Assets; and

2. not later than the Marketing Licensing Date, as to Barr's rights to distribute, market or

sell Oral Opioid Fentanyl using the Oral Opioid Fentanyl Assets.

If Respondents do not grant, license, deliver or otherwise convey the Oral Opioid Fentanyl Assets to Barr within ten (10) Days after the Effective Date as provided above, the Commission may, pursuant to Paragraph IV of this Order, appoint a Divestiture Trustee to license, grant, deliver and otherwise convey the Oral Opioid Fentanyl Assets;

provided, *however*, that, if Respondents have granted, licensed, delivered or otherwise conveyed the Oral Opioid Fentanyl Assets to Barr prior to the date this Order becomes final, and if, at the time the Commission determines to make this Order final, the Commission notifies Respondents that Barr is not an acceptable purchaser of the Oral Opioid Fentanyl Assets, then Respondent shall immediately rescind the transaction with Barr and shall grant, license, deliver or otherwise convey the Oral Opioid Fentanyl Assets within six (6) months from the date the Order becomes final, absolutely and in good faith, at no minimum price, to a Commission-approved Acquirer and only in a manner that receives the prior approval of

Business Information and facilitating the delivery in a manner consistent with this Order.

C. Respondents shall not enforce any agreement against a Third Party or the Commission-approved Acquirer to the extent that such agreement may limit or otherwise impair the ability of the Commission-approved Acquirer to acquire the Product Manufacturing Technology or related equipment from the Third Party. Such agreements include, but are not limited to, agreements with respect to the disclosure of Confidential Business Information related to the Product Manufacturing Technology.

D. Not later than ten (10) Days after the Effective Date, Respondents shall grant a release to each Third Party that is subject to an agreement as described in Paragraph II.C. that allows the Third Party to provide the relevant Product Manufacturing Technology or related equipment to the Commission-approved Acquirer. Within five (5) Days of the execution of each such release, Respondents shall provide a copy of the release to the Commission-approved Acquirer.

E. Any Remedial Agreement that has been approved by the Commission between Respondents (or a Divestiture Trustee) and a Commission-approved Acquirer of the Oral Opioid Fentanyl Assets shall be deemed incorporated into this Order, and any failure by Respondents to comply with any term of such Remedial Agreement related to the Oral Opioid Fentanyl Assets shall constitute a failure to comply with this Order.

F. Respondents shall include in any Remedial Agreement related to the Oral Opioid Fentanyl Assets the following provisions:

1. At the Commission-approved Acquirer's Option, Respondents shall Contract Manufacture and deliver to the Commission-approved Acquirer, in a timely manner and under reasonable terms and conditions, a supply of Oral Opioid Fentanyl, including such Product in Final Finished Form, at Respondents' Supply Cost, for a period of time sufficient to allow the Commission-approved Acquirer (or the Designee of the Commission-approved Acquirer) to obtain all FDA approvals necessary to manufacture Oral Opioid Fentanyl independently of Respondents; *provided, however*, Respondents' obligation to Contract Manufacture shall not exceed six (6) years from the Closing Date.

2. After the Closing Date and continuing for the term of the Contract Manufacture related to Oral Opioid Fentanyl, Respondents will make inventory of Oral Opioid Fentanyl available for sale or resale only to the Commission-approved Acquirer (other than for use in Respondents' own business related to Oral Opioid Fentanyl).

3. The Respondents' obligation to supply Oral Opioid Fentanyl to the Commission-approved Acquirer shall take priority over the manufacture and supply of Oral Opioid Fentanyl for Respondents' own use or sale.

4. Respondents shall make representations and warranties to the Commission-approved

b. assistance to the Commission-approved Acquirer (or the Designee of the Commission-approved Acquirer) to manufacture Oral Opioid Fentanyl in substantially the same manner and quality employed or achieved by Respondent Cephalon; and

c. consultation with knowledgeable employees of Respondents and training, at the request of the Commission-approved Acquirer and at a facility chosen by the Commission-approved Acquirer, until the Commission-approved Acquirer (or the Designee of the Commission-approved Acquirer) obtains all FDA approvals necessary to manufacture Oral Opioid Fentanyl independently of the Respondents and sufficient to satisfy management of the Commission-approved Acquirer that its personnel (or the Designee's personnel) are adequately trained in the manufacture of Oral Opioid Fentanyl.

8. Upon reasonable notice and request from the Commission-approved Acquirer to the Respondents, after the Marketing Licensing Date, Respondent shall provide in a timely manner, at no greater than Direct Cost, assistance with knowledgeable employees of the relevant Respondent to assist the Commission-approved Acquirer to defend against, respond to, or otherwise participate in any litigation related to the Product Intellectual Property related to Oral Opioid Fentanyl.

9. Respondents shall covenant to the Commission-approved Acquirer that, after the Marketing Licensing Date (*except* for the manufacture and Development of Oral Opioid Fentanyl, in which case, the covenant shall begin as of the Closing Date), Respondents shall not join, or file, prosecute or maintain any suit, in Law or equity, against the Commission-approved Acquirer or the Oral Opioid Fentanyl Releasee(s) for the research, Development, manufacture, use, import, distribution, or sale of Oral Opioid Fentanyl (but only as to those Products that are commercialized or in Development as of the Closing Date) under Patents that:

   a. are owned or licensed by Respondent Cephalon as of immediately prior to the closing on the acquisition of CIMA; or

   b. may be assigned, granted, licensed, or otherwise conveyed to Respondents after the Effective Date, if such suit would have the potential to interfere with the Commission-approved Acquirer's freedom to practice in the research, Development, manufacture, use, import, sale, marketing or distribution of Oral Opioid Fentanyl (but only as to those Products that are commercialized or in Development as of the Closing Date) in the Field of pain management.

10. Respondents shall covenant to the Commission-approved Acquirer that, after the Marketing Licensing Date (*except* for the manufacture and Development of Oral Opioid Fentanyl, in which case, the covenant shall begin as of the Closing Date):

a. any Third Party assignee or licensee of the above-described Patents shall agree to provide a covenant not to sue the Oral Opioid Fentanyl Releasees, at least as

J. Upon reasonable notice and request from the Commission-approved Acquirer to the Respondents, Respondents shall provide (in a timely manner and at no greater than Direct Cost) to the Commission-approved Acquirer consultation with, assistance, training, and advice from, knowledgeable employees of Respondents with respect to the Development and manufacture of Oral Opiod Fentanyl, that the Commission-approved Acquirer might reasonably need in order to receive and use the Oral Opioid Fentanyl Assets in a manner consistent with this Order, and shall continue providing such consultation, assistance, training and advice, at the request of the Commission-approved Acquirer, until the Commission-approved Acquirer (or the Designee of the Commission-approved Acquirer) is fully validated, qualified, and approved by the FDA, and able to manufacture Oral Opioid Fentanyl independently of the Respondents.

K. Pending the granting, licensing, delivery or conveyance of the Oral Opioid Fentanyl Assets, Respondents shall take such actions as are necessary to maintain the full economic viability, marketability and competitiveness of the business associated with the Oral Opioid Fentanyl Assets, to minimize any risk of loss of competitive potential for the business associated with the Oral Opioid Fentanyl Assets, and to prevent the destruction, removal, wasting, deterioration, or impairment of any of the Oral Opioid Fentanyl Assets except for ordinary wear and tear.

L. After the Marketing Licensing Date (*except* for the manufacture and Development of Oral Opioid Fentanyl, in which case, this Paragraph shall apply as of the Closing Date), Respondents shall not join, or file, prosecute or maintain any suit, in Law or equity, against the Commission-approved Acquirer or the Oral Opioid Fentanyl Releasee(s) for the research, Development, manufacture, use, import, sale, marketing or distribution of Oral Opioid Fentanyl (but only as to those Products that are commercialized or in Development as of the Closing Date) under the following:

1. any Patents owned or licensed by Respondents as of the Effective Date or acquired after the Effective Date that claim the use of Oral Opioid Fentanyl in the Field of pain management; or

2. that claim any aspect of the research, Development, manufacture, use, import, sale, marketing, or distribution of Oral Opioid Fentanyl other than such Patents that claim inventions conceived by and reduced to practice by Respondents' employees after the Effective Date.

M. Respondents shall maintain manufacturing facilities for the Oral Opioid Fentanyl finished drug product, that are validated, qualified and approved by the FDA, and fully capable of producing Oral Opioid Fentanyl finished drug product and shall Contract Manufacture and supply such finished drug product to the Commission-approved Acquirer until the Commission-approved Acquirer (or the Designee of the Commission-approved Acquirer) is fully validated, qualified and approved by the FDA and able to manufacture Oral Opioid Fentanyl finished drug product in a facility that is independent of Respondents;

provided, however, this obligation shall not exceed six (6) years from the Closing Date;

provided further, however, the Commission may eliminate, or further limit the duration of, the Respondent's obligation under this provision should the Commission determine that the Commission-approved Acquirer is not using commercially reasonable best efforts to secure the FDA approvals necessary to manufacture Oral Opioid Fentanyl finished drug product in a facility that is independent of Respondents.

N. At any time after the Generic Entrant Forbearance Date, Respondents shall not seek to enforce any Patent(s) related to Oral Opioid Fentanyl that is filed pursuant to 21 U.S.C. § 355(b)(1) as a part of the following:

1. the NDA No. 20-747, as supplemented, or amended; or

2. any Application filed by the Respondents for the purposes of obtaining an approval to label a formulation of Oral Opioid Fentanyl as "Sugar-Free" or an equivalent labeling designation,

against any Third Party to the extent that such enforcement might prohibit, limit, or otherwise impair the Third Party's ability to commercialize a Product under an ANDA filed by the Third Party that references such Patent(s) and the Product listed under the above-referenced NDA; *provided, however*, that this Paragraph shall not apply to Patents solely related to Substantially Sugar-Free Formulations of Oral Opioid Fentanyl until Final FDA Approval of OVF.

O. Not later than the Generic Entrant Forbearance Date, Respondents shall make available to the public those patent applications filed by Respondents, not already published, that are related to Oral Opioid Fentanyl.

P. The purpose of the grant, license, delivery and conveyance of the Oral Opioid Fentanyl Assets to a Commission-approved Acquirer is to create an independent, viable and effective competitor in the relevant market in which the Oral Opioid Fentanyl Assets were engaged at the time of the announcement of the Acquisition, and to remedy the lessening of competition resulting from the Acquisition as alleged in the Commission's Complaint.

III.

IT IS FURTHER ORDERED that:

A. At any time after Respondents sign the Consent Agreement in this matter, the Commission may appoint a monitor ("Interim Monitor") to assure that Respondents expeditiously compom

B. The Commission shall select the Interim Monitor, subject to the consent of Respondents, which consent shall not be unreasonably withheld. If neither Respondent has 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 Respondents 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 the Commission.

3. The Interim Monitor shall serve until the later of:

   a. the completion by Respondents of the divestiture of all relevant assets required to be granted, licensed, delivered, or otherwise conveyed pursuant to this Order in a manner that fully satisfies the requirements of the Order and notification by the Commission-approved Acquirer to the Interim Monitor that it is fully capable of producing the relevant Product(s) acquired pursuant to a Remedial Agreement independently of Respondents; or

   b. the completion by Respondents of the last obligation under the Order pertaining to the Interim Monitor's service;

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

4. Subject to any demonstrated legally recognized privilege, the Interim Monitor shall have full and complete access to Respondents' personnel, books, documents, records kept in the normal course of business, facilities and technical information, and such other relevant information as the Interim Monitor may reasonably request, related to

Respondents' compliance with their obligations under the Order, including, but not limited to, their obligations related to the relevant assets. Respondents shall cooperate with any reasonable request of the Interim Monitor and shall take no action to interfere with or impede the Interim Monitor's ability to monitor Respondents' compliance with the Order.

5. The Interim Monitor shall serve, without bond or other security, at the expense of Respondents on such reasonable and customary terms and conditions as the Commission

Divestiture Trustee’s powers, duties, authority, and responsibilities:

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 the Respondents, and the Divestiture Trustee's power shall be terminated. The compensation of the Divestiture Trustee shall be based at least in significant part on a commission arrangement contingent on the divestiture of all of the relevant assets that are required to be divested by this Order.

6. Respondents shall indemnify the Divestiture Trustee and hold the Divestiture Trustee harmless against any losses, claims, damages, liabilities, or y sBhfris(inioution ofies, inall)TJTrit ndirect

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.

G. The Divestiture Trustee appointed pursuant to this Paragraph may be the same person appointed as Interim Monitor pursuant to the relevant provisions of this Order.

V.

IT IS FURTHER ORDERED that:

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

B. Within five (5) Days of the occurrence of each of the following events, Respondent shall notify the Commission, the Commission-approved Acquirer, and the Interim Monitor (if any has been appointed) in writing of the occurrence of such event:

1. the following events related to an Application related to OVF:

    a. filing of an Application;

    b. issuance of an Approvable Letter; and

    c. issuance of an Approval Letter; and

2. the following events related to an Application seeking pediatric exclusivity related to Oral Opioid Fentanyl:

    a. receipt by Respondents of a request from the FDA to submit a pediatric study to the FDA;

    b. submission by the Respondents to the FDA of the protocol related to the pediatric study;

    c. submission by the Respondents of the pediatric study to the FDA; and

    d. receipt by Respondents of grant or denial of Pediatric Exclusivity from the FDA.

3. the following events related to an Application seeking approval of a Substantially Sugar-Free Formulation(s) of Oral Opioid Fentanyl:

    a. filing of an Application;

b. issuance of an Approvable Letter;

c. issuance of a Not Approvable Letter; and

d. issuance of an Approval Letter.

C. Within thirty (30) Days after the date this Order becomes final, and every sixty (60) Days thereafter until Respondents have fully complied with Paragraphs II.A. (*i.e.* has granted, licensed, delivered or otherwise conveyed all relevant assets to the Commission-approved Acquirer in a manner that fully satisfies the requirements of the Order), II.B., II.D., and all its responsibilities to render transitional services to the Commission-approved Acquirer as provided in the Remedial Agreement(s), Respondents shall submit to the Commission a verified written report setting forth in detail the manner and form in which they intends to comply, are complying, and have complied with this Order. Respondents 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. Respondents shall include in their reports, among other things that are required from time to time:

1. a full description of the efforts being made to comply with the relevant Paragraphs of the Order;

2. if Barr is rejected by the Commission pursuant to Paragraph II.A., a description of all substantive contacts or negotiations related to the licensing of the Oral Opioid Fentanyl Assets and the identity of all parties contacted and copies of all written communications to and from such parties, all internal memoranda, and all reports and recommendations concerning completing its obligations to license the Oral Opioid Fentanyl Assets;

3. a detailed plan to deliver all Confidential Business Information required to be delivered to the Commission-approved Acquirer pursuant to Paragraph II.B, and agreed upon by the Commission-approved Acquirer and the Interim Monitor (if applicable) and any updates or changes to such plan;

4. a description of all Confidential Business Information delivered to the Commission-approved Acquirer, including the type of information delivered, method of delivery, and date(s) of delivery;

5. a description of the Confidential Business Information currently remaining to be delivered and a projected date(s) of delivery; and

6. a description of all technical assistance provided to the Commission-approved Acquirer during the reporting period.

D. One (1) year after the date this Order becomes final, annually for the next nine (9) years on the anniversary of the date this Order becomes final, and at other times as the Commission

may require, Respondents shall file a verified written report with the Commission setting forth in detail the manner and form in which they have complied and are complying with this Order.

VI.

IT IS FURTHER ORDERED that Respondents shall notify the Commission at least thirty (30) Days prior to any proposed (1) dissolution of the Respondents, (2) acquisition, merger or consolidation of Respondents, or (3) any other change in the Respondents that may affect compliance obligations arising out of the order, including, but not limited to, assignment, the creation or dissolution of subsidiaries, or any other change in Respondents.

VII.

IT IS FURTHER ORDERED that, for the purpose of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request with reasonable notice to Respondents made to their principal United States offices, Respondents shall permit any duly authorized representative of the Commission:

A. Access, during office hours of Respondents and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda and all other records and documents in the possession or under the control of Respondents related to compliance with this Order; and

B. Upon five (5) Days' notice to Respondents and without restraint or interference from Respondents, to interview officers, directors, or employees of Respondents, who may have counsel present, regarding such matters.

VIII.

IT IS FURTHER ORDERED that this Order shall terminate twenty (20) years from the date on which the Order becomes final.

By the Commission.

Donald S. Clark
Secretary

SEAL
ISSUED:

APPENDIX I
NON-PUBLIC
ORAL OPIOID FENTANYL LICENSE AND SUPPLY AGREEMENT

[Redacted From Public Record Version But Incorporated By Reference]