UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

v.

MORTON GROVE PHARMACEUTICALS, INC., a Delaware corporation, and GOPALAKRISHNAN VENKATESAN, an individual,

Defendants.

Case No. 1:22-cv-04367

Judge: Marvin E. Aspen

CONSENT DECREE OF PERMANENT INJUNCTION

Plaintiff, the United States of America, by and through its undersigned counsel, has filed a complaint for permanent injunction against Morton Grove Pharmaceuticals, Inc., a Delaware corporation (the "Corporate Defendant"), and the Corporate Defendant's current President, Gopalakrishnan Venkatesan, an individual, solely in his capacity as President of the Corporate Defendant (the "Individual Defendant") (collectively, "Defendants"). The Individual Defendant first assumed responsibility for overseeing manufacturing operations at Morton Grove Pharmaceuticals, Inc. in July 2022. Defendants, without admitting or denying the allegations in the Complaint and disclaiming any liability in connection therewith, have waived service of process and appeared and consented to entry of this decree without contest and before any testimony has been taken, and the United States of America, have consented to this decree.

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED as follows:

1. This court has jurisdiction over the subject matter and all parties to this action.

2. The complaint states a cause of action against Defendants under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-399d (the "Act").

3. The complaint alleges that Defendants violate 21 U.S.C. § 331(a) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce drugs that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B) in that they have been manufactured, processed, packed, and held in violation of current good manufacturing practice for drugs ("CGMP"). 21 C.F.R. pts. 210 & 211.

4. The complaint alleges that Defendants violate 21 U.S.C. § 331(k) by causing drugs that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B) in that they have been manufactured, processed, packed, and held in violation of CGMP. 21 C.F.R. pts. 210 & 211.

5. For purposes of this decree, the following definitions shall apply:

A. "Drug(s)" refers to any product that meets the definition in 21 U.S.C. § 321(g), including, but not limited to, finished drugs, drug components, and active pharmaceutical ingredients.

B. "Defendants' Facility" means Morton Grove Pharmaceuticals, 6451 Main St, Morton Grove, IL 60053-2633, and any facility at or from which Corporate Defendant in the future manufactures, processes, packs, repacks, labels, holds, and/or distributes any drug.

C. "CGMP" means current good manufacturing practice requirements for drugs. *See* 21 U.S.C. § 351(a)(2)(B); 21 C.F.R. pts. 210 & 211.

D. A drug is "Medically Necessary" if:

i. It is used to diagnose, treat, or prevent a disease or a serious disease or medical condition; and

ii. No other adequate sources are readily available for that product or alternative products determined by Food and Drug Administration ("FDA") to be adequate substitutes.

E. A drug listed below is deemed to satisfy the requirements of paragraphs D(i) and (ii) and is considered "Medically Necessary" at the time this decree is entered:

i. Carbamazepine oral suspension (anti-epileptic);

ii. Dexamethasone elixir (multiple indications); and

iii. Megestrol acetate oral suspension (gastroenterology).

As and when FDA deems appropriate, and within its sole discretion, FDA may, at any time subsequent to the entry of this decree, review this list of Medically Necessary drugs in this paragraph and order that drugs be added to or removed from this list, based on FDA's determination of whether those drugs satisfy the standard in paragraph 5(D) above.

F. "Notification Guide" shall refer to the document developed by Defendants, and reviewed and approved by FDA, that notifies consumers of Defendants' Medically Necessary products of FDA's findings at each specified facility, so that the consumers may make informed decisions concerning whether to use Defendants' drugs or to transition to alternative products.

6. Defendants represent that the Corporate Defendant decided, for commercial reasons, to discontinue all manufacturing, processing, packing, labeling, holding, and distributing of drugs from Defendants' Facility as of August 2022, to discontinue operations at Defendants' Facility, to undertake an orderly closure of the business, and to subsequently sell the site. Defendants represent that as of the date of entry of this decree, they are not engaged in, either directly or indirectly, manufacturing any drugs at Defendants' Facility and that, as of the date of entry of this decree, they will no longer engage in the processing, packing, labeling, holding, or distributing of any drugs, nor are they causing the manufacture, holding, or distribution of any drugs at or from Defendants' Facility. Notwithstanding this paragraph, Defendants may continue holding noncommercial samples of drug products used solely under Corporate Defendant's written testing program to establish that finished drug products comply with the Act and its implementing regulations; provided, however, that these drug products shall not be commercially distributed.

7. If Defendants intend to resume, either directly or indirectly, manufacturing drugs at or from Defendants' Facility at any time after entry of this decree, or processing, packing, labeling, holding, or distributing any drugs at or from Defendants' Facility, or causing any such activities at or from Defendant's Facility, at any time after entry of this decree, Defendants shall notify FDA in writing in advance of resuming any such activities. This notice shall identify the type(s) of drugs Defendants intend to manufacture, process, pack, label, hold, or distribute and their roles and responsibilities in such activities for the Corporate Defendant. Also, in advance of resuming any such activities, if the Individual Defendant no longer has any responsibilities with regard to such activities, Defendants shall file a motion with this Court seeking to amend this

decree to add, as an Individual Defendant, a new individual who will serve as the president or the chief executive officer of the Corporate Defendant or its successor. In the motion Defendants may move to substitute the new individual for the current Individual Defendant. The United States will not oppose such a motion so long as the United States has sufficient evidence or information regarding the proposed individual's position and responsibilities. In addition, if Defendants intend to resume, either directly or indirectly, manufacturing, processing, packing, labeling, holding, or distributing any drugs at or from Defendants' Facility, Defendants shall not resume any such activities until Defendants have complied with paragraph 9(A)-(E) of this decree, FDA has inspected Defendants' Facility pursuant to paragraph 9(F) of this decree, Corporate Defendant has paid the costs of such inspection(s) pursuant to paragraph 16 of this decree, and Defendants have received written notice from FDA, as required by paragraph 9(G) of this decree, and then Defendants shall resume such activities only to the extent authorized in FDA's written notice.

8. Upon entry of this decree, Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors and assigns, and any and all persons or entities in active concert or participation with any of them who have responsibility for the manufacture, processing, packing, storage, and/or distribution of drugs at Defendants' Facility and received actual notice of this decree by personal service or otherwise (collectively, "Associated Persons") are permanently restrained and enjoined under 21 U.S.C. § 332(a) from directly or indirectly doing or causing to be done any of the following acts:

A. Violating 21 U.S.C. § 331(a), by introducing or delivering, or causing to

be introduced or delivered, into interstate commerce drugs that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B); and

B. Violating 21 U.S.C. § 331(k), by causing drugs that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B).

9. Upon entry of this decree, Defendants and each and all of their Associated Persons are permanently restrained and enjoined under 21 U.S.C. § 332(a) from directly or indirectly manufacturing, processing, packing, labeling, holding, or distributing any drug at or from Defendants' Facility, unless and until:

A. Defendants' methods, facilities, and controls used to manufacture, process, pack, label, and hold drugs are established, operated, and administered in compliance with this decree, the Act, and the Act's implementing regulations;

B. Defendants retain, at Corporate Defendant's expense, an independent person or persons (the "CGMP expert"), who is without any personal or financial ties (including, but not limited to, prior employment by Defendants), other than the retention agreement, to Defendants and their families, and who, by reason of background, training, education, or experience (*see* 21 C.F.R. § 211.34), is qualified to inspect Corporate Defendant's drug manufacturing operations to determine whether the methods, facilities, and controls are operated and administered in conformity with CGMP. Defendants shall notify the FDA in writing of the identity and qualifications of the CGMP expert as soon as they retain such expert;

C. The CGMP expert shall perform a comprehensive inspection of

Defendants' Facility and the methods and controls used to manufacture, process, pack, label, and hold drugs, and certify in writing to FDA that: (1) he or she has inspected Defendants' Facility, methods, processes, and controls; and (2) Defendants' operations are, in the CGMP expert's opinion, in compliance with 21 U.S.C. § 351(a)(2)(B), 21 C.F.R. pts. 210 & 211, and this decree. The CGMP expert's report of the inspection, which shall be submitted to FDA, shall include, but not be limited to, the following:

i. An evaluation of Corporate Defendants' current state of compliance with respect to the deviations set forth on FDA's lists of inspectional observations issued to Defendants since April 2011;

ii. An evaluation of whether Defendants, in a timely manner, thoroughly investigate any unexplained discrepancy or the failure of a batch of drug or any of its components to meet any of the product's or component's specifications, including the extension of such investigation to other batches of the same drug or component and other drugs that may have been associated with the specific failure or discrepancy, as required by 21 C.F.R. § 211.192. Such evaluation shall include, but not be limited to, a determination of whether the assigned root cause(s) to the unexplained discrepancy is scientifically sound and supported with evidence, and whether the corrective action(s) and preventive action(s) are appropriate;

iii. A determination of whether Defendants have established and are following laboratory controls that include scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that components, drug product containers, closures, in-process materials, labeling, and drug products conform to appropriate

standards of identity, strength, quality and purity, as required by 21 C.F.R. § 211.160(b);

iv. An evaluation of whether Defendants clean, maintain, and, as appropriate for the nature of the drug, sanitize and/or sterilize equipment and utensils at appropriate intervals to prevent malfunctions or contamination that would alter the safety, identity, strength, quality, or purity of the drug product beyond the official or other established requirements, as required by 21 C.F.R. § 211.67(a); and

v. A determination of whether Defendants have established and are following adequate laboratory control mechanisms, as required by 21 C.F.R. § 211.160(a);

D. Defendants destroy in accordance with the procedures provided in paragraph 11 all drugs in their possession, custody, or control, except those drugs FDA determined to be Medically Necessary under paragraph 5(E) of this decree;

E. Defendants report to FDA in writing the actions they have taken to:

i. correct the CGMP deviations violations brought to Defendants' attention by FDA, the CGMP expert, and any other source; and

ii. ensure that the methods used in, and the facilities and controls used for, manufacturing, processing, packing, labeling, holding, and distributing drugs are operated and will be continuously administered in conformity with CGMP;

F. FDA representatives, at FDA's discretion, inspect Defendants' Facility to determine whether the requirements of this decree have been met and whether Defendants are operating in conformity with the Act, its implementing regulations, and this decree; and

G. FDA notifies Defendants in writing that they appear to be in compliance

with the requirements set forth in paragraphs 9(A)-(E) of this decree. In no circumstance shall FDA's silence be construed as a substitute for written notification.

10. Notwithstanding paragraph 9, Defendants may continue the following activities at Defendants' Facility:

A. Manufacturing, processing, packing, and labeling Medically Necessary drugs, as defined in paragraph 5(D), at Defendants' Facility, and may distribute such drugs from Defendants' Facility to customers who have received the Notification Guide described in paragraph 5(F), provided that Defendants maintain a record of all sales and distribution of Medically Necessary drugs including, but not limited to, shipping documents and a detailed description of the drugs distributed. Defendants shall make the records described in this paragraph available to FDA immediately upon request; and

B. Manufacturing, processing, packing, labeling, and holding all noncommercial samples of drug products used solely under Corporate Defendant's written testing program to establish that finished drug products comply with the Act and its implementing regulations; provided, however, that these drug products shall not be commercially distributed.

11. Within sixty calendar days after the entry of this decree, Defendants, under FDA's supervision, shall destroy all drugs that are in Defendants' possession, custody, or control at Defendants' Facility except those drugs determined to be Medically Necessary under paragraph 5(E) of this decree. Corporate Defendant shall bear the costs of destruction and the costs of FDA's supervision. Defendants shall not dispose of any drugs in a manner contrary to the provisions of the Act, any other federal law, or the laws or any state or territory, as defined in the

Act, in which the drugs are disposed.

12. After Defendants have complied with paragraphs 9(A)-(E) and received FDA's written notification pursuant to paragraph 9(G), Defendants shall retain an independent person or persons who shall meet the criteria described in paragraph 9(B) to conduct audits of Defendants' Facility no less frequently than once every six months for a period of no less than five years (hereinafter, the "Auditor"). Such audits shall include, at a minimum, an evaluation of Defendants' compliance with the six CGMP systems described in FDA Compliance Program 7356.002. The first audit shall occur not more than six months after Defendants have received FDA's written notification pursuant to paragraph 9(G). If Defendants choose, the Auditor may be the same person or persons retained as the CGMP expert described in paragraph 9(B).

A. At the conclusion of each audit inspection, the Auditor shall prepare a detailed written audit report analyzing whether Defendants' operations are in compliance with CGMP and identifying any deviations from such requirements ("Audit Report Observations"). As a part of every audit report, the Auditor shall assess the adequacy of corrective actions taken by Defendants to correct all previous Audit Report Observations. The Auditor shall deliver the audit reports contemporaneously to Defendants and FDA by electronic mail, courier service, or overnight delivery service, no later than fifteen business days after the date the audit inspection is completed. Defendants shall maintain the audit reports in separate files at Defendants' Facility and shall promptly make the audit reports available to FDA upon request.

B. If an audit report contains any observations indicating that Defendants' drugs are not in compliance with CGMP, Defendants shall, within fifteen calendar days of receipt

of the audit report, submit a written response to each Audit Report Observation contemporaneously to the Auditor and FDA. If an audit report contains any observations indicating that Defendants' drugs are not in compliance with CGMP, then Defendants shall correct all Audit Report Observations within fifteen calendar days of receipt of the audit report, unless FDA notifies Defendants that a shorter time period is necessary. If, after receiving the audit report, Defendants believe that correction of the deviations will take longer than fifteen calendar days, Defendants shall, within ten calendar days of receipt of the audit report, submit to FDA in writing a proposed schedule for completing corrections ("Audit Correction Schedule"). The Audit Correction Schedule must be reviewed and approved by FDA in writing prior to implementation by Defendants. In no circumstance shall FDA's silence be construed as a substitute for written approval. Defendants shall complete all corrections according to the approved audit correction schedule. Immediately upon correction, Defendants shall submit documentation of their corrections to the Auditor and to FDA. Within thirty calendar days of the Auditor's receipt of Defendants' documentation of corrections, unless FDA notifies Defendants that a shorter time period is necessary, or within the time period provided in a correction schedule approved by FDA, the Auditor shall review the actions that Defendants took to correct the Audit Report Observations. Within five business days of beginning that review, the Auditor shall report in writing to FDA whether each of the Audit Report Observations has been corrected and, if not, which Audit Report Observations remain uncorrected.

C. Defendants' retention agreement with the Auditor must permit the Auditor to communicate and/or meet directly with FDA, either upon the initiative of the Auditor or upon

FDA's request, and without Defendants' presence, prior knowledge, or approval, to discuss his or her review of Defendants' Facility.

13. If at any time after entry of this decree, FDA determines, based on the results of an inspection, the analysis of a sample, a report, or data prepared or submitted by Defendants, the CGMP expert, the Auditor, or any other information, that Defendants have failed to comply with any provision of this decree, have violated the Act or its implementing regulations, or that additional corrective actions are necessary to achieve compliance with this decree, the Act, or its implementing regulations at Defendants' Facility, FDA may, as and when it deems necessary, notify Defendants in writing of the noncompliance and order Defendants to take appropriate corrective action, including, but not limited to, ordering Defendants to immediately take one or more of the following actions at Defendants' Facility:

A. Cease manufacturing, processing, packing, labeling, holding, or distributing any or all drugs;

B. Recall, at Corporate Defendant's expense, any drug that in FDA's judgment is adulterated or otherwise in violation of this decree, the Act, or its implementing regulations;

C. Destroy, at Corporate Defendant's expense, any drug in their possession, custody, or control, that in FDA's judgment is adulterated or otherwise in violation of this decree, the Act, or its implementing regulations;

C. Revise, modify, expand, or continue to submit any reports or plans prepared pursuant to this decree;

D. Submit additional reports or information to FDA as requested;

E. Assess liquidated damages, as provided by paragraph 22 of this decree;

F. Issue a safety alert; and/or

G. Take any other corrective actions as FDA, in its discretion, deems necessary to bring Defendants into compliance with this decree, the Act, or its implementing regulations.

This remedy shall be separate and apart from, and in addition to, any other remedy available to the United States under this decree or under the law.

14. Upon receipt of any order issued by FDA pursuant to paragraph 13, Defendants shall immediately and fully comply with the terms of the order. Any cessation of operations or other action described in paragraph 13 shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with this decree, the Act, and its implementing regulations, and that Defendants may resume operations. The cost of FDA inspections, sampling, testing, travel time, and subsistence expenses to implement the remedies set forth in paragraph 13 shall be borne by corporate Defendant at the rates specified in paragraph 16.

15. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to inspect Defendants' Facility and take any other measures necessary to monitor and ensure continuing compliance with the terms of this decree. During inspections, FDA representatives shall have immediate access to buildings, equipment, raw ingredients, in-process materials, finished products, containers, packaging material, labeling, and other material therein, and shall be permitted to: take photographs; make video and audio recordings; take samples of Corporate Defendant's raw ingredients, in-process materials, finished products,

containers, packaging material, labeling, and other material; and examine and copy all records relating to the manufacture, processing, packing, labeling, holding, and distribution of any and all drugs and their components. Defendants shall permit inspections upon presentation of a copy of this decree and appropriate credentials. The inspection authority that this decree grants is separate from, and in addition to, FDA's inspection authority in 21 U.S.C. § 374.

16. Corporate Defendant shall reimburse FDA for the costs of all FDA inspections, investigations, supervision, analyses, examinations, and reviews that FDA deems necessary to evaluate Defendants' compliance with any part of this decree, at the standard rates prevailing at the time the costs are incurred. As of the date of entry of this decree, these rates are: $105.46 per hour or fraction thereof per representative for inspection and investigative work; $126.24 per hour or fraction thereof per representative for analytical or review work; $0.59 per mile (plus tolls) for travel expenses by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate for subsistence expenses where necessary. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

17. Within ten calendar days of the entry of this decree, Defendants shall post a copy of this decree in a common area at Defendants' Facility and shall ensure that the decree remains posted for as long as the decree remains in effect.

18. Within ten calendar days of the date of entry of this decree, Defendants shall provide a copy of the decree by personal service or certified mail (return receipt requested) to Associated Persons, each and all of their directors, officers, agents, representatives, employees,

attorneys, successors and assigns, and any and all persons or entities in active concert or participation with any of them. Within thirty calendar days of the date of entry of this decree, Defendants shall provide to FDA an affidavit stating the fact and manner of their compliance with this paragraph, identifying the names, addresses, and positions of all persons who have received a copy of this decree.

19. In the event that either of the Defendants becomes associated with any additional Associated Person(s) at any time after entry of this decree, Defendants immediately shall provide a copy of this decree, by personal service or certified mail (restricted delivery, return receipt requested), to such Associated Person(s). Within ten calendar days of each time any of the Defendants becomes associated with any such additional Associated Person(s), Defendants shall provide to FDA an affidavit stating the fact and manner of their compliance with this paragraph, identifying the names, addresses, and positions of all Associated Persons who received a copy of this decree pursuant to this paragraph. Within ten calendar days of receiving a request from FDA for any information or documentation that FDA deems necessary to evaluate Defendants' compliance with this paragraph, Defendants shall provide such information or documentation to FDA.

20. Defendants shall notify FDA in writing at least fifteen calendar days before any change in ownership, name, or character of Corporate Defendant's business that occurs after entry of this decree, including an incorporation, reorganization, creation of a subsidiary, relocation, dissolution, bankruptcy, assignment, sale, or any other change in the structure or identity of the Corporate Defendant, or the sale or assignment of any business assets, such as buildings,

equipment, or inventory that may affect obligations arising out of this decree. Defendants shall provide a copy of this decree to any prospective successor or assign at least thirty calendar days prior to any sale or assignment. Defendants shall furnish FDA with an affidavit of compliance with this paragraph no later than ten calendar days prior to such assignment or change in ownership.

21. All notifications, correspondence, and communications to FDA required by the terms of this decree shall be addressed to the Director of FDA's Division of Pharmaceutical Quality Operations III, at ORAPHARM3_RESPONSES@fda.hhs.gov.

22. If Defendants fail to comply with any provision of the Act, its implementing regulations, and/or this decree with respect to any of Defendants' products and/or Defendants' Facility, including any time frame imposed by this decree, then, on written notice of FDA in this proceeding, Corporate Defendant shall pay to the United States of America: five thousand dollars in liquidated damages for each day such violation continues; an additional sum of five thousand dollars in liquidated damages for each violation; and further additional sum equal to the retail value of drugs that have been received, manufactured, processed, packed, repacked, labeled, held, and/or distributed in violation of the Act, its implementing regulations, and/or this decree. The remedy in this paragraph shall be in addition to any other remedies available to the United States under this decree or the law.

23. Should the United States bring and prevail in a contempt action to enforce the terms of this decree, Corporate Defendant shall, in addition to other remedies, reimburse the United States for its attorneys' fees (including overhead), investigational and analytical expenses, expert

witness fees, and court costs relating to such contempt proceedings.

24. Defendants shall abide by the decisions of FDA, and FDA's decisions shall be final in implementing this decree. All decisions by the FDA in implementing this decree shall be vested in FDA's discretion and, if contested, shall be reviewed by this court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review by the court of any final decision that FDA rendered pursuant to this decree shall be based exclusively on the written record before FDA at the time the decision was made. No discovery shall be taken by either party.

25. If, and for so long as, the Individual Defendant ceases to be employed by or to act on behalf of the Corporate Defendant, he shall not be subject to this decree except as to such Individual Defendant's act(s) or failures(s) to act under this decree prior to the time such individual ceased to be employed by or to act on behalf of the Corporate Defendant.

26. This Court retains jurisdiction over this action and the parties thereto for the purpose of enforcing and modifying this decree and for the purpose of granting such additional relief as may be necessary or appropriate.

SO ORDERED, this 19th day of August, 2022.

Marvin E. Aspen

UNITED STATES DISTRICT JUDGE

Entry consented to:

For Plaintiff

BRIAN M. BOYNTON
Principal Deputy Assistant Attorney General
Civil Division

ARUN G. RAO
Deputy Assistant Attorney General

GUSTAV W. EYLER
Director
Consumer Protection Branch

ALLAN GORDUS
Assistant Director

/s/ Christina Parascandola
CHRISTINA PARASCANDOLA
Senior Litigation Counsel
Consumer Protection Branch
Department of Justice
Washington, D.C. 20044
(202) 514-3097
christina.parascandola@usdoj.gov

JOHN R. LAUSCH, JR.
United States Attorney

/s/ Donald R. Lorenzen
DONALD R. LORENZEN
Special Assistant United States Attorney
Senior Litigation Counsel
Consumer Protection Branch
219 South Dearborn St., 5th Floor
Chicago, Illinois 60604
(312) 353-5330
donald.lorenzen@usdoj.gov

OF COUNSEL:

MARK RAZA
Chief Counsel
Food and Drug Administration

PERHAM GORJI
Deputy Chief Counsel for Litigation

JOSHUA A. DAVENPORT
Associate Chief Counsel for Enforcement
United States Department of Health and Human Services
Office of the General Counsel
White Oak 31, Room 4426A
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

For Defendants

GOPALAKRISHNAN VENKATESAN
Individually and on behalf of
MORTON GROVE
PHARMACEUTICALS, INC.

Attorney for Defendant
Gopalakrishnan Venkatesan:

JAMES P. ELLISON
Hyman, Phelps & McNamara PC
700 Thirteenth Street, NW
Suite 1200
Washington, D.C. 20005
Telephone: (202) 737-5600

Attorneys for Defendant
Morton Grove Pharmaceuticals:

SHELDON BRADSHAW
KYLE SAMPSON
JESSICA RINGEL
King & Spalding LLP
1700 Pennsylvania Ave, NW
Washington, D.C. 20006-4707
Telephone: (202) 626 9225

For Defendants

GOPALAKRISHNAN VENKATESAN
Individually and on behalf of
MORTON GROVE
PHARMACEUTICALS, INC.

Attorney for Defendant
Gopalakrishnan Venkatesan:

JAMES P. ELLISON
Hyman, Phelps & McNamara PC
700 Thirteenth Street, NW
Suite 1200
Washington, D.C. 20005
Telephone: (202) 737-5600

Attorneys for Defendant
Morton Grove Pharmaceuticals:

SHELDON BRADSHAW
KYLE SAMPSON
JESSICA RINGEL
King & Spalding LLP
1700 Pennsylvania Ave, NW
Washington, D.C. 20006-4707
Telephone: (202) 626 9225