

MONITOR AGREEMENT

This Monitor Agreement (“Monitor Agreement”) entered into this 21st day of January 2016 between Francis J. Civile and GAVIS Pharmaceuticals LLC and Novel Laboratories Inc. (collectively, “Respondent”), provides as follows:

WHEREAS, the United States Federal Trade Commission (the “Commission”), in *In the Matter of Lupin Ltd.* (Commission File No. FTC File No. 151-0202), has accepted or will shortly accept for public comment an Agreement Containing Consent Order, incorporating a Decision and Order (the “Order”), which, among other things, requires Respondent to divest or transfer certain defined assets and, to ensure that Respondent comply with its obligations under the Order, provides for the appointment of a Monitor;

WHEREAS, the Commission may appoint Francis J. Civile as such monitor (the “Monitor”) pursuant to the Order to monitor Respondent compliance with the terms of the Order and with the Remedial Agreements referenced in the Order, and Francis J. Civile has consented to such appointment;

WHEREAS, the Order further provides or will provide that Respondent shall execute a Monitor Agreement, subject to the prior approval of the Commission, conferring all the rights, powers and authority necessary to permit the Monitor to carry out such duties and responsibilities pursuant to the Order;

WHEREAS, this Monitor Agreement, although executed by the Monitor and Respondent, is not effective for any purpose, including but not limited to imposing rights and responsibilities on Respondent or the Monitor under the Order, until it has been approved by the Commission; and

WHEREAS, the parties to this Monitor Agreement intend to be legally bound;

NOW, THEREFORE, the parties agree as follows:

1. Capitalized terms used herein and not specifically defined herein shall have the respective definitions given to them in the Order. The term “Monitored Assets” means the Mesalamine Assets as defined in the Order.
2. The Monitor shall have all of the powers and responsibilities conferred upon the Monitor by the Order, including but not limited to:
 - a. supervising the divestiture of the Monitored Assets;
 - b. supervising the performance of any transition required by the Order.

For avoidance of doubt, Monitor’s powers and responsibilities over Respondent shall expire at 11:59 p.m. on the date that Lupin completes its acquisition of Respondent.

3. Respondent hereby agrees that it will fully and promptly comply with all terms of

the Order requiring them to confer all rights, powers, authority and privileges upon the Monitor, or to impose upon itself any duties or obligations with respect to the Monitor, to enable the Monitor to perform the duties and responsibilities of the Monitor hereunder.

4. Respondent further agrees that:

- a. it will use reasonable best efforts to ensure that the relevant Commission-approved Acquirer of the affected assets enters into an agreement with the Monitor governing the facilitation of the Monitor's duties under the Order and the exchange of information between the Commission-approved Acquirer and the Monitor;
- b. no later than ten (10) business days after the Commission approves this Monitor Agreement, it will provide the Monitor with the following, as applicable:
 - (1) a copy of the Remedial Agreements (or drafts thereof) relating to the Monitored Assets, including any exhibits, schedules and appendices;
 - (2) a copy of the offering or information memoranda (if any), or similar documents and information, provided to the Commission-approved Acquirer relating to the sale of the Monitored Assets;
 - (3) copies of correspondence with, and written reports or minutes of meetings of all substantive contacts and discussions with, any Commission-approved Acquirer relating to the Monitored Assets or Remedial Agreements;
 - (4) an inventory and description of the Monitored Assets, including a complete inventory of any existing FDA approvals and pending FDA approvals for the products included in the Monitored Assets and identifying the person(s) responsible for taking such actions as are required to maintain or complete such approvals; and
 - (5) copies of any other relevant documents, as requested, including but not limited to significant product development and manufacturing reports, FDA correspondence/minutes, marketing assessments, annual sales reports for current year-to-date and last year, related to the Monitored Assets.
- c. it will designate a senior individual as a primary contact for the Monitor and provide a written list of the principal individuals to be involved in the transitioning of the Monitored Assets to the Commission-approved Acquirer, together with their locations, telephone numbers, electronic mail

address, and responsibilities, and will provide the Monitor with written notice of any changes in such personnel occurring thereafter;

- d. it will use reasonable efforts to provide the Monitor with prompt notification (but not later than such notification is available to other meeting participants) of significant meetings, including date, time and venue, scheduled after the execution of this Monitor Agreement, relating to the manufacture, registration, regulatory approvals, marketing, sale and divestiture of the Monitored Assets, and such meetings may be attended by the Monitor or his representative, at the Monitor's option, or at the request of the Commission or staff of the Commission;
- e. it will provide the Monitor with the minutes, if any, of the above-referenced meetings as soon as practicable and, in any event, not later than when those minutes are available to any employee of the Respondent other than Respondent's attorneys;
- f. it will provide the Monitor with all relevant correspondence, meeting minutes, telephone summaries, reports, sent to or received from the FDA after the execution of this Monitor Agreement relating to the Monitored Assets, and will provide prompt notice of any and all meetings or communications with the FDA relating to or affecting the Monitored Assets;
- g. it will provide the Monitor with electronic or hard copies, as may be appropriate, of all reports submitted to the Commission pursuant to the Order, simultaneous with the submission of such reports to the Commission;
- h. to the extent not reflected in the reports submitted to the Commission pursuant to the Consent Agreement and the Order, it will provide every (3) months commencing one (1) month after the Consent Agreement is accepted by the Commission for public comment, or as reasonably requested by the Monitor, full and detailed electronic or hard copy reports to the Monitor reasonably describing all of Respondent's activities and obligations under the Order during that period concerning the Monitored Assets including, without limitation to the extent applicable:
 - (1) all significant activities concerning the assistance, advice and consultation provided to any Commission-approved Acquirer generally as required in the relevant Paragraphs of the Order;
 - (2) as applicable, all significant activities concerned with the development, regulatory aspects, manufacture, supply and technology transfer of the products included in the Monitored Assets including, without limitation, negotiation and operation of

any supply agreements and actual supply and inventory; and

- (3) as applicable, all minutes and records of significant meetings, action plans, and follow-ups to actions plans and meetings, with the Commission-approved Acquirer related to the research, development, regulatory aspects, manufacture and supply, and technology transfer of the products included in the Monitored Assets and, upon request, Respondent shall provide the Monitor with any records exchanged at such meetings, or such other records that the Monitor may reasonably require relating to the research, development, regulatory aspects, manufacture and supply, and technology transfer of the products included in the Monitored Assets;

provided however, that, at the time the Order becomes final, the reports described in this paragraph shall be due to the Monitor either as requested by the Monitor, or within five (5) business days of the date that Respondent file their reports with the Commission as required pursuant to the relevant provision(s) of the Order;

- i. it will comply with the Monitor's reasonable requests for onsite visits to Respondent's facilities (or to any contract manufacturer's facility) used to manufacture the products included in the Monitored Assets; and
 - j. it will comply with the Monitor's reasonable requests for follow-up discussions or supplementary information concerning any reports provided to or requested by the Monitor pursuant to this Monitor Agreement, including, as applicable: meetings and discussions with the principal staff involved in any activities relating to the research, development, regulatory aspects, manufacture, sale and/or divestiture of the Monitored Assets or any product comprised therein and, further including, actions necessary to maintain all necessary FDA approvals to develop, manufacture and sell any of the products included in the Monitored Assets in the United States and to prevent the destruction, removal, wasting, deterioration or impairment of the Monitored Assets, and will provide the Monitor with access to and hard copies of all other data, records or other information that the Monitor reasonably believes are necessary to the proper discharge of his responsibilities under the Order.
5. Respondent shall promptly notify the Monitor of any significant written or oral communication that occurs after the date of this Monitor Agreement between the Commission and Respondent related to the Monitored Assets in the Order or this Monitor Agreement, together with electronic or hard copies (or, in the case of oral communications, summaries), as may be reasonably requested by the Monitor, of such communications.

6. Respondent agrees that to the extent authorized by the Order, the Monitor shall have the authority to employ, at the expense of the Respondent, and with the consent of Respondent, which will not unreasonably be withheld, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties and responsibilities.
7. The Monitor and any other parties employed pursuant to Paragraph 6 above (the "Designees") shall maintain the confidentiality of all information provided to the Monitor by Respondent. Such information shall be used by the Monitor and his Designees only in connection with the performance of the Monitor's duties pursuant to this Agreement. Such information shall not be disclosed by the Monitor or his Designees to any third party, other than:
 - a. persons employed by, or working with, the Monitor under this Monitor Agreement and who have executed a confidentiality agreement consistent with the provisions of this Monitor Agreement; or
 - b. persons employed at the Commission and working on this matter.
8. The Monitor shall maintain a record and inform the Commission and the Respondent of all persons (other than representatives of the Commission) to whom confidential information related to this Monitor Agreement has been disclosed.
9. Upon termination of the Monitor's duties under this Monitor Agreement, the Monitor shall return, at Respondent's expense, to Respondent all material provided to the Monitor by Respondent that is confidential to Respondent and that it is entitled to have returned to them under the Order, or shall have it destroyed, at Respondent's request and expense. Monitor shall destroy any materials prepared by the Monitor and shall delete any electronic files that contain or reflect any confidential information of Respondent. Nothing herein shall abrogate the Monitor's duty of confidentiality, including the obligation to keep such information confidential for a period of ten (10) years after the termination of this Monitor Agreement;
10. The Monitor shall keep confidential for a period of ten (10) years all other aspects of the performance of his duties under this Monitor Agreement and shall not disclose any confidential or proprietary information relating thereto. To the extent that the Monitor wishes to retain any employee, agent, consultant or any other third party to assist the Monitor in accordance with the Order, the Monitor shall ensure that such persons have executed a confidentiality agreement in a form agreed upon by the Monitor and Respondent.

For the purpose hereof, information shall not be considered confidential or proprietary to the extent that it is or becomes part of the public domain (other than as the result of any action by the Monitor or by any employee, agent, affiliate or consultant of the Monitor), or to the extent that the recipient of such

information can demonstrate that such information was already known to the recipient at the time of receipt from a source other than the Monitor, Respondent, or any director, officer, employee, agent, consultant or affiliate of the Monitor or Respondent, when such source is entitled to make such disclosure to such recipient.

11. Nothing in this Monitor Agreement shall require Respondent to disclose any material or information that is subject to a legally recognized privilege or that Respondent is prohibited from disclosing by reason of law, court order or an agreement with a third party.
12. The Monitor shall not have a fiduciary responsibility to the Respondent, but shall have fiduciary duties to the Commission.
13. Each party shall be reasonably available to the other to discuss any questions or issues that either party may have concerning compliance with the Order as it relates to Respondent.
14. Respondent will pay the Monitor **REDACTED** all reasonable time spent in the performance of the Monitor's duties, *including* all monitoring activities related to the efforts of the Commission-approved Acquirer of the Monitored Assets, all work in connection with the negotiation and preparation of this Monitor Agreement, and all reasonable and necessary travel time. The Monitor's hourly rate should be reviewed and may be adjusted by agreement with Respondent every six months. For avoidance of doubt, Monitor shall only bill Respondent for time related to the Mesalamine Assets.
 - a. In addition, Respondent will pay (i) all out-of-pocket expenses reasonably incurred by the Monitor in the performance of the Monitor's duties, including any auto, train or air travel (at business class rates for international air travel exceeding 5 hours), and international telephone calls in the performance of the Monitor's duties and (ii) all fees and disbursements reasonably incurred by such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties.
 - b. When requested in connection with the performance of his duties under the Monitor Agreement, airline tickets will be purchased and prepaid by Respondent and provided to the Monitor. Personal use of the Monitor's automobile in connection with the performance of his duties under this Monitor Agreement shall be reimbursed at the current IRS standard automobile mileage rate (for 2015, 57.5 cents per mile).
 - c. The Monitor shall provide details and an explanation of all matters for which the Monitor submits an invoice or expense report to Respondent.

Monitor shall submit invoices and expense reports to Respondent on a quarterly basis. At its own expense, Respondent may retain an independent auditor to verify such invoices. Respondent will promptly pay invoices and expense reimbursements submitted by the Monitor upon receipt of such invoices and expense reports, but no later than thirty (30) days after receipt. Late payments after thirty (30) days are subject to an interest surcharge of 1-1/2% per month.

- d. All payments for invoices and expense reports shall be made in full in US dollars by ACH direct deposit to the Monitor's designated U.S. bank account (*details to be provided by Monitor*). Any ACH charges or wire transfer charges are to be paid by Respondent.
 - e. Invoices and expense reports from Monitor are to be sent electronically to ars@novellabs.net, copying amanda.reeves@lw.com and patrick.english@lw.com, to avoid any delays in processing for payment.
 - f. The Monitor shall have full and direct responsibility for compliance with all applicable laws, regulations and requirements pertaining to work permits, income and social security taxes, unemployment insurance, worker's compensation, disability insurance, and the like.
 - g. The Monitor shall continue to perform his duties during the pendency of any dispute as set forth in paragraph 19, unless otherwise directed by the Compliance Division or a court of competent jurisdiction. In the event that Respondent disputes any portion of the Monitor's invoices, Respondent shall pay the undisputed portion in the ordinary course and may withhold only the disputed portion pending the outcome of the dispute resolution process.
15. Respondent hereby confirms its obligation to indemnify the Monitor and hold the Monitor harmless in accordance with and to the extent required by the Order. Respondent shall indemnify the Monitor and any subcontractor and their respective agents, partners, principals, officers and employees (the "Indemnified Parties") and hold the Indemnified Parties harmless (regardless of form of action, whether in contract, statutory law, tort or otherwise) against any losses, claims, damages, liabilities or expenses arising out of or in connection with, the performance reasonably required under this Monitor Agreement of the Monitor's duties and obligations including all reasonable fees of counsel and other reasonable 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 misfeasance, gross negligence, willful or wanton acts, or bad faith by the Monitor.
16. The Monitor's maximum liability to the Respondent relating to services rendered pursuant to this Monitor Agreement (regardless of the form of the action, whether

in contract, statutory law, tort, or otherwise) shall be limited to the total sum of the fees paid to the Monitor by Respondent, except to the extent resulting from the misfeasance, gross negligence, willful or wanton acts, or bad faith by the Monitor or any of his subcontractors, agents, partners, principals, officers or employees, in which case the liability is not so limited.

17. Respondent agrees that the Respondent's obligations to indemnify the Monitor extend to any agreement that is entered between the Monitor and any Commission-approved Acquirer and relates to the Monitor's responsibilities under the Monitor Agreement and/or the Order, subject to Respondent having the ability first to review such an agreement and request reasonable changes.
18. Upon this Monitor Agreement becoming effective, the Monitor shall be permitted, and Respondent shall be required, to notify all Commission-approved Acquirers of his appointment as Monitor.
19. In the event of a disagreement or dispute between Respondent and the Monitor concerning Respondent's obligations under the Order and, in the event that such disagreement or dispute cannot be resolved by the parties, any party may seek the assistance of the responsible individual in the Commission's Compliance Division to resolve the issue. In the case of any disagreement or dispute between Respondent and the Monitor not relating to Respondent's obligations under the Order, and in the event that such disagreement or dispute cannot be resolved by the parties, the parties shall submit the matter to binding arbitration (before a single arbitrator) before the American Arbitration Association under its Commercial Arbitration Rules. Binding arbitration shall not be available, however, to resolve any disagreement or dispute concerning the Respondent's obligations pursuant to the Order.
20. This Monitor Agreement shall be subject to the substantive law of the State of New Jersey (regardless of any other jurisdiction's choice of law principles).
21. This Monitor Agreement shall terminate no later than the date set forth in the relevant provision of the Order or the date on which the Commission has appointed a substitute monitor pursuant to the Order, provided however, that the Commission may extend this Monitor Agreement as may be necessary or appropriate to accomplish the purposes of the Order. The confidentiality obligations of this Monitor Agreement shall survive its termination.
22. In the event that, during the term of this Monitor Agreement, the Monitor becomes aware that he has or may have a conflict of interest that may affect or could have the appearance of affecting the performance by the Monitor, or persons employed by, or working with, the Monitor, of any duty under this Monitor Agreement, the Monitor shall promptly inform both Respondent and the Commission of such conflict or potential conflict.

23. In the performance of his functions and duties under this Monitor Agreement, the Monitor shall exercise the standard of care and diligence that would be expected of a reasonable person in the conduct of his own business affairs.
24. It is understood that the Monitor will be serving under this Monitor Agreement as an independent contractor and that the relationship of employer and employee shall not exist between Monitor and Respondent.
25. This Monitor Agreement is for the sole benefit of the parties hereto and their permitted assigns and the Commission, and nothing herein express or implied shall give or be construed to give any other person any legal or equitable rights hereunder.
26. This Monitor Agreement contains the entire agreement between the parties hereto with respect to the matters described herein and replaces any and all prior agreements or understandings, whether written or oral.
27. Any notices or other communications required to be given hereunder shall be deemed to have been properly given, if sent by mail, overnight courier, or fax (with acknowledgment of receipt of such fax having been received), to the applicable party at its address below (or to such other address as to which such party shall hereafter notify the other party).

If to the Monitor, to:

Francis J. Civile
1 Corda Lane
Warren, New Jersey 07059

Telephone: (732) 428-7012
Facsimile: (732) 428-7240
Mobile: (973) 727-6832
Email: fjciville@aol.com

If to Respondent, to:

Amanda P. Reeves
Latham & Watkins LLP
555 11th Street NW
Washington, DC 20004
Telephone (202) 637-2183
Mobile (434) 825-1128
Email amanda.reeves@lw.com

If to the Commission, to:

Federal Trade Commission

600 Pennsylvania Avenue, NW
Washington, DC 20580
Attn.: Jennifer Lee
Telephone: (202) 326-2246
Email: jlee@ftc.gov

28. This Monitor Agreement may be signed in counterparts.

IN WITNESS WHEREOF, the parties hereto have executed this Monitor Agreement as of the date first above written.

Francis J. Civile



Francis J. Civile

GAVIS Pharmaceuticals LLC and Novel
Laboratories Inc.

By counsel:

Amanda P. Reeves
Latham & Watkins LLP



Amanda P. Reeves