

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA**

FEDERAL TRADE COMMISSION,)

Plaintiff,)

v.)

LUNDBECK INC.,)

Defendant.)

_____)

STATE OF MINNESOTA,)

Plaintiff,)

v.)

LUNDBECK INC.,)

Defendant.)

_____)

08-cv-6379 (JNE/JJG)

**PLAINTIFFS' [DRAFT]
REMEDY ORDER**

(Related Case)

08-cv-6381 (JNE/JJG)

It is ORDERED, ADJUDGED and DECREED:

I. Definitions

As used in this Order:

- A. "Lundbeck" means Lundbeck, Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Lundbeck, and the respective directors, officers, employees, agents, representatives, predecessors, successors, and assigns of each. Lundbeck is the successor to Ovation Pharmaceuticals, Inc.
- B. "Commission" means the Federal Trade Commission.

- C. “Acquirer” means a Person approved by the Commission to acquire the NeoProfen Assets that Lundbeck is required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to this Final Judgment.
- D. “Agency(ies)” means any government 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 a Product. The term “Agency” includes, without limitation, the United States Food and Drug Administration (“FDA”), and the United States Drug Enforcement Agency (“DEA”).
- E. “ANDA” means an Abbreviated New Drug Application, as defined under 21 U.S.C. § 355(j).
- F. “API” means active pharmaceutical ingredient.
- G. “GMP” means current Good Manufacturing Practice as set forth in the United States Federal, Food, Drug, and Cosmetic Act, as amended, and includes all rules and regulations promulgated by the FDA thereunder.
- H. “Closing Date” means the date on which the Divestiture Trustee consummates a transaction to assign, grant, license, divest, transfer, deliver, or otherwise convey assets or rights related to NeoProfen to an Acquirer pursuant to this Final Judgment.
- I. “Confidential Business Information” means all information owned by, or in the possession or control of, Lundbeck that is not in the public domain and that is directly related to the research, Development, manufacture, marketing, commercialization, importation, exportation, cost, supply, sales, sales support, or use of the Divestiture Product(s); *provided however*, that the restrictions contained in this Final Judgment regarding Lundbeck’s use, conveyance, provision, or disclosure of “Confidential Business Information” shall not apply to the following:
1. information that subsequently falls within the public domain through no violation of this Final Judgment or breach of confidentiality or non-disclosure agreement with respect to such information by Lundbeck;
 2. information that is required by law to be publicly disclosed;
 3. information that does not directly relate to NeoProfen;

4. information relating to either Lundbeck's general business strategies or practices relating to research, Development, manufacture, marketing or sales of Products that does not discuss with particularity NeoProfen; or
 5. information specifically excluded from the NeoProfen Assets.
- J. "Development" means all preclinical and clinical drug development activities, including formulation, test method development and stability testing, toxicology, process development, manufacturing scale-up, development-stage manufacturing, quality assurance/quality control development, statistical analysis and report writing, conducting clinical trials for the purpose of obtaining any and all approvals, licenses, registrations or authorizations from any Agency necessary for the manufacture, use, storage, import, export, transport, promotion, marketing, and sale of a Product (including any government price or reimbursement approvals), Product approval and registration, and regulatory affairs related to the foregoing.
- K. "Direct Cost" means a cost not to exceed the cost of labor, material, travel and other expenditures to the extent the costs are directly incurred to provide the relevant assistance or service.
- L. "Divestiture Trustee" means any trustee appointed by the Commission to effect the divestiture required by Section VI of this Final Judgment.
- M. "Geographic Territory" means the United States of America, including all its territories and possessions, unless otherwise specified.
- N. "FDA" means the United States Food and Drug Administration.
- O. "Indocin IV Product" means all Products that contain the active pharmaceutical ingredient generically known as Indocin IV (indomethacin sodium injectable in Development, manufactured, marketed or sold by Lundbeck pursuant to NDA 018878, and any supplements, amendments, or revisions thereto.
- P. "Interim Monitor" means any monitor appointed pursuant to Section V of this Final Judgment.
- Q. "NDA" means new drug application for a Product filed or to be filed with the FDA pursuant to the Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, as amended; 21 CFR Part 314, and all supplements, amendments, and revisions thereto, any preparatory work, drafts and data necessary for the preparation

thereof, and all correspondence between Defendant Lundbeck and the FDA related thereto.

- R. “NeoProfen Assets” means all of Lundbeck’s rights, title and interest in and to, the following assets:
1. NDA No. 021903, and any supplements, amendments, or revisions thereto;
 2. Product Scientific and Regulatory Material related to the NeoProfen Product;
 3. NeoProfen API Agreement; and
 4. Any other assets relating to the NeoProfen Product sold by Abbott Laboratories, Inc., to Lundbeck pursuant to the Asset Purchase Agreement dated January 18, 2006.
- S. “NeoProfen Product” means all Products that contain the active pharmaceutical ingredient generically known as NeoProfen (ibuprofen lysine) in Development, manufactured, marketed or sold by Lundbeck pursuant to NDA No. 021903 and any supplements, amendments, or revisions thereto.
- T. “Patents” means all patents, patent applications, including provisional patent applications, invention disclosures, certificates of invention and applications for certificates of invention and statutory invention registrations, in each case existing as of the Closing Date, and includes all reissues, additions, divisions, continuations, continuations-in-part, supplementary protection certificates, extensions and reexaminations thereof, all inventions disclosed therein, and all rights therein provided by international treaties and conventions, related to any Product of or owned by Lundbeck as of the Closing Date.
- U. “Person” means any individual, partnership, joint venture, firm, corporation, association, trust, unincorporated organization, or other business or Government Entity, and any subsidiaries, divisions, groups or affiliates thereof.
- V. “Product” means any pharmaceutical, biological, or generic composition containing any formulation or dosage of a compound referenced as its pharmaceutically, biologically, or genetically active ingredient.
- W. “Product Intellectual Property” means all of the following related to NeoProfen:

1. Patents;
 2. Product Trademarks, trade secrets, know-how, techniques, data, inventions, practices, methods, and other confidential or proprietary technical, business, research, Development and other information; and
 3. Rights to obtain and file for patents and copyrights and registrations thereof; *provided, however*, “Product Intellectual Property” does not include the corporate names or corporate trade dress of “Lundbeck,” or the corporate names or corporate trade dress of any other corporations or companies owned or controlled by Lundbeck or the related logos thereof.
- X. “Product Manufacturing Technology” means all manufacturing technology, trade secrets, know-how, and proprietary information (whether patented, patentable or otherwise) related to the manufacture of the NeoProfen Product including, but not limited to, the following: all product specifications, processes, product designs, plans, trade secrets, ideas, concepts, manufacturing, engineering, and other manuals and drawings, standard operating procedures, flow diagrams, chemical, safety, quality assurance, quality control, research records, clinical data, compositions, annual product reviews, regulatory communications, control history, current and historical information associated with the FDA applications conformance and cGMP compliance, and labeling and all other information related to the manufacturing process, supplier lists, and other master documents necessary for the manufacture, control and release of the NeoProfen Product that are owned or controlled by Lundbeck or which Lundbeck has the right to receive.
- Y. “Product Scientific and Regulatory Material” means all technological, scientific, chemical, biological, pharmacological, toxicological, regulatory, and clinical trial materials and information related to the NeoProfen Product that is owned and controlled by Lundbeck or which Lundbeck has a right to receive including, but not limited to:
1. Pharmacokinetic study reports related to the NeoProfen Product;
 2. Bioavailability study reports (including reference listed drug information) related to the NeoProfen Product;
 3. Bioequivalence study reports (including reference listed drug information) related to the NeoProfen Product;

4. All correspondence to Lundbeck from the FDA and from Lundbeck to the FDA relating to the NDA submitted by, on behalf of, or acquired by, Lundbeck related to the NeoProfen Product;
 5. Annual and periodic reports related to the above-described NDA, including any safety update reports;
 6. FDA approved Product labeling related to the NeoProfen Product;
 7. Currently used product package inserts (including historical change of controls summaries) related to the specified NeoProfen Product;
 8. FDA approved patient circulars and information related to the NeoProfen Product;
 9. Adverse events/serious adverse event summaries related to the NeoProfen Product;
 10. Summary of Product complaints from physicians related to the NeoProfen Product;
 11. Summary of Product complaints from customers related to the NeoProfen Product; and
 12. Product recall reports filed with the FDA related to the NeoProfen Product.
- Z. “Product Trademark(s)” means all proprietary names or designations, trademarks, service marks, trade names, and brand names, including registrations and applications for registration therefore (and all renewals, modifications, and extensions thereof) and all common law rights, and the goodwill symbolized thereby and associated therewith, for the NeoProfen Product.
- AA. “Remedial Agreement” means any agreement between a Divestiture Trustee and an Acquirer that has been approved by the Commission to accomplish the requirements of this Final Judgment, including all amendments, exhibits, attachments, agreements, and schedules thereto, related to the relevant assets or rights to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed, and that has been approved by the Commission to accomplish the requirements of the Final Judgment.

- BB. “Retained Product(s)” means any Product(s) owned by Lundbeck that are not the NeoProfen Product.
- CC. “Third Party (ies)” means any non-governmental Person other than the following: Lundbeck or the Acquirer of the NeoProfen Product.

II. Appointment of Trustee to Divest NeoProfen Assets and Account for Monopoly Profits to Be Disgorged

- A. The Commission shall appoint a Divestiture Trustee:
 - 1. To assign, grant, license, divest, transfer, deliver or otherwise convey the NeoProfen Assets in a manner that satisfies the requirements of this Final Judgment. The Divestiture Trustee shall have two (2) years after the date the Commission approves the Trust Agreement described herein to accomplish the divestiture, which shall be subject to the prior approval of the Commission. If, however, at the end of the two (2) year period, the Divestiture Trustee has submitted a plan of divestiture, the Commission may ask the Court to extend the divestiture period to effect that divestiture; and
 - 2. To calculate the profits Defendant Lundbeck realized as a result of its unlawful acquisition of NeoProfen, according to the Court’s instructions; and
 - 3. To submit a report to the Court setting forth the result of the calculation of profits specified in Section II.A.2 and the basis for the result.
- B. The Commission shall select the Divestiture Trustee, subject to the consent of Defendant Lundbeck, which consent shall not be unreasonably withheld. If Defendant Lundbeck has not opposed, in writing, including the reasons for opposing, the selection of a proposed Divestiture Trustee within ten (10) days after notice by the staff of the Commission to Defendant Lundbeck of the identity of any proposed Divestiture Trustee, Defendant Lundbeck shall be deemed to have consented to the selection of the proposed Interim Monitor. The Divestiture Trustee appointed pursuant to this Final Judgment may be the same person appointed as an Interim Monitor pursuant to Section VI of this Final Judgment.
- C. Not later than ten (10) days after the appointment of the Divestiture Trustee, Defendant Lundbeck shall execute an agreement that, subject to the prior approval of the Commission, confers on the Divestiture Trustee all the rights and powers necessary to permit the Divestiture to divest the NeoProfen Assets

in compliance with the relevant requirements of the Final Judgment and in a manner consistent with the purposes of the Final Judgment.

- E. After the appointment of a Divestiture Trustee becomes effective, only the Divestiture Trustee shall have the right, subject to the prior approval of the Commission, to sell the NeoProfen Assets. The Divestiture Trustee shall have the power and authority to accomplish the divestitures to an Acquirer(s) acceptable to the Commission at such price and on such terms as are then obtainable upon reasonable effort by the Divestiture Trustee, subject to the provisions of Sections II, through VII of this Final Judgment, and shall have such other powers as this Court deems appropriate. The Divestiture Trustee shall notify the Commission and Defendant Lundbeck within two (2) business days following the execution of a Remedial Agreement with an Acquirer. Subject to Section II (G) of this Final Judgment, the Divestiture Trustee may hire at the cost and expense of Defendant Lundbeck any investment bankers, attorneys, or other agents, who shall be solely accountable to the trustee, reasonably necessary in the trustee's judgment to assist in the divestiture.
- F. Defendant Lundbeck shall not object to a sale by the Divestiture Trustee on any ground other than the Divestiture Trustee's malfeasance. Any such objections by Defendant Lundbeck must be conveyed in writing to the Commission and the Divestiture Trustee within ten (10) calendar days after receiving the notification from the Divestiture Trustee required by Section II (E).
- G. The Divestiture Trustee shall serve, without bond or other security, at the cost and expense of Defendant Lundbeck, on such reasonable and customary terms and conditions as the Commission or the Court may set. The Divestiture Trustee shall have the authority to employ, at the cost and expense of Defendant Lundbeck, such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are necessary to carry out the Divestiture Trustee's duties and responsibilities. The Divestiture Trustee shall account for all monies derived from the divestiture and all expenses incurred. After approval by the Commission of the account of the Divestiture Trustee, including fees for the Divestiture Trustee's services, the Divestiture Trustee's trust agreement 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 Final Judgment.
- H. Defendant Lundbeck shall use its best efforts to assist the Divestiture Trustee in accomplishing the required divestiture. Defendant Lundbeck shall provide

the Divestiture Trustee and any consultants, accountants, attorneys, and other persons retained by the trustee full and complete access to the personnel, books, records, and facilities of the assets to be divested, and Defendant Lundbeck shall develop financial and other information relevant to such assets as the Divestiture Trustee may reasonably request, subject to reasonable protection for trade secret or other confidential research, development, or commercial information. Defendant Lundbeck shall take no action to interfere with or to impede the Divestiture Trustee's accomplishment of the divestiture. Any delays in divestiture caused by Defendant Lundbeck shall extend the time for divestiture under this Section II in an amount equal to the delay, as determined by the Commission or this Court.

- I. After its appointment, the Divestiture Trustee shall file monthly reports with the Commission setting forth the Divestiture Trustee's efforts to accomplish the divestitures ordered under this Final Judgment. Such reports shall include the name, address, and telephone number of each person who, during the preceding month, made an offer to acquire, expressed an interest in acquiring, entered into negotiations to acquire, or was contacted or made an inquiry about acquiring, any interest in the NeoProfen Assets, and shall describe in detail each contact with any such person. The Divestiture Trustee shall maintain full records of all efforts made to divest the NeoProfen Assets.
- J. If the Divestiture Trustee has not accomplished the divestiture ordered under this Final Judgment within two (2) years after its appointment, the Divestiture Trustee shall promptly file with the Court a report setting forth (1) the Divestiture Trustee's efforts to accomplish the required divestiture, (2) the reasons, in the Divestiture Trustee's judgment, why the required divestiture has not been accomplished, and (3) the Divestiture Trustee's recommendations. To the extent such reports contain information that the Divestiture Trustee deems confidential, such reports shall not be filed in the public docket of the Court. The Divestiture Trustee shall at the same time furnish such report to the Commission, which may ask the Court to take such action as it shall deem appropriate to carry out the purpose of the Final Judgment, which may, if necessary, include extending the trust and the term of the Divestiture Trustee's appointment.
- K. The Divestiture Trustee shall use commercially reasonable efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission, subject to Defendant Lundbeck's absolute and unconditional obligation to divest expeditiously and at no minimum price. The divestiture shall be made in the manner and to an Acquirer as required by this Final Judgment; *provided, however*, that if the Divestiture Trustee receives bona fide offers from more than one acquiring Person, and if the Commission

determines to approve more than one such acquiring Person, the Divestiture Trustee shall divest to the acquiring Person selected by Defendant Lundbeck from among those approved by the Commission; *provided further, however*, that Defendant Lundbeck shall select such Person within five (5) days after receiving notification of the Commission's approval.

- L. Defendant Lundbeck shall indemnify the Divestiture Trustee and hold the Divestiture Trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Divestiture Trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Divestiture Trustee.
- M. The Divestiture Trustee shall have no obligation or authority to operate or maintain the relevant assets required to be divested by this Final Judgment; *provided, however*, that the Divestiture Trustee appointed pursuant to this Section II may be the same Person appointed as Interim Monitor pursuant to the Section VI of this Final Judgment.
- N. Defendant Lundbeck may require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, that such agreement shall not restrict the Divestiture Trustee from providing any information to the Commission or the Court.
- O. If the Commission or the Court determines that a Divestiture Trustee has ceased to act or failed to act diligently, the Commission may appoint a substitute Divestiture Trustee in the same manner as provided in this Section II.
- P. The Court may on its own initiative or at the request of the Commission or the Divestiture Trustee issue such additional orders or directions as may be necessary or appropriate to accomplish the divestiture required by this Final Judgment.

III. Divestiture

- A. Defendant Lundbeck is ordered and directed within ten (10) days after notice of the entry of this Final Judgment by the Court to consent to the appointment of a Divestiture Trustee, pursuant to Section II, of this Final Judgment to assign, grant, license, divest, transfer, deliver or otherwise convey the

NeoProfen Assets to an Acquirer that receives the prior approval of the Commission, and only in a manner that receives the prior approval of the Commission;

- B. At the option of the Acquirer of the NeoProfen Assets, and upon reasonable notice and request, Lundbeck shall provide, in a timely manner, at no greater than Direct Cost, assistance of knowledgeable employees of Lundbeck to assist the Acquirer in the transfer of the Product Scientific and Regulatory Materials related to the NeoProfen Product in order to obtain the necessary approvals for the manufacture and sale of the NeoProfen Product within the Geographic Territory.
- C. Defendant Lundbeck shall:
1. Pending divestiture of the NeoProfen Assets, Defendant Lundbeck shall:
 - a. Not use, directly or indirectly, any Confidential Business Information related to the research, Development, manufacturing, marketing, or sale of NeoProfen other than as necessary to comply with the following: (1) the requirements of the Final Judgment; (2) Defendant Lundbeck's obligations to an Acquirer under the terms of any Remedial Agreement related to the NeoProfen Assets; or (3) applicable Law;
 - b. Not disclose or convey any such Confidential Business Information, directly or indirectly, to any Person except the relevant Acquirer or Persons specifically authorized by the relevant Acquirer or the Commission or the Court to receive such information;
 - c. Not provide, disclose or otherwise make available, directly or indirectly, any such Confidential Business Information related to the marketing or sales of NeoProfen to the employees associated with business related to those Retained Products that contain the same API or that are approved for the same use as NeoProfen
 2. Submit to the Acquirer of the NeoProfen Assets, at Defendant Lundbeck's expense, all Confidential Business Information related to the NeoProfen Assets;
 3. Deliver such Confidential Business Information to such Acquirer:
 - a. In good faith;

- b. In a timely manner, *i.e.*, as soon as practicable, avoiding any delays in transmission of the respective information; and
 - c. In a manner that ensures its completeness and accuracy and that fully preserves its usefulness;
- 4. Pending complete delivery of all such Confidential Business Information to the Acquirer, provide the Acquirer and the Divestiture Trustee with access to all such Confidential Business Information and employees who possess or are able to locate such information for the purposes of identifying the books, records, and files directly related to the NeoProfen Assets that contain such Confidential Business Information and facilitating the delivery in a manner consistent with this Final Judgment;
- 5. Not disclose or convey any such Confidential Business Information, directly or indirectly, to any Person except the Acquirer of the NeoProfen Assets, Interim Monitor, the Divestiture Trustee, or other Persons specifically authorized by such Acquirer to receive such information; and
- 6. Assure that Defendant Lundbeck's counsel (including in-house counsel under appropriate confidentiality arrangements) shall not retain unredacted copies of documents or other materials provided to an Acquirer or access to original documents provided to an Acquirer, except under circumstances where copies of documents are insufficient or otherwise unavailable, and for the following purposes:
 - a. To assure Defendant Lundbeck's compliance with this Final Judgment, any Remedial Agreement, any law (including, without limitation, any requirement to obtain regulatory licenses or approvals, and rules promulgated by the Commission), any data retention requirement of any applicable Government Entity, or any taxation requirements; or
 - b. To defend against, respond to, or otherwise participate in any litigation, investigation, audit, process, subpoena or other proceeding relating to the divestiture or any other aspect of NeoProfen or assets and businesses associated with the NeoProfen Assets; *provided, however*, that Defendant Lundbeck may disclose such information as necessary for the purposes set forth in this Section III pursuant to an appropriate confidentiality

order, agreement or arrangement; *provided further, however*, that pursuant to this Section III, Defendant Lundbeck shall: (1) require those who view such unredacted documents or other materials to enter into confidentiality agreements with the Acquirer (but shall not be deemed to have violated this requirement if such Acquirer withholds such agreement unreasonably); and (2) use best efforts to obtain a protective order to protect the confidentiality of such information during any adjudication.

- D. Defendant Lundbeck shall not enforce any agreement against a Third Party or an Acquirer of the NeoProfen Assets to the extent that such agreement may limit or otherwise impair the ability of such Acquirer to acquire or use the Product Manufacturing Technology (including all related intellectual property) related to the NeoProfen Product acquired by such Acquirer from the Third Party. Such agreements include, but are not limited to, agreements with respect to the disclosure of Confidential Business Information related to such Product Manufacturing Technology.
- E. Not later than ten (10) days after the Closing Date, Defendant Lundbeck shall grant a release to each Third Party that is subject to an agreement as described in Section III.D that allows the Third Party to provide the relevant Product Manufacturing Technology to the relevant Acquirer of the NeoProfen Assets. Within five (5) days of the execution of each such release, Defendant Lundbeck shall provide a copy of the release to such Acquirer.
- F. Not later than thirty (30) days after entry of this Final Judgment, Defendant Lundbeck shall provide written notification of the restrictions on the use of the Confidential Business Information related to the NeoProfen Assets by Defendant Lundbeck's personnel to all of Defendant Lundbeck's employees who:
1. Are or were directly involved in the research, Development, manufacturing, distribution, sale or marketing of the NeoProfen Product;
 2. Are directly involved in the research, Development, manufacturing, distribution, sale or marketing of Retained Products that contain the same active pharmaceutical ingredient or that are approved for use, or in Development for use, in the same field as the NeoProfen Product; and/or

3. May have Confidential Business Information related to the NeoProfen Product.

Defendant Lundbeck shall give such notification by e-mail with return receipt requested or similar transmission, and keep a file of such receipts for three (3) year after the Closing Date. Defendant Lundbeck shall provide a copy of such notification to the Acquirer. Defendant Lundbeck shall maintain complete records of all such agreements at Defendant Lundbeck's registered office within the United States of America and shall provide an officer's certification to Plaintiff stating that such acknowledgment program has been implemented and is being complied with. Defendant Lundbeck shall provide the Acquirer with copies of all certifications, notifications and reminders sent to Defendant Lundbeck's personnel.

- G. Defendant Lundbeck shall not join, file, prosecute or maintain any suit, in law or equity, against the Acquirer for the research, Development, manufacture, use, import, export, distribution, or sale of the NeoProfen Product under Patents that:

1. Are owned or licensed by Defendant Lundbeck as of the Closing Date that claims a method of making, using, or administering, or a composition of matter, relating to the NeoProfen Products, or that claims a device relating to the use thereof;
2. Are owned or licensed at any time after the Closing Date by Defendant Lundbeck that claim any aspect of research, Development, manufacture, use, import, export, distribution, or sale of the NeoProfen Products, other than such patents that claim inventions conceived by and reduced to practice after the Closing Date;

if such suit would have the potential to interfere with the Acquirer's freedom to practice the following: (1) the research, Development, or manufacture of the NeoProfen Product; or (2) the use, import, export, supply, distribution, or sale of the NeoProfen Product within the Geographic Territory.

- H. Defendant Lundbeck shall also covenant to the Acquirer that as a condition of any assignment, transfer, or license to a Third Party of the Patents described in Section III.H, the Third Party shall agree to provide a covenant whereby the Third Party covenants not to sue the Acquirer under such patents, if the suit would have the potential to interfere with the Acquirer's freedom to practice the following: (1) the research, Development, or manufacture of the NeoProfen Product; or (2) the use, import, export, supply, distribution, or sale of the NeoProfen Product within the Geographic Territory.

- I. Upon reasonable written notice and request from the Acquirer of the NeoProfen Assets to Defendant Lundbeck, Defendant Lundbeck shall provide, in a timely manner, at no greater than Direct Cost, assistance of knowledgeable employees of Defendant Lundbeck to assist that Acquirer to defend against, respond to, or otherwise participate in any litigation related to the Product Intellectual Property related to the NeoProfen Product, if such litigation would have the potential to interfere with the Acquirer's freedom to practice the following: (1) the research, Development, or manufacture of the NeoProfen Product; or (2) the use, import, export, supply, distribution, or sale of the NeoProfen Product within the Geographic Territory.
- J. Defendant Lundbeck shall not seek, directly or indirectly, pursuant to any dispute resolution mechanism incorporated in any Remedial Agreement, or in any agreement related to the NeoProfen Product, a decision the result of which would be inconsistent with the terms of this Final Judgment and/or the remedial purposes thereof.
- K. The purpose of the divestiture of the NeoProfen Assets and the related obligations imposed on Defendant Lundbeck by this Final Judgment is:
 - 1. To ensure the continued use of such assets in the research, Development, manufacture, distribution, sale and marketing of the NeoProfen Product within the Geographic Territory;
 - 2. To create a viable and effective competitor in the relevant market alleged in the Complaint who is independent of Defendant Lundbeck; and
 - 3. To remedy fully the lessening of competition resulting from the Acquisition as alleged in the Plaintiff's Complaint and as found by this Court.

IV. Other Equitable Relief

Defendant shall pay into an escrow account to be established by the Commission and the State of Minnesota the amount ordered by this Court after receipt of the report of the Divestiture Trustee pursuant to Section II.A.3.

- A. Payment shall be made within thirty (30) days after receipt of notice of entry of this Final Judgment;
- B. Payment shall be made by wire transfer of funds; and,

- C. In the event of a default or delay in payment, interest at the rate of eighteen (18) percent per annum shall accrue thereon from the date of the default or delay to the date of payment.

V. Asset Maintenance

- A. Defendant Lundbeck shall not sell, transfer, encumber or otherwise impair the NeoProfen Assets (other than in the manner prescribed in the Final Judgment) nor take any action that lessens the full economic viability, marketability or competitiveness of the businesses related to the NeoProfen Assets.
- B. Defendant Lundbeck shall maintain the operations of the NeoProfen Assets in the regular and ordinary course of business and in accordance with past practice (including regular repair and maintenance of the assets of such business) and shall use its best efforts to preserve the existing relationships with the following: suppliers; vendors and distributors; customers; Agencies; employees; and others having business relations with the NeoProfen Assets. Respondents' responsibilities shall include, but are not limited to, the following:
1. Providing the NeoProfen Assets with sufficient working capital to operate at least at current rates of operation, to meet all capital calls with respect to such business and to carry on, at least at their scheduled pace, all capital projects, business plans and promotional activities for the NeoProfen Assets;
 2. Continuing, at least at their scheduled pace, any additional expenditures for the NeoProfen Assets, authorized prior to receipt of notice of entry of the Final Judgment including, but not limited to, all research, Development, manufacturing, distribution, marketing and sales expenditures;
 3. Providing such resources as may be necessary to respond to competition against the NeoProfen Assets and/or to prevent any diminution in sales of the NeoProfen Assets prior to divestiture;
 4. Making available for use by the NeoProfen Assets funds sufficient to perform all routine maintenance and all other maintenance as may be necessary to, and all replacements of, the NeoProfen Assets;

5. Providing the NeoProfen Assets with such funds as are necessary to maintain the full economic viability, marketability and competitiveness of the NeoProfen Assets;
 6. Providing such support services to the NeoProfen Assets as were being provided to such business by Defendant Lundbeck as of the date of receipt of notice that the Final Judgment was entered; and
 7. Maintaining a work force at least as equivalent in size, training, and expertise to what has been associated with the NeoProfen Assets for the last fiscal year.
- C. Defendant Lundbeck shall adhere to and abide by the Remedial Agreement (which agreement shall not vary or contradict, or be construed to vary or contradict, the terms of the Final Judgment, it being understood that nothing in the Final Judgment shall be construed to reduce any obligations of Defendant Lundbeck under such agreement), which are incorporated by reference into this Final Judgment and made a part hereof.

VI. Appointment of Interim Monitor

- A. Any time after receipt of notice of the entry of this Final Judgment by the Court, the Commission shall appoint an Interim Monitor to assure that Defendant Lundbeck expeditiously complies with all of its obligations and performs all of its responsibilities as required by this Final Judgment and the Remedial Agreement.
- B. The Commission shall select the Interim Monitor, subject to the consent of Defendant Lundbeck, which consent shall not be unreasonably withheld. If Defendant Lundbeck has not 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 Defendant Lundbeck of the identity of any proposed Interim Monitor, Defendant Lundbeck 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, Defendant Lundbeck 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 Defendant Lundbeck's compliance with the relevant requirements of the Final Judgment in a manner consistent with the purposes of the Final Judgment.

- D. After an Interim Monitor is appointed, Defendant Lundbeck shall consent to the following terms and conditions regarding the powers, duties, authority, and responsibilities of the Interim Monitor:
1. The Interim Monitor shall have the power and authority to monitor Defendant Lundbeck's compliance with: the divestiture and asset maintenance obligations of the Final Judgment; the restrictions on the use, conveyance, provision, or disclosure of the identified confidential business information under the Final Judgment; and, the related requirements of the Final Judgment and Order. The Interim Monitor 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 Final Judgment 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 date the Divestiture Trustee completes the divestiture of the NeoProfen Assets in a manner that fully satisfies the requirements of this Final Judgment and until the earliest of:
 - a. The date the Acquirer is approved by the FDA to manufacture NeoProfen and able to manufacture NeoProfen in commercial quantities, in a manner consistent with cGMP, independently of Defendant Lundbeck;
 - b. The date the Acquirer notifies the Commission and Defendant Lundbeck of its intention to abandon its efforts to manufacture such Divestiture Product; or
 - c. The date of written notification from staff of the Commission that the Interim Monitor, in consultation with staff of the Commission, has determined that the Acquirer has abandoned its efforts to manufacture NeoProfen; *provided*, however, that, the Interim Monitor's service shall not exceed three (3) years from the date the Final Judgment becomes final; *provided* further, however, that the Commission may ask the Court to extend or modify this period as may be necessary or appropriate to accomplish the purposes of the Final Judgment.

- E. Subject to any demonstrated legally recognized privilege, the Defendant Lundbeck shall provide the Interim Monitor full and complete access to Defendant Lundbeck's 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 Defendant Lundbeck's compliance with its obligations under the Final Judgment, including, but not limited to, its obligations related to the NeoProfen. Defendant Lundbeck shall cooperate with all reasonable requests of the Interim Monitor and shall take no action to interfere with or impede the Interim Monitor's ability to monitor Defendant Lundbeck's compliance with the Final Judgment.
- F. The Interim Monitor shall serve, without bond or other security, at the expense of Defendant Lundbeck, on such reasonable and customary terms and conditions as the Commission or this Court may set. The Interim Monitor shall have authority to employ, at the expense of Defendant Lundbeck, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Interim Monitor's duties and responsibilities.
- G. Defendant Lundbeck shall indemnify the Interim Monitor and hold the Interim Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Interim Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Interim Monitor.
- H. Defendant Lundbeck shall report to the Interim Monitor in accordance with the requirements of this Final Judgment and/or as otherwise provided in any agreement approved by the Commission. The Interim Monitor shall evaluate the reports submitted to the Interim Monitor by Defendant Lundbeck, and any reports submitted by an Acquirer with respect to the performance of Defendant Lundbeck's obligations under the Final Judgment or any Remedial Agreement(s). Within thirty (30) days from the date the Interim Monitor receives these reports, the Interim Monitor shall report in writing to the Commission concerning performance by Defendant Lundbeck of its obligations under the Final Judgment; provided, however, beginning one hundred twenty (120) days after Defendant Lundbeck has filed its final report pursuant to Section VIII and every one hundred twenty (120) days thereafter, the Interim Monitor shall report in writing to the Commission concerning progress by the Acquirer toward obtaining FDA approval to manufacture

NeoProfen and obtaining the ability to manufacture NeoProfen in commercial quantities, in a manner consistent with cGMP, independently of Defendant Lundbeck.

- I. Defendant Lundbeck may require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement; provided, however, that such agreement shall not restrict the Interim Monitor from providing any information to the Commission or the Court.
- J. The Commission may, among other things, require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Interim Monitor's duties.
- K. If the Commission determines that the Interim Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Interim Monitor in the same manner as provided in this Section VI.
- L. The Commission may on its own initiative, or at the request of the Interim Monitor, ask the Court to issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Final Judgment.
- M. The Interim Monitor appointed pursuant to this Final Judgment may be the same person appointed as a Divestiture Trustee pursuant to Section II of this Final Judgment.

VII. Remedial Agreement

With respect to the Remedial Agreement:

- A. It shall include a specific reference to this Final Judgment, the remedial purposes thereof, and provisions to reflect the full scope and breadth of Defendant Lundbeck's obligations to the Acquirer pursuant to this Final Judgment.
- B. It shall include a representation from the Acquirer that such Acquirer shall use commercially reasonable efforts to secure the approvals necessary to manufacture, or to have manufactured by a Third Party, in commercial quantities, NeoProfen and to have any such manufacture be independent of Defendant Lundbeck, all as soon as reasonably practicable.

- C. Defendant Lundbeck shall not modify or amend any of its terms without the prior approval of the Commission.

VIII. Compliance Reports and Notifications

- A. Within thirty (30) days after the receipt of notice of the entry of this Final Judgment, and every sixty (60) days thereafter until Defendant Lundbeck has fully complied with its obligations under Sections II through VII of this Final Judgment, Defendant Lundbeck shall submit to the Commission a verified written report setting forth in detail the manner and form in which it intends to comply, is complying, and has complied with this Final Judgment. Defendant Lundbeck shall submit at the same time a copy of their report concerning compliance with this Final Judgment to the appointed Interim Monitor and Divestiture Trustee. Defendant Lundbeck shall include in its reports, among other things that are required from time to time, a full description of the efforts being made to comply with the relevant sections of the Final Judgment, all internal memoranda, and all reports and recommendations concerning completing the obligations.
- B. One (1) year after receipt of notice of the entry of this Final Judgment, annually for the next nine years on the anniversary of the date of such notice, and at other times as the Commission or the Court may require, Defendant Lundbeck 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 the Final Judgment.
- C. Defendant Lundbeck shall notify the Commission at least thirty (30) days prior to:
1. Any proposed dissolution of Defendant Lundbeck;
 2. Any proposed acquisition, merger or consolidation of Defendant Lundbeck; or
 3. Any other change in Defendant Lundbeck including, but not limited to, assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of this Final Judgment.

IX. Compliance Inspection

- A. For purposes of determining or securing compliance with this Final Judgment, or of determining whether the Final Judgment should be modified or vacated, and subject to any legally recognized privilege, and upon written request and upon five (5) days notice to Defendant Lundbeck made to its principal United States offices, registered office of its United States subsidiary, or its headquarters address, Defendant Lundbeck shall, without restraint or interference, permit any duly authorized representative of the Commission:
1. Access, during business office hours of such Defendant Lundbeck 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 Defendant Lundbeck related to compliance with this Final Judgment, which copying services shall be provided by Defendant Lundbeck at the request of the authorized representative(s) of the Commission and at the expense of Defendant Lundbeck; and
 2. To interview officers, directors, or employees of Defendant Lundbeck, who may have counsel present, regarding such matters.

X. Retention of Jurisdiction

This Court retains jurisdiction to enable any party to this Final Judgment to apply to this Court at any time for further orders and directions as may be necessary or appropriate to carry out or construe this Final Judgment, to modify any of its provisions, to enforce compliance, and to punish violations of its provisions.

XI. Expiration of Final Judgment

Unless this Court grants an extension, this Final Judgment shall expire ten (10) years from the date of its entry.

Dated: , 2010

Joan N. Ericksen
United States District Judge