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COVER SHEET

PATENTS ONLY

FORM PTO-1595  
(Rev. 6-93)  
OMB No. 0651-0011 (exp 4/94)

U.S. DEPARTMENT OF COMMERCE  
Patent and Trademark Office

To the Hon. Commissioner of Patents and Trademarks: Please record the attached original documents or copy thereof.

## 1. Name of conveying party(ies):

Novo Nordisk A/S  
Novo Alle  
DK-2880 Bagsvaerd, Denmark

Additional name(s) of conveying party(ies) attached? ☐ Yes ☒ No

## 2. Name and address of receiving party(ies):

Name: Novo Nordisk FemCare A/G  
Internal Address

Street Address: Andreasstrasse 15, CH-8050 Zurich,  
Switzerland

Additional name(s) & address(es) attached? ☐ Yes ☒ No

## 3. Nature of conveyance:

- ☒ Assignment ☐ Merger  
☐ Security Agreement ☐ Change of Name  
☐ Other \_\_\_\_\_

Execution Date: 08/20/2004

## 4. Application number(s) or patent number(s):

If this document is being filed together with a new application, the execution date of the application is: \_\_\_\_\_

A. Patent Application No.(s)

B. Patent No.(s) 5,860,946

Additional numbers attached? ☐ Yes ☒ No

## 5. Name and address of the party to whom correspondence concerning document should be mailed:

Name: Reza Green, Esq.

Internal Address:

Novo Nordisk Inc.

Street Address: 100 College Road West

City: Princeton State: NJ Zip 08540

## 6. Total number of applications and patents involved: one

7. Total fee (37 CFR 3.41) \$ 40.00

☐ Enclosed

☒ Authorized to be charged to deposit account

## 8. Deposit account number

14-1447

(Attach duplicate copy of this page if paying by deposit account)

DO NOT USE THIS SPACE

## 9. Statement and signature.

To the best of my knowledge and belief, the foregoing information is true and any attached copy is a true copy of the original document.

Reza Green, Reg. No. 38,475

Name of person signing

  
Signature

December 22, 2005

Date

Total number of pages including cover sheet, attachment, document: 10

ORIGINAL

RECEIVED	MODTAGE DATO:
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*Cc: La Hv*

## Research and Development Agreement

between

Novo Nordisk A/S  
Novo Allé  
DK-2880 Bagsvaerd  
Denmark  
(hereinafter referred to as "NNAS")

and

Novo Nordisk FemCare AG  
Andreasstrasse 15  
8050 Zürich  
Switzerland

(hereinafter referred to as "NN FemCare AG")



**PREAMBLE:**

WHEREAS, all intellectual property rights belonging to NNAS as well as the commercialisation rights to these products have been assigned to NN FemCare AG pursuant to a Capital Increase Agreement of 1 July 2004 between the Parties;

WHEREAS, NN FemCare AG is thus the owner of intellectual property rights relating to certain pharmaceutical products within Hormone Replacement Therapy for climacteric women, including the products marketed under the names Novofem®, Activelle®, Estrofem®, and Vagifem®;

WHEREAS, NN FemCare AG will be carrying on a business selling such products to its customers,

WHEREAS, NN FemCare AG wishes NNAS to carry out certain discovery, development and market positioning activities relating to the Products;

WHEREAS, NNAS is willing to render such services on the terms and conditions set out in this Agreement;

NOW, THEREFORE, the Parties agree as follows:

**1. Definitions**

- 1.1 "ARMDP" shall mean an Annual Research and Market Development Programme agreed in writing once per annum by the Parties and adopted as Appendix 1 hereto, outlining the activities to be undertaken for NNHRTAG and the compensation to be paid to NNAS for the Services hereunder for the next whole calendar year.
- 1.2 "Calendar Quarter" shall mean each 3 successive calendar months starting on 1 January, 1 April, 1 July or 1 October, respectively.
- 1.3 "Effective Date" shall mean 1 July 2004.
- 1.4 "Field" shall mean any research, discovery, regulatory development and clinical positioning/research relating to the Products including efforts, which shall enable the marketing of ultra low dose variants of certain Products
- 1.5 "Services" shall mean any activities within the Field, requested and approved by NN FemCare AG, undertaken by NNAS, and entered into the ARMDP, signed by both Parties. Services shall exclude any work carried out by NNAS under the (i) the Manufacture and Supply Agreement of 1 July 2004 between the Parties, (ii) the Distribution Agreement of 1 July 2004 between the Parties or (iii) the Service Agreement of 1 July 2004 between the Parties.

**2. Research and Market Development Services**

- 2.1 As of the Effective Date, NNAS shall carry out the projects defined in the ARMDP. NN FemCare AG may request NNAS to carry out additional projects, and such project(s) shall be deemed part of the Services when entered into the ARMDP and mutually signed by the Parties. On NN FemCare AG's request, NNAS shall cease activities in certain projects and in case of termination of

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projects the ARMDP shall be updated within 2 calendar months from the receipt of NN FemCare AG's request.

- 2.2 Nothing contained herein shall constitute any obligation on the part of NN FemCare AG to obtain any services from NNAS hereunder. Subject to Clauses 5.1, and 12.2, NN FemCare AG is free to obtain similar services from any third party if NN FemCare AG so decides.
- 2.3 Both Parties acknowledge that time is of the essence in this Agreement. Services provided by NNAS shall be timely completed and submitted to NN FemCare AG, and NNAS therefore warrants that it shall use reasonable efforts to allocate the necessary qualified human resources to comply with the requirements of Services defined in the ARMDP.
- 2.4 NNAS shall comply with all current legal and regulatory requirements applicable to the Services.
- 2.5 NNAS shall timely communicate all data hereunder to NN FemCare AG, and NNAS and NN FemCare AG shall mutually define appropriate communication routines. Data otherwise retained by NNAS shall be available upon request for review by NN FemCare AG. NNAS agrees to provide NN FemCare AG with certified photocopies of these data upon request. NNAS agrees to retain free of charge all data generated by NNAS in connection with the Services until 15 (fifteen) years after the date of completing any individual Project hereunder.
- 2.6 NNAS shall have the right to subcontract parts of Services. The terms and conditions stated in this Agreement will also apply to said subcontractor(s), and NNAS shall assume full responsibility for the performance or non-performance of its subcontractors, and shall be liable for any damages, costs or expenses arising from or out of such subcontracting.

### **3. Establishment of the Annual Research and Market Development Programme (ARMDP)**

- 3.1 Services to be provided by NNAS will be based on an ARMDP approved by NN FemCare AG, governing the following calendar year. The ARMDP will be built on a 2-year activity plan with a detailed first-year budget and an outline budget for the subsequent year.
- 3.2 The Parties agree to initiate ARMDP negotiations each October. A draft ARMDP is to be finalized by each 1 November for management approval in NNAS and NN FemCare AG respectively. The ARMDP governing the next calendar year shall be signed by each 15 December.

### **4. Management of Research and Development Services**

- 4.1 NNAS shall establish and maintain standard operating procedures for organising, monitoring, and controlling the Services, and shall comply with such procedures in force at any time, and these shall apply with exception of any and all major decision points of the projects which shall be approved by

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NN FemCare AG. NNAS shall provide NN FemCare AG with online access to the latest, controlled versions of such procedures.

- 4.2 NN FemCare AG shall be entitled to appoint one representative to attend and speak at meetings in all relevant NNAS boards managing Projects in relation to the Services hereunder. The Parties agree to list in Appendix 3 the persons to represent NN FemCare AG in any specific committee.
- 4.3 Any and all information submitted to relevant NNAS boards or committees cf. Clause 4.2, shall be submitted to NN FemCare AG. Any and all resolutions, operational decisions, recommendations and proposals made by such NNAS boards and any meeting minutes from such boards relating to the Services shall immediately be submitted to the NN FemCare AG representative on the board in question.
- 4.4 All major decisions on individual projects as set forth in the ARMDP shall be subject to NN FemCare AG approval. NN FemCare AG approval shall be required for any decisions regarding, but not limited to, the following issues: Approval of Project milestones, allocating resources to Projects, out-licensing projects, the course of action in case of deviations, discontinuation of projects, or any other decisions that may affect the ARMDP, may affect the scope and/or objective of an individual project, or may lead to the termination of any individual project. Decisions of an operational nature related to organising, monitoring, and controlling upon the Services shall be taken by NNAS according to established procedures.

#### **5. Term and Termination**

- 5.1 This Agreement shall take effect on the Effective Date and shall continue until terminated by NN FemCare AG with a written notice of twelve (12) months.
- 5.2 Failure by either Party to this Agreement to comply with material obligations and conditions hereof shall entitle the other Party to give to the Party in default notice requiring it to remedy such default. If such default is not remedied within fifteen (15) days counted from receipt of such notice, the notifying Party shall be entitled to terminate this Agreement by giving notice to take effect immediately.
- 5.3 In the event of either Party assigning or making any composition or sequestration of assets for the benefit of creditors, becoming insolvent, going into liquidation, becoming bankrupt or dissolving, the other Party may terminate this Agreement forthwith by notice in writing.

#### **6. Quality**

- 6.1 NNAS shall use its best workmanship and skills in rendering the Services to NN FemCare AG and shall comply with all current regulatory requirements and applicable guidelines as considered to be necessary and/or appropriate. NNAS shall have a Quality System in place to assure proper conduct of Services to be performed and controlled, cf. 1 July 2004 Service Agreement between the Parties. In particular, NNAS shall train staff involved in the provision of the Services in order to ensure that proper skills and competencies are in place on an ongoing basis.

**7. Visits, Audits and/or Inspections**

- 7.1 Representatives of NN FemCare AG may visit NNAS' facilities at reasonable times and with reasonable frequency during normal business hours to observe the progress of the Services. Assistance will be given in scheduling and carrying out such visits. During these visits the representatives may examine relevant documents, facilities, records and any other relevant resources.
- 7.2 Either Party shall allow all applicable health authorities or tax authorities to inspect and conduct reviews of documents, facilities, records, and any other resources that are deemed by the authority to be related to the Services. In the event such health authorities or tax authorities contact one Party only, then that Party is obliged to promptly inform the other Party.
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**9. Proprietary and Confidential Information**

- 9.1 Each Party undertakes to treat all proprietary and confidential information of the other Party as strictly confidential and therefore not to disclose it to any third party, and to make no commercial use of it without the express written consent of the other Party. Either Party may disclose proprietary and confidential information only to professional staff that need to know in order to carry out the obligations under this Agreement, provided that such recipients are bound by obligations of confidentiality and non-use which are equal to the terms of this Agreement.
- 9.2 Each Party and its professional staff undertake not to publish, disclose or commit to any third party any information disclosed hereunder or information relating to the performance of the Services. However, this obligation shall not apply to information which

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- (a) was generally available to the public on the date of signature of this Agreement;
- (b) was published with the consent of the other Party;
- (c) was made available to the public by a third Party who did not acquire directly or indirectly the information from NNAS and/or NN FemCare AG;
- (d) was disclosed to any regulatory authority or any patent authority or was disclosed as a result of statutory requirements or following a court order.

9.3 All obligations of confidentiality and non-disclosure set forth in this Agreement will survive, without limitation, the expiration or earlier termination, for whatever reason, of this Agreement.

#### **10. Intellectual Property Rights**

10.1 Intellectual property rights relating to the Products, relating to or resulting from the Projects, any of the Project reports and/or any data, information or results achieved, developed, discovered, designed, produced or manufactured by the Parties' individual or joint work with any of the Services and Projects and other work performed hereunder shall be deemed vested in and be the exclusive property of NN FemCare AG, including but not limited to all inventions, improvements or discoveries, whether patentable or registrable or not, copyrights, know-how, utility models and designs.

10.2 Any pertaining tangible material, whether original or copy, in writing, computerised, tape-recorded or otherwise, shall be submitted to NN FemCare AG as soon as possible upon NN FemCare AG's request or upon termination of this Agreement.

10.3 Upon request, NNAS shall at any time inform NN FemCare AG of the status of the Services and shall keep NN FemCare AG advised of all results that may form the basis for commercial exploitation by NN FemCare AG. In the event that any results, which may subject for commercial exploitation by NN FemCare AG, are generated in the course of the Services, NNAS shall irrevocably assign to NN FemCare AG all rights to such results made by NNAS and/or its employees alone or in co-operation with NN FemCare AG. NNAS shall have no claim for any remuneration for such rights other than that to be received in accordance with Article 8 of this Agreement. In the event of any patentable or otherwise registrable result, NN FemCare AG shall be entitled to apply for patents or other registrations worldwide, and NNAS shall give NN FemCare AG any assistance that the latter may reasonably require in preparing, filing, prosecuting and defending any such claims.

10.4 Notwithstanding, NN FemCare AG shall defray any statutory remuneration to the inventor.

#### **11. Governing Law and Dispute Resolution**

11.1 Both Parties will use their best efforts to settle all matters in dispute amicably. All disputes and differences of any kind related to this Agreement, which cannot be solved amicably by the Parties, shall be referred to arbitration as described below.

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- 11.2 All disputes arising out of or in connection with the present Agreement shall be finally settled under the Rules of Arbitration of the International Chamber of Commerce by three (3) arbitrators appointed in accordance with the said Rules.
- 11.3 The arbitration shall take place in Zurich, Switzerland, and shall be conducted in the English language. The award of the arbitrators shall be final and binding on both Parties. The Parties bind themselves to carry out the awards of the arbitrators.
- 11.4 This Agreement shall be construed and interpreted pursuant to the laws of Switzerland to the exclusion of any rule that would refer the subject matter to another forum. The English wording in this Agreement shall prevail.
- 11.5 Notwithstanding Article 11.1-11.4, without resorting to prior arbitration and in addition to any other remedies provided by law, either Party shall be entitled to seek temporary and permanent injunctive relief against any threatened or actual breach of this Agreement or the continuation of any such breach in any court of competent jurisdiction.
- 12. Miscellaneous**
- 12.1 NNAS may not transfer or assign any of its obligations hereunder to any third party without NN FemCare AG's prior written acceptance.
- 12.2 This Agreement constitutes the entire agreement between the Parties with respect to the Services. None of the provisions of this Agreement shall be amended or modified except in writing signed by the Parties hereto.
- 12.3 The appendices to this Agreement shall form an integral part of the Agreement and shall be regarded as incorporated into the Agreement in every respect. In case of inconsistency between the terms and conditions of any Appendix and this Agreement, the latter shall prevail to the extent of such inconsistency, but no further.

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EXECUTED ON THE EFFECTIVE DATE:

On behalf of NNAS

Name: Lise Kingo Jensen

Title: Executive Vice President

Name: Lars Almbloom Jørgensen

Title: Executive Vice President

On behalf of NN FernCare AG

Name: Ole F. Ramsby

Title: Member of the Board

Name: Kåre Schultz

Title: Chairman of the Board

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