



Current Agreements

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Second amendment to development and licensing agreement for oral parathyroid hormone

SmithKline Beecham
Unigene Laboratories

Oct 13 2003

Second amendment to development and licensing agreement for oral parathyroid hormone

Companies:	SmithKline Beecham Unigene Laboratories
Announcement date:	Oct 13 2003 Development and licensing agreement for oral parathyroid hormone First amendment to development and licensing agreement for oral parathyroid hormone Third amendment to development and licensing agreement for oral parathyroid hormone Fourth amendment to development and licensing agreement for oral parathyroid hormone Fifth amendment to development and licensing agreement for oral parathyroid hormone Sixth amendment to development and licensing agreement for oral parathyroid hormone Amended and restated development and licensing agreement for oral parathyroid hormone
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Details

Announcement date:	Oct 13 2003
Start date:	Oct 13 2003
Industry sectors:	Bigpharma Pharmaceutical
Therapy areas:	Musculoskeletal » Osteoporosis Biological compounds
Technology types:	Drug delivery Peptides
Deal components:	Development Licensing
Stages of development:	Phase II
Geographic focus:	Worldwide

Financials

Termsheet

Not available.

Press Release

Not available.

Filing Data

Not available.

Contract

AMENDMENT NO. 2 TO

LICENSE AGREEMENT

DATED AS OF APRIL 13, 2002

BY AND BETWEEN

UNIGENE LABORATORIES, INC.

AND

SMITHKLINE BEECHAM CORPORATION

This Amendment No. 2 ("Amendment No. 2") dated as of October 14, 2003 ("Amendment Date"), to the License Agreement (referred to hereinafter as the "Agreement") entered into as of the 13th of April, 2002, by and between Unigene Laboratories, Inc. ("Unigene"), a Delaware corporation, and SmithKline Beecham Corporation, a GlaxoSmithKline company ("GSK"), a Pennsylvania corporation.

RECITALS:

WHEREAS, GSK and Unigene entered into the Agreement to provide for the license grant by Unigene to GSK of certain Licensed Technology (as defined in the Agreement) to discover, develop, make, have made, market, sell and import certain Licensed Products (as defined in the Agreement) throughout the world under the Unigene Patent Rights (as defined in the Agreement) and Unigene Know-How (as defined in the Agreement); and

WHEREAS, GSK and Unigene have also entered into a Phase I Clinical Manufacture and Supply Agreement dated November 20, 2002 (the "Phase I Agreement"); and

WHEREAS, pursuant to Section 11.10 of the Agreement, the Parties to the Agreement may, by written instruments specifically referring to and executed in the same manner as the Agreement, amend the Agreement; and

WHEREAS, the Parties hereto desire to amend the Agreement as provided herein, and any capitalized terms used herein shall have the meaning set forth in the Agreement;

NOW THEREFORE, for and in consideration of the premises and the mutual promises and benefits contained herein, GSK and Unigene hereby agree as follows:

1. For the purpose of clarification, the Parties agree and acknowledge that pursuant to Appendix C of the Agreement, Unigene has provided know-how and technology related to cell banks, including *** cell banks, designated as *** and as *** by Unigene,

and a *** cell bank, designated as *** by Unigene, all of which know-how and technology is Unigene Know-How, and/or, to the extent included therein, Unigene Patent Rights.

2. Pursuant to Paragraph 2.4 of the Phase I Agreement, the Parties have agreed and acknowledged that the cGMP *** cell bank referenced therein and designated as *** by GSK utilizes Unigene Know-How and/or Unigene Patent Rights and that all right, title and interest to such bank belongs to Unigene, whether created by GSK or Unigene, jointly or solely.

3. The Parties hereby agree and acknowledge that all right, title and interest to any cell bank set forth on Appendix A (including without limitation the underlying cell line) belongs to Unigene (the "Licensed Cell Banks"). The Parties agree that Appendix A shall be amended in writing by the Parties from time to time, promptly as additional cell banks may be provided or created in accordance with the Agreement and Phase I Agreement. For purposes of this Amendment No. 2, a cell bank shall mean a cell line that has been grown, aliquoted and stored under controlled conditions to ensure the sterility and genetic stability of the cell line. Notwithstanding the forgoing, and for the avoidance of doubt, the Parties agree and acknowledge that:

(a) all proprietary cell banks provided by Unigene to GSK shall be added to Appendix A;

(b) in the event that

(i) Unigene has provided a proprietary cell bank to GSK, and

(ii) GSK does no more to the cell bank than ***, wherein if the ***, the new *** is known in the public domain, Unigene shall continue to own such cell bank in both its original and newly created forms, and the newly created form shall be added to Appendix A;

and

(c) in the event GSK solely creates a cell bank that utilizes *** and which newly created cell bank incorporates GSK intellectual property in its plasmid vector or the *** such that a new *** that contains GSK Know-How or GSK intellectual property is created, such newly created cell line (and any cell bank based on the cell line) shall be owned solely by GSK and shall not be set forth on Appendix A. The parties agree and acknowledge that nothing in this Paragraph 3(c) is intended to in any way amend the provisions of Article 6 of the Agreement with respect to the subject matter of this Paragraph 3(c). To clarify, while ***, nothing in Section 6.2.1. of the Agreement is intended to or shall grant Unigene rights to such incorporated GSK intellectual property independent of GSK Dependent Improvements.

To facilitate amendment of Appendix A, GSK shall use commercially reasonable efforts to provide prompt written notice to Unigene of the creation of any additional cell bank using any Licensed Cell Bank, Unigene Patent Rights and/or Unigene Know-How. Any information shared with Unigene in this regard shall be deemed "Confidential Information" within the meaning of Article 8, and shall be subject to the terms and conditions thereof. For purposes of this Item 3, "proprietary cell line" shall mean either (a) bacterial, yeast, insect or mammalian source cells *** claimed by Unigene Patent Rights or containing Unigene Know-How, or (b) a recombinant cell line claimed by Unigene Patent Rights or containing Unigene Know-How.

4. Upon the termination of this Agreement, GSK shall return to Unigene any cell bank owned by Unigene; provided, however, that in the event GSK utilizes its own proprietary medium with such cell bank, GSK shall be entitled to destroy such modified cell bank.

5. The Parties agree and acknowledge that Licensed Cell Banks are Unigene Know-How, and/or, to the extent included therein, Unigene Patent Rights, and are therefore Licensed Technology included within the license grant in Section 2.1 of the Agreement, and GSK has the rights to use the Licensed Cell Banks as described therein. To the extent that in the absence of this Amendment No. 2, any Licensed Cell Bank would be considered a Joint Invention, GSK Invention or GSK Know-How under any provision of the Agreement, such provision is expressly amended and superseded by this Amendment No. 2, as to Licensed Cell Banks only.

IN WITNESS WHEREOF, the Parties hereto have caused this Amendment to be duly executed by their authorized representatives as of the Amendment Date.

UNIGENE LABORATORIES, INC. SMITHKLINE BEECHAM CORPORATION,

a GlaxoSmithKline Company

By: /s/ Ronald S. Levy

By: /s/ Donald F. Parman

Name: Ronald S. Levy Name: Donald F. Parman

Title: Executive Vice President Title: Vice President & Secretary

Appendix A

Licensed Cell Banks

Type

Designation (Designator)

*** Cell Bank *** (Unigene)

*** Cell Bank *** (Unigene)

*** Cell Bank *** (Unigene)

*** Cell Bank *** (GSK)

*** Cell Bank *** (Unigene)

*** Cell Bank *** (Unigene)

*** ** (Unigene)