



FORM 8-K

SCHERING PLOUGH CORP - sgp

Filed: December 21, 2007 (period: December 20, 2007)

Report of unscheduled material events or corporate changes.

Table of Contents

[8-K - FORM 8-K](#)

[Item 1.01. Entry into a Material Definitive Agreement](#)

[Item 9.01. Financial Statements and Exhibits.](#)

[SIGNATURES](#)

[EXHIBIT INDEX](#)

[EX-10.1 \(EX-10.1: AMENDED DISTRIBUTION AGREEMENT\)](#)

[EX-99.1 \(EX-99.1: PRESS RELEASE\)](#)

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 or 15(d) of
The Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): December 20, 2007

SCHERING-PLOUGH CORPORATION

(Exact Name of Registrant as Specified in its Charter)

New Jersey
(State or Other Jurisdiction
of Incorporation)

1-6571
(Commission
File Number)

22-1918501
(IRS Employer
Identification No.)

2000 Galloping Hill Road
Kenilworth, NJ 07033
(Address of Principal Executive Office)

Registrant's telephone number, including area code: (908) 298-4000

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
-
-

Item 1.01. Entry into a Material Definitive Agreement

On December 20, 2007, Schering-Plough (Ireland) Company (“Schering-Plough”), Centocor, Inc, and CNA Development, LLC entered into an Amendment Agreement to a previous Distribution Agreement dated April 3, 1998 (the “Amended Distribution Agreement”). The Amended Distribution Agreement will, among other changes, extend the terms of Schering-Plough’s marketing rights to REMICADE and golimumab and modify the profit sharing terms to REMICADE and golimumab.

The foregoing description of the Amended Distribution Agreement does not purport to be complete and is qualified in its entirety by reference to the Amended Distribution Agreement, which is filed as Exhibit 10.1 hereto, and is incorporated into this report by reference below.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

EXHIBIT NO.	DESCRIPTION
10.1	Amendment Agreement to the Distribution Agreement, dated December 20, 2007, between Centocor, Inc., CNA Development, LLC, and Schering-Plough (Ireland) Company.*
99.1	Press Release, dated December 21, 2007, entitled "Centocor, Schering-Plough revise agreement covering Remicade, Golimumab".

*Portions of this exhibit have been omitted and filed separately with the Securities and Exchange Commission pursuant to a confidential treatment request.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Schering-Plough Corporation

By: /s/ Susan Ellen Wolf
Susan Ellen Wolf
Corporate Secretary,
Vice President — Corporate Governance and
Associate General Counsel

Date: December 21, 2007

EXHIBIT INDEX

<u>Exhibit Number</u>	<u>Description</u>
10.1	Amendment Agreement to the Distribution Agreement, dated December 20, 2007, between Centocor, Inc., CNA Development, LLC, and Schering-Plough (Ireland) Company.*
99.1	Press Release, dated December 21, 2007, entitled "Centocor, Schering-Plough revise agreement covering Remicade, Golimumab".

*Portions of this exhibit have been omitted and filed separately with the Securities and Exchange Commission pursuant to a confidential treatment request.

AMENDMENT AGREEMENT

to the

DISTRIBUTION AGREEMENT

dated April 3, 1998

by and between

CENTOCOR, INC.,

CNA DEVELOPMENT, LLC

(as licensee to Centocor, Inc.'s worldwide rights to Golimumab Product),

and

SCHERING-PLOUGH (IRELAND) COMPANY

(as successor in interest to Schering-Plough Ltd.)

DECEMBER 20, 2007

Portions of this exhibit have been omitted and filed separately pursuant to an application for confidential treatment filed with the Securities and Exchange Commission pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended. Omissions are designated as [* *].

AMENDMENT AGREEMENT

This Amendment Agreement (hereinafter the “Amendment Agreement”), dated as of December 20, 2007 (the “**Amendment Date**”), is made by and between Centocor, Inc. a corporation organized under the laws of Pennsylvania with its principal office at 800 Ridgeview Drive, Horsham, Pennsylvania (“**Centocor**”), CNA Development, LLC, a limited liability company organized under the laws of Delaware (“**CNA Development**”, and collectively with Centocor, the “**Centocor Parties**”); and Schering-Plough (Ireland) Company, a corporation organized under the laws of Ireland, with offices at Rathdrum, County Wicklow, Ireland (“**Schering-Plough**”) (Schering-Plough and the Centocor Parties, each referred to from time to time herein as a “**Party**” and collectively as the “**Parties**”). To the extent set forth herein, this Amendment Agreement modifies and amends the Distribution Agreement referenced below.

RECITALS

WHEREAS, on April, 3, 1998, Centocor and Schering-Plough Ltd., a corporation organized under the laws Switzerland with its principal offices at Weystrasse 20, CH 6000 Lucerne, Switzerland (“SPL”) entered into a Distribution Agreement, as previously amended (the “**Distribution Agreement**”) and SPL subsequently assigned the Distribution Agreement to its Affiliate, Schering-Plough, under the terms of that certain Assignment and Assumption Agreement, dated August 25, 2005; and

WHEREAS, pursuant to the terms of the Distribution Agreement the Parties and their respective Affiliates have been developing and commercializing the chimeric anti-TNF monoclonal antibody Product (known as cA2 or infliximab) in the Territory under the Trademark REMICADE (the “**Remicade Product**”); and

WHEREAS Centocor has developed a fully human anti-TNF monoclonal antibody product known as golimumab (the “**Golimumab Product**”) through Phase IIb clinical trials and, prior to the exercise by Schering-Plough of its rights under Section 12.1 of the Distribution Agreement to participate in the continued development and commercialization of the Golimumab Product as a Product under the Distribution Agreement (the “**Golimumab Option**”), Centocor licensed the worldwide rights to Golimumab Product, subject to the Golimumab Option, to its Affiliate, CNA Development; and

WHEREAS Schering-Plough has exercised its Golimumab Option rights and Schering-Plough and Centocor subsequently arbitrated a disagreement over the duration of Schering-Plough’s rights to the Golimumab Product under the Distribution Agreement resulting in a final decision by the arbitrator that the term of Schering-Plough’s rights to the Golimumab Product under the Distribution Agreement will continue for a period of fifteen years from the date of first Commercial Sale of Golimumab Product in the Territory; and

WHEREAS Centocor has appealed the decision of the arbitrator and Centocor and Schering-Plough have recently engaged in good faith discussions in an attempt to settle and finally resolve their dispute over the term of Schering-Plough's rights to Golimumab Product as well as to resolve certain additional outstanding issues related to the development and commercialization of Remicade Product and/or Golimumab Product under the terms of the Distribution Agreement, and now desire to document their mutual agreement on all such matters, as set forth in detail herein; and

WHEREAS Centocor has therefore agreed to terminate and permanently withdraw its appeal of the aforementioned arbitrator's decision in conjunction herewith and as provided herein; and

WHEREAS CNA Development is also in agreement with all of the amendments and modifications to the Distribution Agreement set forth herein pertaining to the Golimumab Product;

NOW THEREFORE, in consideration of the foregoing premises and the mutual covenants herein contained, the Parties hereby agree as follows:

Except as otherwise expressly set forth in this Amendment Agreement, the capitalized terms used herein (whether in the singular or plural) shall have the respective meanings set forth in the Distribution Agreement.

ARTICLE 1
DISTRIBUTION AGREEMENT AMENDMENTS, CLARIFICATIONS AND MODIFICATIONS

The following amendments, clarifications and modifications to the Distribution Agreement shall become effective immediately upon execution of this Amendment Agreement:

1.1 Clarification of Product Definition. The definition of Product shall include, without limitation, the Remicade Product and the Golimumab Product, as well as any Improvements to either such Product. However, for clarity, the occurrence of the term "Product" in the first sentence of the second whereas clause of the Distribution Agreement and in the proviso to the "Cost of Goods Sold" definition shall be deemed to refer to Remicade Product only, and all references in the Distribution Agreement to the "Product" as being "described" or "set forth" in Appendix A to that agreement shall be deemed to be references to the relevant Product as described in the revised Appendix A attached hereto. In addition, the various references to "Trademark" in Section 4.3(b) of the Distribution Agreement, when used in connection with the term "Product", shall be deemed to refer to the relevant Trademark for each of Remicade Product and Golimumab Product, respectively, it being understood that the Product Committee shall be responsible for agreeing upon the Trademark(s) to be used for Golimumab Product in the Territory. The Parties also agree that the references to "Product" appearing in third paragraph of Section 5.1 of the Distribution Agreement shall be deemed to only refer to Remicade Product and that the "Manufacture and Supply

Agreement” referred to in that paragraph is the Remicade Supply Agreement (as defined below).

1.2 Affiliate Definition; Delegation and Assignment. The last sentence of the definition of “Affiliate” (i.e., the sentence: “Any reference in this Agreement to Centocor or Schering-Plough includes the Affiliates of that Party unless the context clearly indicates to the contrary.”) is hereby deleted. Notwithstanding such deletion, and consistent with Section 12.8 of the Distribution Agreement, it is understood and agreed that each Party may license and/or delegate or assign any rights and the performance of any of its obligations under the Distribution Agreement to an Affiliate without the prior consent of the other Party.

1.3 Affiliate-Controlled IP. The Parties acknowledge that either Party may from time to time during the Term propose that proprietary technology, materials, processes, know-how, data, information, patent rights and/or other intellectual property rights that are owned or controlled by an Affiliate of such Party (“**Affiliate-Controlled IP**”) be utilized by the Parties in the development, manufacture and/or commercialization of one or more Products in the Territory. Centocor is under no obligation to agree to any such proposal by Schering-Plough. It is further understood that any use of Affiliate-Controlled IP (i) shall be subject to the prior approval requirement in Section 6.2(a)(i) of the Distribution Agreement if it would result in obligations to directly or indirectly pay license fees, milestones, royalties or other payments to one or more unaffiliated third parties in the case of any Centocor Affiliate-Controlled IP and (ii) shall be subject to a comparable prior consent requirement in the case of any Schering-Plough Affiliate-Controlled IP. The Parties further agree that the Party making available such Affiliate-Controlled IP to the other Party shall not charge or require reimbursement from the other Party (or the other Party’s Affiliates) for, or include in the calculation of Contribution Income, any licensee fees, milestones, royalties or other payments due or payable to its Affiliates as a result of the use of such Affiliate-Controlled IP in connection with development, manufacture and/or commercialization of the Products in the Territory, with the exception of such amounts that are pass through amounts payable by such Affiliate(s) to unaffiliated third party licensors as a result of such use of such Affiliate-Controlled IP. In addition, any costs and expenses previously incurred by or on behalf of such Affiliates in the development of such Affiliate-Controlled IP shall not be included in Product Development Costs unless expressly agreed by the Parties in writing. Nothing in this Section 1.3 shall be construed as (i) granting (whether expressly or by implication) to either Party any licenses or other rights to any Affiliate-Controlled IP that has not, as of the Amendment Date, already been utilized by written agreement of the Parties for the development, manufacture or commercialization of the Products in the Territory, or (ii) obligating either Party to make available any new or additional Affiliate-Controlled IP for such use. For the avoidance of doubt, it is understood that Centocor may (without Schering-Plough’s prior consent) utilize, and grant Schering-Plough the right to utilize, any new or additional Centocor proprietary technology, materials, processes, know-how, data, information, patent rights and/or other intellectual property rights or any Centocor Affiliate-Controlled IP in connection with the development, manufacture and commercialization of Products in the Territory; provided that such utilization does not

result in (x) any requirement for additional consideration or compensation to be paid by Schering-Plough or its Affiliates in connection with such Affiliate-Controlled IP, (y) any development costs associated with such Affiliated-Controlled IP being included as Product Development Costs, or (z) any additional Affiliate or unrelated third party pass-through costs being included in the calculation of Contribution Income.

1.4 Term of the Distribution Agreement. Section 8.1 of the Distribution Agreement is hereby deleted and replaced in its entirety with the following:

“8.1 **Term**. The term of this Agreement (the “Term”) shall commence on the Effective Date and continue for a period ending on the later to occur of the last day of the Remicade Term or the Golimumab Term, unless this Agreement is earlier terminated pursuant to the provisions of this Agreement. The foregoing notwithstanding, in the event that prior to the expiration of the Term (as defined above) Schering-Plough acquires rights, pursuant to Section 12.1 of this Agreement, to any additional fully human anti-TNF monoclonal antibodies developed by Centocor through transgenic animals or plants or other technology (an “**Additional Section 12.1 Product**”), then the term of this Agreement shall be extended, solely with respect to such Additional Section 12.1 Product, to expire on the fifteenth anniversary of the date of the first Commercial Sale of such Additional Section 12.1 Product in the European Union after the grant of the first Marketing Approval of such Additional Section 12.1 Product in the European Union.”

The following new definitions are hereby added to Article 1 of the Distribution Agreement:

“**Remicade Term**” shall mean the period beginning on the Effective Date and ending on September 1, 2014.

“**Golimumab Term**” shall mean the period beginning on the date of the first Commercial Sale of Golimumab Product to occur in the European Union after the grant of the first Marketing Approval of Golimumab Product in the European Union (the “**First Golimumab Commercial Sale**”), and ending upon the fifteenth (15th) anniversary of such date.

For clarity, in the event that the Term of the Distribution Agreement is extended due to the acquisition by Schering-Plough of rights to any Additional Section 12.1 Products, any such extension of the Term shall have no effect on the expiration of Schering-Plough’s rights to the Remicade Product or the Golimumab Product, each of which shall still expire and revert to Centocor, respectively, on expiration of the Remicade Term (in the case of Remicade Product) or on expiration of the Golimumab Term (in the case of Golimumab Product).

1.5Milestone Payments. The Parties acknowledge and agree that the various payments provided for in Sections 3.1, 3.2 and 3.3 of the Distribution Agreement have been paid with respect to Remicade Product, and that the development and commercialization of Golimumab Product does not and will not give rise to any additional payment obligations under those Sections of the Distribution Agreement.

1.6Separate Contribution Income Calculations for Golimumab Product and Remicade Product. For convenience and transparency to product line information, the Parties agree that Contribution Income will be calculated separately for Remicade Product and Golimumab Product based upon the Net Sales of each such Product in the Territory. Nonetheless, for the purpose of clarity, the manner and elements of calculating Contribution Income will be the same for Remicade Product and Golimumab Product, and shall continue to be as set forth in Section 6.2 of the Distribution Agreement and Section 7.1 of the Supply Agreement, dated September 15, 1999, between Centocor and Schering-Plough, as amended (the “**Remicade Supply Agreement**”). For further clarity, the Parties agree that the \$150,000,000 Net Sales threshold in Section 6.2(c) shall apply separately to Golimumab Product and to Remicade Product, rather than to the aggregated Product sales, for all periods prior to the Trigger Date (as defined below).

1.7Golimumab Costs Prior to the First Golimumab Product Marketing Approval. The Parties acknowledge and agree that, subject to the terms and conditions set forth in this Section 1.7, the Parties shall have the right to include in the Contribution Income calculation any Marketing Expenses and/or sales costs related to the commercialization of Golimumab Product in the Territory that are incurred prior to the first Marketing Approval of Golimumab Product in the Territory (collectively, the “**Pre-Approval Marketing and Sales Costs**”). The total of all Pre-Approval Marketing and Sales Costs incurred for the 2006 and 2007 Agreement Years that are to be included in the Contribution Income calculation for the Products shall be subject to the caps on such amounts set forth in Schedule 1.7 (attached hereto). With respect to the 2008 Agreement Year and any subsequent Agreement Years (or partial Agreement Year) occurring prior to the Trigger Date, the Parties shall be permitted to include in the Contribution Income calculation for the Products in the relevant Agreement Year those Pre-Approval Marketing and Sales Costs that are incurred in such Agreement Year in connection with the performance of the Country Marketing Plans established for Golimumab Product in the Territory. For clarity, the Parties agree that notwithstanding the date on which the first Commercial Sale of Golimumab Product in the Territory occurs, the inclusion of Pre-Approval Marketing and Sales Costs in the calculation of Contribution Income shall become effective on the Amendment Date. The foregoing notwithstanding, to the extent that the aggregate total of all Pre-Approval Marketing and Sales Costs incurred by Schering-Plough over the entire period extending from January 1, 2006 to the Trigger Date exceeds [**] dollars (\$[**]) (the “**Pre-Approval Cost-Sharing Cap**”), Schering-Plough shall be solely responsible for all such Pre-Approval Marketing and Sales Costs in excess of the Pre-Approval Cost-Sharing Cap, shall not be entitled to any reimbursement from or cost sharing by Centocor for such excess amounts, and shall not include such excess amounts in the Contribution Income calculation. For clarity, the

costs of any ongoing or future Phase III or Phase IIIb studies for the Golimumab Product shall not be included in determining Pre-Approval Marketing and Sales Costs.

1.8 Tanabe Rights. Without modifying the provisions of Section 2.3(a) of the Distribution Agreement, the Parties agree that Schering-Plough's rights in that section will not be triggered in the event that Tanabe Seiyaku Co. Ltd. ("**Tanabe**"), or any of Tanabe's Affiliates or successors in interest, grants to Centocor or a Centocor Affiliate co-promotion rights, co-marketing rights or other semi-exclusive commercialization rights (e.g., where Tanabe, its Affiliates or successors in interest, and/or its or their third party sublicensees or distributors, still hold non-exclusive or co-exclusive rights to distribute, market, promote and/or sell Product in the relevant country(ies)) to one or more Products in any one or more of the following countries: Japan, Taiwan or Indonesia. It is acknowledged and agreed that Schering-Plough's rights under Section 2.3(a) no longer apply to the Peoples Republic of China.

1.9 Rights to Cilag Autoinjector; Reimbursement of Development Costs. The Parties have agreed to develop and commercialize the Golimumab Product utilizing the autoinjector device developed by Cilag GmbH International ("**Cilag**"), an Affiliate of Centocor (the "**Cilag Autoinjector**"). Centocor shall be responsible for procuring the grant of any licenses, sublicenses or other rights from Cilag that are necessary to develop, manufacture and/or commercialize the Golimumab Product with the Cilag Autoinjector in the Territory; provided that any financial obligations to Cilag arising in connection with such license shall be subject to the provisions of Section 1.3 and Section 1.11 of this Amendment Agreement. In consideration for such rights and the Autoinjector Development Costs (as defined below) incurred by Cilag, Schering-Plough shall make a one time payment of twenty million five hundred thousand dollars (\$20,500,000) within ten (10) business days after the Amendment Date. In addition, within thirty (30) days after the date of submission of the first application for Regulatory Approval of Golimumab Product in the EMEA, Schering-Plough shall pay to Centocor a milestone payment in the amount equal to the lesser of four million two hundred and fifty thousand dollars (\$4,250,000) or the amount determined as follows:

- (i) **[**]** percent **[**]** of the total of all Autoinjector Development Costs incurred as of the date of such EMEA submission, minus
- (ii) twenty million five hundred thousand dollars (\$20,500,000).

Such milestone payment shall be made pursuant to an invoice (with supporting documentation in reasonable detail) to be provided to Schering-Plough by Centocor. Thereafter, to the extent that Schering-Plough's total payments made pursuant to this Section 1.9 are less than twenty-four million, seven hundred and fifty thousand dollars (\$24,750,000) and at all times subject to the Autoinjector Reimbursement Cap (as defined below), Centocor shall include **[**]** percent **[**]** of the ongoing Autoinjector Development Costs incurred in a given calendar quarter in the quarterly Product

Development Cost billings for such calendar quarter under the Distribution Agreement. As used in this Section 1.9, the term “**Autoinjector Development Costs**” means the development costs incurred by Cilag in connection with the development of the Cilag Autoinjector (including Cilag’s or its Affiliates’ FTE costs, but excluding any Centocor FTE costs incurred on or after the Amendment Date); provided, however, that any costs and expenses incurred in connection with activities specifically directed to the use of the Cilag Autoinjector for any products other than Golimumab Product shall be excluded. The term “**Autoinjector Reimbursement Cap**” means an aggregate total of [**] dollars (\$[**]) of Autoinjector Development Costs which is the maximum amount that will be subject to sharing and/or reimbursement by Schering-Plough under the terms of this Section 1.9. The Parties acknowledge and agree that the aggregate total of all of Schering-Plough’s payments pursuant to this Section 1.9 shall not exceed an amount equal to [**] percent ([**]%) of the Autoinjector Reimbursement Cap (i.e., twenty-four million, seven hundred and fifty thousand dollars (\$24,750,000)), and that Schering-Plough shall have no obligation to reimburse or share in any portion of Autoinjector Development Costs that exceed the Autoinjector Reimbursement Cap. The Parties agree that any payments due under this Section 1.9 shall be paid by Schering-Plough directly to Cilag on Centocor’s behalf.

1.10 Supplies of Cilag Autoinjector. (a) Schering-Plough hereby agrees to exclusively source all of its requirements for supplies of autoinjector devices for use in connection with the development and commercialization of Golimumab Product in the Territory from Centocor or its Affiliates and Centocor or its Affiliates shall be responsible for supplying to Schering-Plough such quantities of Cilag Autoinjector as it may order in accordance with the Autoinjector Supply Agreement (as defined below) for development and commercialization of the Golimumab Product in the Territory. As soon as practicable after the Amendment Date, the Parties will in good faith negotiate and enter into a supply agreement with respect to the Cilag Autoinjector (the “**Autoinjector Supply Agreement**”) which shall be consistent with the terms of the Distribution Agreement, as amended hereby, and the non-product and/or price specific terms of the Remicade Supply Agreement. The Autoinjector Supply Agreement shall, in any event, include provisions to provide that:

- (i) in the event of an actual or projected shortfall in supplies of Cilag Autoinjector, (x) Centocor shall ensure (A) that the available inventory and production capacity for that device is appropriately allocated based upon the collective firm orders and forecast requirements of the Parties for supplies of Cilag Autoinjector for use in connection with Golimumab Product (whether inside or outside the Territory) and any other firm orders and forecast requirements of Centocor or its Affiliates for supplies of the Cilag Autoinjector for the development and commercialization of Centocor’s or its Affiliates’ other products, and (B) that such supply quantity allocated to Golimumab Product requirements would be split between Schering-Plough (and its Affiliates), on the one hand, and Centocor (and its Affiliates) on the other hand, in
-

the same proportion as their respective firm orders and forecast requirements for supplies of Cilag Autoinjector for use in connection with Golimumab Products such that the shortfall in such supplies would be shared between them and (y) to the extent any such actual or projected shortfall results in forecasted market shortages for the Cilag Autoinjector, Schering-Plough and Centocor will jointly pursue alternative sourcing to ensure continued supply of autoinjector devices to both Parties; and

- (ii) in the event that Centocor develops a new autoinjector device for use with Golimumab Product and does not permit Schering-Plough to commercialize Golimumab Product utilizing such new device, Schering-Plough will be relieved of its obligations to source autoinjector devices for the Golimumab Product exclusively from Centocor.

The Parties will agree upon an initial price per unit to be paid by Schering-Plough for supplies of the Cilag Autoinjector under the Autoinjector Supply Agreement, which determination shall be made in connection with the determination of the initial supply price for Golimumab Product pursuant to Section 1.16. The supply price for the Cilag Autoinjector shall also be subject to periodic review and adjustment, as necessary, by the Product Committee in connection with any review and adjustment of the supply price for Golimumab Product pursuant to Section 6.1 of the Distribution Agreement. The foregoing notwithstanding, for purposes of Contribution Income calculations, the actual cost per unit of Cilag Autoinjector, without mark-up and subject to the application of the cap as set forth under Section 1.11, shall be used.

(b) *Alternative Devices.* In the event that the Parties agree to develop and/or commercialize Golimumab Product in the Territory using an alternative autoinjector device, the Parties shall also agree upon mutually acceptable arrangements for the manufacture and supply of supplies of the alternative device, it being understood that if a Party (or one of its Affiliates) has either internally developed such alternative device or licensed or acquired rights to such alternative device, that Party shall be primarily responsible for procuring the manufacture and supply of all requirements for supplies of the alternative device for use in connection with the Golimumab Product in the Territory. To the extent that Schering-Plough is the Party responsible for procuring supplies of such alternative autoinjector device, the Parties shall, upon request by Centocor, also negotiate in good faith and enter into a supply agreement for the manufacture and supply on commercially reasonable terms of Centocor's requirements of such device for use in connection with Golimumab Product in countries outside the Territory. Any such supply agreement shall be consistent with the terms of the non-product and/or price specific terms of the Remicade Supply Agreement, including without limitation clauses to provide that in the event of an actual or projected shortfall in supplies of such device, (i) Schering-Plough shall ensure that the available inventory and production capacity for that device is appropriately allocated based upon the Parties' firm orders and forecast requirements for the device for use in connection with Golimumab Products both within and outside the Territory and (ii) to the extent any such actual or projected shortfall results in forecasted market shortages for the device, Schering-Plough and Centocor will jointly pursue alternative sourcing to ensure continued supply of autoinjector devices to both Parties.

1.11 Cost of Cilag Autoinjector for Contribution Income Purposes. The actual cost per unit for autoinjector devices for Golimumab Product will be included in the calculation of Contribution Income; provided that such cost will be subject to a cap of [**] dollars (\$[**]) per unit throughout the Term of the Distribution Agreement. The same principles for determining actual cost used in Appendix B to the Distribution Agreement with respect to Remicade Product shall be used in determining the actual cost per unit of the Cilag Autoinjector.

To the extent Cilag's actual per unit cost for the Cilag Autoinjector device exceeds [**] dollars (\$[**]) per unit, such excess costs shall not be included in the calculation of Contribution Income and Centocor shall be solely responsible for such excess costs and shall not be entitled to any reimbursement from Schering-Plough for such excess costs. The costs of all third party royalties, license fees and milestones under third party licenses existing as of the Amendment Date are included in the capped \$[**] price. Any additional royalties due under future third-party licenses shall be included in the Contribution Income calculation and shall not be included in the cap calculation; provided that Centocor shall not enter into any additional agreements with third parties that include provisions requiring the payment of license fees, milestones, royalties or other payments relating to the sale of the Autoinjector in the Territory without the prior consent of Schering-Plough.

1.12 Golimumab Crohn's Disease Indication. The Parties agree to allow the Product Committee a period of six (6) months from the Amendment Date (the "**CD Decision Period**") to reach a final decision on whether or not to develop Golimumab Product for a Crohn's Disease indication (the "**CD Development Program**"). In the event that at the end of the CD Decision Period, the Product Committee still cannot agree on whether to develop Golimumab Product for a Crohn's Disease indication, then Schering-Plough shall be permitted to pursue the independent development and commercialization of Golimumab Product for Crohn's Disease in accordance with the provisions set forth in Sections 1.12(a)-(n) of this Amendment Agreement, as well as such other supplemental terms and conditions as the Parties may agree upon in writing during the CD Decision Period (collectively, the "**Crohn's Terms**"). The development plan and budget for the CD Development Program will be finalized and a copy provided to Centocor at least six (6) weeks prior to the end of the CD Decision Period (the "**CD Development Plan and Budget**").

(a) *Conduct of the CD Development Program*. In the event that Schering-Plough decides to proceed with independent development of Golimumab Product for Crohn's Disease pursuant to this Section 1.12, Schering-Plough will be responsible for the conduct of the CD Development Program in accordance with the CD Development Plan and Budget (including as it may be amended) and shall have the right to select and utilize third party contractors in connection with the performance of the CD Development Program. Schering-Plough will be responsible for, but shall consult with Centocor with regard to the design of the overall CD Development Program, and shall provide Centocor a reasonable opportunity to review and comment on the protocols proposed for each clinical trial to be conducted as part of the CD Development Program. Schering-Plough shall in good faith reasonably consider any comments timely provided by Centocor with regard to the CD Development Program and/or such protocols. For clarity and without limiting the scope of the Centocor MAH Matters described in Section 1.12(e), below, it is understood and agreed that Schering-Plough shall have final decision making authority over the scope of the CD Development Plan and Budget and any amendments thereto.

(b) *Centocor Contract Assistance*. Schering-Plough may desire to contract with Centocor for the performance by Centocor of certain activities within the scope of the CD Development Program on Schering-Plough's behalf and at Schering-Plough's

cost. In such event, Schering-Plough shall so notify Centocor and the Parties shall discuss in good faith the scope and terms governing any such contracted activities; provided that it is understood that Centocor shall not be under any obligation to perform any such activities on Schering-Plough's behalf unless such scope and terms have been agreed in writing. The Parties acknowledge and agree, however, that whether or not they enter into any such contract for the performance by Centocor of activities within the scope of the CD Development Program, Centocor is obligated under this Amendment Agreement to perform the activities described in Sections 1.12(d), (e), (j), (k), (l) and (m) in support of the CD Development Program. Any Centocor internal FTE costs incurred in the performance of any such contracted activities or any of the obligations described in Sections 1.12(d), (e), (j), (k), (l) and (m), shall be charged at the rate of \$250,000 per FTE. Any and all amounts paid by Schering-Plough to Centocor under such contract shall be included in Schering-Plough's out-of-pocket development costs for the purposes of determining the amount to be paid by Centocor if it exercises its option under Section 2.1(c)(ii) of the Distribution Agreement, as amended hereby, to share in the Contribution Income derived from the Crohn's Disease indication (the "**CD Option Right**").

(c) *Pre-Exercise Product Development Costs.* Unless and until such time as Centocor exercises its CD Option Right, Schering-Plough will be solely responsible for all costs and expenses incurred in connection with the performance of the CD Development Program. To the extent that Centocor performs any activities requested by Schering-Plough in support of the CD Development Program, Schering-Plough shall reimburse Centocor's costs and expenses incurred in the performance of such activities (with any Centocor internal FTEs being reimbursed at the rate set forth in Section 1.12(b) of this Amendment Agreement). Any such reimbursements shall be paid quarterly within thirty (30) days after receipt of invoices (together with supporting documentation in reasonable detail) by Schering-Plough from Centocor. Notwithstanding the foregoing and except as otherwise agreed in any contract for services as contemplated under Section 1.12(b) with respect to such services, Schering-Plough shall not be obligated to reimburse Centocor for any such costs and expenses in excess of one hundred and five percent (105%) of the amount budgeted for the relevant Agreement Year for the activities being performed by Centocor in connection with the CD Development Program unless such excess costs and expenses are approved by Schering-Plough in writing in advance.

(d) *Golimumab Product Supply During CD Development Program.* Centocor shall be responsible for manufacturing and supplying all clinical supplies of bulk unlabeled Golimumab Product and placebo needed for the conduct of the CD Development Program. Consistent with the provisions of Section 2.1(c)(ii) of the Distribution Agreement, as amended hereby, and the terms of the Golimumab Supply Agreement (as defined in Section 1.16 below), Centocor shall provide such supplies of Golimumab Product and placebo pursuant to written forecasts and orders to be provided by Schering-Plough. In addition, effective upon Schering-Plough's written notice to Centocor no later than the end of the CD Decision Period (a "**Packaging & Labeling Notice**"), Centocor shall be responsible for performing the clinical packaging and labeling of all clinical supplies of Golimumab Product and placebo needed for conduct of the CD Development Program,

in accordance with, and as more fully set forth in, the Golimumab Supply Agreement. If Schering-Plough fails to provide a Packaging & Labeling Notice prior to the expiration of the CD Decision Period, then Schering-Plough shall be solely responsible for the clinical packaging and labeling of all clinical supplies of Golimumab Product and placebo needed for conduct of the CD Development Program. For clarity, Centocor shall also be responsible for providing supplies of Cilag Autoinjector required by Schering-Plough for the conduct of the CD Development Program in accordance with the terms of the Autoinjector Supply Agreement.

(e) *MAH Responsibilities*. Centocor will continue to hold the marketing authorizations for Golimumab Product in accordance with the terms of the Distribution Agreement and, accordingly, will therefore also have primary responsibility for certain matters pertaining to the product safety and regulatory compliance aspects of the development and commercialization of Golimumab Product for the Crohn's Disease indication in the Territory (the "**MAH Matters**"), specifically including those matters listed on Exhibit A attached hereto. During the Term, Centocor shall promptly execute any delegation agreements or other documentation that the Parties mutually agree are necessary or appropriate, consistent with the terms of this Section 1.12, in order for Schering-Plough to conduct the CD Development Program and/or commercialize Golimumab Product in the Territory for the Crohn's Disease indication.

(f) *CD Development Program Updates*. Schering-Plough shall provide quarterly updates to the Product Committee on the status of the CD Development Program, including activities engaged in and the budget expenditures against such activities, and shall otherwise keep Centocor informed of significant developments or changes to the CD Development Plan and Budget.

(g) *Centocor Opt-In Following Successful Completion of Phase III*. Schering-Plough shall notify Centocor in writing (as provided in Section 2.1(c) of the Distribution Agreement) upon Successful Completion (to be defined) of the Phase III studies to be conducted under the CD Development Program (the "**Successful Completion Notice**"). The Parties will use good faith efforts to discuss and agree upon a definition of Successful Completion during the CD Decision Period; it being understood that a decision by Schering-Plough's executive management following completion of such Phase III studies that the data and results of the CD Development Program are adequate to proceed with preparation and submission of an application for Regulatory Approval of Golimumab Product for the Crohn's Disease indication in the European Union shall de facto mean that such studies have been Successfully Completed. The Successful Completion Notice shall include (i) top line safety and efficacy results from the studies along with associated tables and figures as well as (ii) the total estimated amount (the "**Preliminary CD Development Amount**") of Schering-Plough's out-of-pocket development costs from the CD Development Program through the Opt In Date (as defined below) (together with supporting documentation in reasonable detail). Schering-Plough will also promptly provide Centocor with any other specific data available from the studies that is reasonably requested by Centocor to aid in assessment of its CD Option Right. Upon receipt of a Successful Completion Notice (and any additional data reasonably requested by Centocor as provided above), Centocor shall have a period of

sixty (60) days (the “**Review Period**”) to exercise the CD Option Right by providing written notice to Schering-Plough (the date of such notice of exercise, the “**Opt In Date**”) and within ten (10) Business Days after any such Opt In Date Centocor shall reimburse Schering-Plough for seventy-five percent (75%) of the Preliminary CD Development Amount. Within ninety (90) days after the Opt In Date the Parties will complete a true-up of the total amount of Schering-Plough’s out-of-pocket development costs from the CD Development Program actually incurred through the Opt In Date (the “**Final CD Development Amount**”) as compared to the Preliminary CD Development Amount. If requested by Centocor, such true-up process will be subject to an audit to be conducted by Centocor’s independent auditors (at Centocor’s expense) to confirm the Final CD Development Amount, and (if necessary) the ninety (90) day true up period shall be extended by the reasonable period of time necessary for Centocor to complete such audit. The Final CD Development Amount shall include, without limitation, (i) the Centocor internal FTE costs that are billed and paid by Schering-Plough up through the Opt In Date, but shall not include any Schering-Plough internal FTE costs, and (ii) any amounts paid by Schering-Plough to Centocor as reimbursement for costs and expenses incurred by Centocor in performance of activities requested by Schering-Plough in support of the CD Development Program (including without limitation payments for supplies of Golimumab Product and/or placebos). Within ten (10) Business Days after the Final CD Development Amount is established (including as such amount may be confirmed or modified following the exercise of Centocor’s audit right): (i) if the Final CD Development Amount is greater than the Preliminary CD Amount, then Centocor shall pay to Schering-Plough an amount equal to seventy-five percent (75%) of the difference between such amounts; or (ii) if the Final CD Development Amount is less than the Preliminary CD Amount, then Schering-Plough shall pay to Centocor an amount equal to seventy-five percent (75%) of such difference. The CD Option Rights shall expire if Centocor fails to exercise the CD Option Rights by the end of the Review Period (the “**Option Expiry Date**”). Schering-Plough’s expenses in procuring Golimumab Product for the CD Development Program shall be included in the costs and expenses of the CD Development Program for which Schering-Plough is responsible and will be included in the amount to be paid by Centocor if it exercises the CD Option Right.

(h) *Centocor Opt In Prior to Successful Completion of Phase III.* Centocor may exercise its CD Option Right at any time prior to receipt of a Successful Completion Notice by providing an early exercise notice to Schering-Plough (the “**Early Exercise Notice**”); provided that Centocor shall only be permitted one (1) opportunity to exercise its CD Option Right through an Early Exercise Notice. Upon receipt of the Early Exercise Notice, Schering-Plough shall provide (i) any specific data that is available from the CD Development Program studies that may be reasonably requested by Centocor in the Early Exercise Notice and (ii) the Preliminary CD Development Amount (together with supporting documentation in reasonable detail). Centocor shall have a 60-day Review Period upon receipt of such information to confirm the exercise of its CD Option Right. If Centocor confirms its exercise in writing, such date shall constitute the Opt In Date for purposes of Section 1.12(g), which section will then govern the rights and obligations with respect to exercise of the CD Option Right. If Centocor does not confirm its exercise in writing prior to the end of such 60-day Review Period, the Early

Exercise Notice shall be deemed to have lapsed, Centocor's rights under this Section 1.12(h) will have been exhausted, and the CD Option Right shall remain in effect in accordance with Section 1.12(g).

(i) *Opt-in Implications.* In the event that Centocor exercises the CD Option Right, the CD Terms related to responsibility for and conduct of the CD Development Program shall cease to apply effective as of the Opt In Date and the development of Golimumab Product for the Crohn's Disease indication shall thereafter be conducted jointly by the parties in accordance with the terms set forth in the Distribution Agreement.

(j) *Opt-out Implications.* In the event that Centocor does not exercise the CD Option Right, then (i) Schering-Plough shall thereafter retain one hundred percent (100%) of all Contribution Income resulting from the sale of Golimumab Product in the Territory for the Crohn's Disease indication (for clarity, Centocor shall continue to share in Contribution Income resulting from the sale of Golimumab Product in the Territory for Rheumatoid Arthritis and any other indications that are developed by the Parties within the scope of the Distribution Agreement); (ii) Centocor shall continue to manufacture and supply and Schering-Plough shall continue to purchase its requirements of Golimumab Product for the Crohn's Disease indication from Centocor at Centocor's actual cost as set forth in Section 1.12(d) (above), and (iii) the restrictions set forth in Section 2.1(c) of the Distribution Agreement on use of a different dosage form, formulation and trademark shall not apply to sales of Golimumab Product in the Territory for Crohn's Disease, and Schering Plough shall have the right to utilize the same formulations, dosage forms and trademarks as are used for non-Crohn's Disease indication Golimumab Product sales; provided that prior to the first Commercial Sale of Golimumab Product after Regulatory Approval for Crohn's Disease Schering-Plough and Centocor shall agree upon an appropriate commercially reasonable means for determining sales of Golimumab Product in the Territory for Crohn's Disease as opposed to sales for other indications (an example being the mechanism used by Centocor for determining royalty bearing sales of Product in the Territory under the Kennedy Agreement.)

(k) *Restrictions on Use of Data.* If Centocor does not exercise its CD Option Right, Centocor and its Affiliates shall not have any rights to use (or cross-reference), or to grant any third party any rights to use (or cross-reference), any of the data and information generated by the CD Development Program to prepare, file or otherwise support any application for Regulatory Approval in any country outside the Territory of Golimumab Product for use in the treatment of Crohn's Disease (or any other inflammatory bowel disease). Centocor will acquire such rights solely in the event that, and effective upon the date that, it exercises the CD Option Right in accordance with the provisions of this Section 1.12. However, Centocor shall at all times have the right to use the data from the CD Development Program solely to meet its legal obligations as the marketing authorization holder for Golimumab Product, including, but not limited to adverse event reporting and, to the extent requested by regulatory authorities, cross-indication analyses. Any other use of such data by Centocor or its Affiliates prior to the exercise of the Opt In Date shall be subject to Schering-Plough's prior written approval, which shall not be unreasonably withheld.

(l) *Schering-Plough's Access to Information.* Centocor shall provide Schering-Plough with rights to use and reasonable access to any data and information in its or its Affiliates' possession or control related to Golimumab Product that is necessary to enable Schering-Plough to plan and conduct the CD Development Program. In addition, Centocor shall upon request reasonably cooperate with Schering-Plough to support the conduct of the CD Development Program by (x) making available relevant Centocor personnel to provide technical information and/or assist Schering-Plough in preparing submissions and/or responses to inquiries from regulatory authorities related to Golimumab Product, (y) providing appropriately trained and experienced personnel who, collectively, are knowledgeable with respect to the Golimumab Product and Centocor's internal processes, to work with Schering-Plough personnel to coordinate activities being performed by Centocor or its Affiliates with regard to the CD Development Program pursuant to this Section 1.12 or any separate contract entered into by the Parties as contemplated in Section 1.12(b) and (z) being named as the sponsor of clinical trials and/or holder of relevant applications (such as INDs and Clinical Trial Applications under the Clinical Trial Directive) for Crohn's Disease if and to the extent that Schering-Plough and/or its Affiliates are not able to perform such functions due to regulatory constraints.

(m) *Selection of Clinical Study Sites.* Schering-Plough will be responsible for the selection of clinical study sites for the CD Development Program, and shall have the right to include study sites in any country, including the United States, in any clinical studies conducted as part of the CD Development Program; provided that prior to selecting any site in the United States, Schering-Plough shall give Centocor prior written notice identifying such potential site. To the extent that either (i) Centocor has clinical studies already underway at such site for a product being studied in Crohn's Disease patients, or (ii) Centocor objects to such site based on reasonable quality or compliance concerns stemming from Centocor's legal obligations as marketing authorization holder for the Golimumab Product, then Centocor shall so notify Schering-Plough to that effect and Schering-Plough shall select a different clinical study site. If a United States site is selected, Centocor shall be responsible for any corresponding FDA submissions. For purposes of this Section 1.12(m), a Centocor clinical study shall be considered "underway" at a given site only during the period of time beginning on the effective date of the definitive contract with such study site for the conduct of the study and ending on the date on which patient enrollment for the study at such site has been completed.

(n) *Agreement limited to Crohn's Indication.* The terms set forth above in Sections 1.12(a) through (m) shall apply only to Schering-Plough's CD Development Program and, if applicable, commercialization of Golimumab Product for that indication in the Territory. Any efforts by the Parties to develop other additional indications for any Product shall continue to be governed by Section 2.1(c) of the Distribution Agreement with the specific terms for such development to be agreed between the Parties as contemplated under Section 2.1(c).

1.13 Withdrawal of Arbitration Appeal. Centocor agrees that on or promptly after the Amendment Date it will (i) execute a Dismissal Agreement (in the form attached hereto as Exhibit B) pursuant to F.R.A.P. 42(b) withdrawing with prejudice and without

costs its appeal of the matter captioned, Centocor, Inc. v. Schering-Plough, Ltd., No. 06-4995 (3d Cir.) (the “**Appeal**”) pending before the United States Court of Appeals for the Third Circuit, (ii) pay any fees due to the court with respect to the Appeal and execute any additional documents and/or perform or cause to be performed any other reasonable actions that may be necessary to accomplish withdrawal of the Appeal.

1.14 Golimumab Product License Grant. In order to facilitate Schering-Plough’s right to participate in the development and commercialization of Golimumab Product on the terms set forth in the Distribution Agreement (as amended hereby) and as contemplated under Section 12.1 of the Distribution Agreement, Centocor and CNA Development agree to grant to Schering-Plough certain license rights as set forth in a License Agreement to be executed by Centocor, CNA and Schering-Plough on the date hereof, in the form of Exhibit B (the “**Golimumab License Agreement**”).

1.15 Failure to Achieve the Trigger Date. In the event that the Trigger Date does not occur and Schering-Plough’s rights to Remicade Product expire on September 1, 2014, then Centocor shall cause its Affiliate, Cilag, to repay to Schering-Plough within thirty (30) days after such date an amount equal to the lesser of (i) twenty-four million seven hundred and fifty thousand dollars (\$24,750,000) or (ii) the aggregate total of all payments received by Cilag from Schering-Plough pursuant to Section 1.9 of this Amendment Agreement.

1.16 Golimumab Supply Agreement. As soon as practicable after the Amendment Date (and in any event prior to expiration of the CD Decision Period), the Parties will in good faith negotiate and enter into a supply agreement with respect to bulk unlabeled Golimumab Product (the “**Golimumab Supply Agreement**”). Such Golimumab Supply Agreement shall be consistent with the terms of the Distribution Agreement, as amended hereby, and the Remicade Supply Agreement, including for the avoidance of doubt, provisions to provide that: (i) Golimumab Product will be supplied by Centocor or its designated Affiliate at an initial supply price per unit to be determined by the Parties in a manner consistent with Section 6.1 of the Distribution Agreement; (ii) the Product Committee will periodically review and adjust the supply price for Golimumab Product as necessary in accordance with Section 6.1 of the Distribution Agreement; and (iii) in the event that Centocor receives a Packaging & Labeling Notice from Schering-Plough during the CD Decision Period, the packaging and labeling of clinical supplies of Golimumab Product and placebo for the CD Development Program shall be performed by Centocor on terms to be agreed. For clarity, the Parties agree that determination of the initial supply price for Golimumab Product, and any subsequent adjustments to the supply price, shall take into consideration the supply price (and any adjustments to such price) for the Cilag Autoinjector. The foregoing notwithstanding, for purposes of Contribution Income calculations, the actual Cost of Goods Sold for Golimumab Product, without mark-up and subject to the application of any applicable Golimumab COGS Cap, shall be used.

ARTICLE II

CONTINGENT AMENDMENTS, CLARIFICATIONS AND SUPPLEMENTAL AGREEMENTS

The amendments, clarifications and modifications agreements set forth in this Article II shall become effective upon, and only upon, the date of the first Marketing Approval for Golimumab Product in the European Union (the “**Trigger Date**”); provided,

however, that if no such Marketing Approval has been obtained by September 1, 2014 (the “**Cut-Off Date**”) then the provisions of this Article II shall lapse and have no further effect and the Trigger Date will be deemed not to have occurred should such a Regulatory Approval for Golimumab Product be obtained in the European Union after the Cut-Off Date:

2.1 Term of the Distribution Agreement. The Remicade Term is hereby extended to expire on the later of (i) September 1, 2014 or (ii) the last day of the Golimumab Term.

2.2 Division of Contribution Income. The division of Contribution Income resulting from Net Sales of Products in the Territory shall be governed by the terms set forth in Section 6.2 of the Distribution Agreement; provided that starting with Net Sales of Products for the 2010 Agreement Year and for each Agreement Year thereafter, the percentage of Contribution Income to be allocated between Schering-Plough and Centocor shall be as set forth below and the provisions of Section 6.2(c) (including the \$150 million sales threshold contained therein) shall no longer apply. For clarity, the applicable percentage will be used to divide Contribution Income arising from all Net Sales of Remicade Product and Net Sales of Golimumab Product in the Territory during the applicable Agreement Year.

Contribution Income Split

<u>Agreement Year</u>	<u>S-P</u>	<u>Centocor</u>
2010	60%	40%
2011	58%	42%
2012	55%	45%
2013	52%	48%
2014	50%	50%
All subsequent years	50%	50%

In the event that the Trigger Date occurs after January 1, 2010, the provisions of Section 6.2(c) shall apply to the portion of the Agreement Year prior to the Trigger Date (with the \$150 million sales threshold pro-rated to the portion of the Agreement Year prior to the Trigger Date) and for the remainder of such Agreement Year, the Contribution Income split specified above for such Agreement Year shall apply.

2.3 Additional Third Party Royalties included in calculation of Contribution Income.

(a) *Kennedy Royalty*. Royalties actually paid by or on behalf of Centocor to the Kennedy Institute (“**Kennedy**”) pursuant to the Agreement between Centocor and Kennedy, dated January 1, 1992 (as amended on July 29, 2004, the “**Kennedy Agreement**”), based upon sales of Products in the Territory occurring on or after the Trigger Date will be included in the calculation of Contribution Income for each of the relevant Products in accordance with and subject to the terms set forth in Section 6.2(a)(i)

of the Distribution Agreement. Centocor shall remain solely responsible for any and all royalties paid or payable to Kennedy based upon sales of Products in the Territory prior to the Trigger Date, and no such amounts shall be included in the calculation of Contribution Income or otherwise subject to sharing or reimbursement by Schering-Plough. In addition, in the event that Centocor at any time during the remaining Term of the Distribution Agreement amends its agreement with Kennedy in any way that results in an increase in the royalty rate payable to Kennedy on sales of any Product, unless and until such amendment is approved in writing by Schering-Plough, Centocor shall be solely responsible for the incremental increase in royalties which shall not be included in the calculation of Contribution Income. For clarity, the foregoing approval requirement shall not be construed to apply to changes in royalty amounts or calculations that result from labeling changes, additional indications or royalty calculation methodology under Section 3.07 of the Kennedy Agreement, and not from an amendment entered into by Centocor and Kennedy. The Parties agree that to the extent royalties are payable under the Kennedy Agreement on sales of more than one Product in the Territory, the same methodology shall be used to determine eligible sales and to calculate royalties due and payable for each of the relevant Products.

(b) *Third Party Royalties on Golimumab Product.* All third-party royalties due with respect to sales of Golimumab Product will be included in the Contribution Income calculation and the provisions of Section 6.2(a)(i) shall apply only to Remicade Product; provided that as of the Trigger Date, Centocor shall not enter into any other additional agreements with third parties that include provisions requiring the payment of license fees, milestones, royalties or other payments relating to commercialization of Golimumab Product in the Territory without the prior consent of Schering-Plough.

2.4 Cost of Goods Sold Definition. Effective as of the Trigger Date, the proviso in the definition of “**Cost of Goods Sold**” shall be deleted and replaced with the following language: “*provided, however,* that (i) the Cost of Goods Sold for finished Remicade Product will not exceed the Remicade COGS Cap, as adjusted pursuant to Section 6.2(f) and (ii) commencing with the sixth (6th) full Agreement Year after the First Golimumab Commercial Sale, the Cost of Goods Sold for finished Golimumab Product will not exceed the Golimumab COGS Cap, as adjusted pursuant to Section 6.2(g). For the avoidance of doubt, (i) the actual COGS for Golimumab Product (without any cap) shall apply with respect to all Golimumab Product sales prior to the beginning of the sixth full Agreement Year after the First Golimumab Commercial Sale and (ii) the Remicade COGS Cap and any Golimumab COGS Cap shall not supersede or otherwise alter the caps on fill and finish and packaging costs that are established in accordance with the cost neutrality (such cost neutrality being determined based solely upon any impact on the Contribution Income calculation) obligations of Section 5.1 of this Agreement. To the extent that Schering-Plough is or becomes responsible for conducting fill and finish and/or packaging activities for a Product as a result of the exercise of its rights under Section 5.1 of this Agreement it shall have the right to select the country(ies) in which it conducts such activities in order to minimize Schering-Plough’s costs related

to such Product(s);provided that it continues to satisfy the aforementioned cost neutrality obligation.

2.5Remicade COGS Adjustment. The following new Section 6.2(f) shall be inserted in the Distribution Agreement:

“(f)Remicade Product COGS Adjustment. The Cost of Goods Sold for Contribution Income purposes for Remicade Product shall be capped (the “**Remicade COGS Cap**”) at \$[**] per gram, including also the respective per gram and per vial caps for each manufacturing component in use as set forth on Schedule 6.2(f) (the “**Initial Cap**”), until the Trigger Date. If the Trigger Date occurs prior to January 1, 2010, then commencing with sales of Remicade Product by Schering-Plough in the Territory after the Trigger Date, the Remicade COGS Cap shall be \$[**] per gram through December 31, 2009. From January 1, 2010, until December 31, 2011, the Remicade COGS Cap shall be \$[**] plus the lesser of [**] percent ([**]%) of such amount or the adjustment in Centocor’s actual cost of goods for the bulk portion during the 2009 Agreement Year. From January 1, 2012 and every two years thereafter, the Remicade COGS Cap shall be similarly adjusted for the bulk portion by the lesser of [**]% or the documented change in Centocor’s actual cost of goods for the bulk portion during the immediately preceding Agreement Year. The Remicade COGS Cap so determined will be reviewed by the parties in the 4th quarter of the year prior to the scheduled commencement of each bi-annual revision. In the event that the Trigger Date does not occur prior to January 1, 2010, the Initial Cap will continue to apply; provided, however that the above reset calculation will continue to be made in parallel and upon the occurrence of the Trigger Date, the then prevailing numeric result of such parallel calculation shall become the new Remicade COGS Cap and shall be reviewed and reset bi-annually thereafter as described above. For clarity, the Parties intend that this parallel calculation of the cap shall commence in 2008 and be updated every two years in this manner. The Parties agree that Cost of Goods Sold for the Remicade Product bulk portion for Contribution Income purposes shall at all times be equal to the lesser of actual Cost of Goods Sold or the then current Remicade COGS Cap. In addition, the Remicade COGS Cap parallel calculation shall not *decline* from any one year to the next, but instead shall only either remain the same as the prior year or increase pursuant to the calculations described above. An example demonstrating the Remicade COGS Cap calculation is set forth in Schedule 6.2(f) hereto.”

2.6Golimumab COGS Adjustment. The following new Section 6.2(g) shall be inserted in the Distribution Agreement:

“(g)Golimumab Product COGS Adjustment. The Cost of Goods Sold for Contribution Income purposes for Golimumab Product shall be uncapped and reflect the actual Cost of Goods Sold for the first five full years after the Trigger Date. Commencing with the sixth (6th) full Agreement Year after the Trigger Date, the Cost of Goods Sold for Contribution Income purposes for finished Golimumab Product shall be capped (the “**Golimumab COGS Cap**”) at the lesser of (x) the actual Cost of Goods Sold for finished Golimumab Product during the fifth (5th) full Agreement Year after the

Trigger Date escalated by the CPI-U Index Average Change (as defined below) since the beginning of such sixth (6th) Agreement Year after the Trigger Date (i.e., Column B on Schedule 6.2(g) and (y) the actual Cost of Goods Sold for finished Golimumab Product during the prior Agreement Year adjusted by the CPI-U Index Average Change since the beginning of the prior Agreement Year (i.e., Column C on Schedule 6.2(g)). A sample calculation demonstrating the Golimumab COGS Cap adjustment process is set forth in Schedule 6.2(g) hereto. The Parties may in the future agree to utilize an alternative measure to the CPI-U Index Average Change. The Parties agree that Cost of Goods Sold for Golimumab Product for Contribution Income purposes shall at all times be the lesser of actual Cost of Goods Sold or the then current Golimumab COGS Cap. For purposes of this clause (g), "CPI-U Index Average Change" means the simple mathematical average of the cumulative year-to-year changes in the following two indices published by the U.S. Department of Labor, Bureau of Labor Statistics: (1) the CPI-U, US City Average, All Items and (2) the CPI-U, US City Average, All Items Less Food and Energy. In other words, the percentage change in the two indices will be added together and then divided by two."

2.7 No Product-Specific Termination. Without limitation to any other rights or remedies available under the Distribution Agreement, the Parties confirm and agree that in assessing whether a breach with respect to either Remicade Product or Golimumab Product is "material" for purposes of the Distribution Agreement termination rights under Section 8.2(a), the breach must be material to the Remicade Product and Golimumab Product development and commercialization efforts collectively and not individually. Other than as expressly provided in this Amendment Agreement with respect to the failure to achieve the Trigger Date, the development and commercialization rights with respect to Remicade Product and Golimumab Product may not be separately terminated unless specifically agreed to by Parties in writing.

ARTICLE III

MISCELLANEOUS

3.1 Definitions. All capitalized terms used in this Amendment Agreement that are not otherwise defined herein shall have the meanings set forth in the Distribution Agreement.

3.2 Access to Records. For clarity, the provisions of Section 6.4 of the Distribution Agreement shall also apply to the books and records of the Parties related to all matters provided for in this Amendment Agreement; provided that the limitation therein restricting audits to the 24-month period prior to the date of request for access shall not apply in connection with any audit under Section 1.12(g) or Section 1.9 of this Amendment Agreement. An audit under Section 1.12(g) or Section 1.9 shall also not count toward the single inspection that each Party is permitted per calendar year under Section 6.4 of the Distribution Agreement.

3.3 Effect of Amendment Agreement; Joinder. Except as expressly modified or amended by or otherwise directly in conflict with this Amendment Agreement, the Distribution Agreement and License Agreement all side letters and supplementary agreements executed in connection therewith shall remain in full force and effect in accordance with their stated terms. There are no agreements, restrictions, promises, warranties, covenants or undertakings regarding the matters addressed in this Amendment Agreement other than those expressly set forth or referred to herein. The Distribution Agreement and License Agreement, as modified, amended, clarified or modified by this Amendment Agreement, supersede all prior agreements and undertakings between the parties with respect to the subject matters addressed in this Amendment Agreement.

3.4 Non-Waiver. By entering into this Amendment Agreement, neither Schering-Plough nor Centocor waives or concedes any interpretation, position, right, claim or defense that pertains to the Distribution Agreement, Remicade Supply Agreement or any other related agreement including, but not limited to, any interpretation, position, right, claim or defense with respect to matters not specifically addressed herein.

3.5 Expenses. Each party shall bear the expenses and costs, including attorney fees, it incurs in connection with the preparation of this Amendment Agreement.

3.6 Counterparts. This Amendment Agreement may be executed by the parties in separate counterparts, each of which when so executed and delivered is deemed an original. All such counterparts together constitute but one and the same instrument.

IN WITNESS WHEREOF, the parties have caused this Amendment Agreement to be signed by their duly authorized representatives as of the date and year first written above.

CENTOCOR, INC.

By: _____
Name:
Title:
Date: December 20, 2007

SCHERING-PLOUGH (IRELAND) COMPANY

By: _____
Name:
Title:
Date: December 20, 2007

CNA DEVELOPMENT, LLC

By: _____
Name:
Title:
Date: December 20, 2007

News Release

FOR IMMEDIATE RELEASE**Media Contacts:**

Centocor
Michael Parks
215-325-4010
cell: 215-983-8000

Schering-Plough
Rosemarie Yancosek
908-298-7476

Investor Contacts:

Centocor
Louise Mehrotra
732-524-6491
Tina Pinto
732-524-2034

Schering-Plough
Robyn Brown
908-298-7436

**CENTOCOR, SCHERING-PLOUGH REVISE AGREEMENT
COVERING REMICADE, GOLIMUMAB**

HORSHAM, PA and KENILWORTH, NJ, Dec. 21, 2007 — Centocor, Inc. and Schering-Plough Corporation (NYSE: SGP) today announced they have revised their 1998 distribution agreement regarding the development, commercialization and distribution of both REMICADE® (infliximab), an anti-tumor necrosis factor (anti-TNF) alpha therapy for chronic inflammatory disorders, and golimumab, Centocor's next-generation, human, anti-TNF alpha therapy which is currently in Phase 3 trials. Effective upon regulatory approval of golimumab in the EU, the revised agreement will extend the duration of Schering-Plough's rights to exclusively market REMICADE in its current marketing territories outside the United States beyond 2014 to match the current duration of its exclusive marketing rights for golimumab product. Schering-Plough's marketing rights to both products will now extend for 15 years after the first golimumab commercial sale.

In addition, Centocor will receive a progressively increased share of profits on Schering-Plough's distribution of both products in the Schering-Plough marketing territory between 2010 and 2014, and remaining fixed thereafter for the remainder of the term.

The revised agreement will also allow Schering-Plough to independently develop and market golimumab for the Crohn's disease indication in its territories, with an option for Centocor to participate in the program.

The parties have also agreed to utilize an autoinjector device developed by Centocor affiliate Cilag GmbH International in the commercialization of golimumab in their respective territories and have further agreed to share the autoinjector development costs. The autoinjector would allow patients to self-administer golimumab subcutaneously. The revised agreement provides for Schering-Plough to make an upfront payment of \$20.5 million in the 2007 fourth quarter for rights to the autoinjector device.

Centocor exclusively markets REMICADE and upon approval will market golimumab in the United States. Schering-Plough has held exclusive marketing rights to REMICADE outside of the United States, Japan and certain Asian countries. In 2005, Schering-Plough exercised an option under the 1998 agreement with Centocor for license rights to develop and commercialize golimumab in the same territories as REMICADE.

REMICADE is approved to treat such indications as rheumatoid arthritis, early rheumatoid arthritis, psoriatic arthritis, Crohn's disease, ankylosing spondylitis, plaque psoriasis and ulcerative colitis. Golimumab is currently in Phase 3 trials for the treatment of rheumatoid arthritis, psoriatic arthritis and ankylosing spondylitis and is being investigated for administration by either monthly subcutaneous injection or every 12-week intravenous (IV) infusion. The companies anticipate filing applications with the U.S. Food and Drug Administration and the European Medicines Agency in 2008 seeking approval for golimumab in these therapeutic areas.

About Centocor

Centocor is harnessing the power of world-leading research and biomanufacturing to deliver innovative biomedicines that transform patients' lives. Centocor has already brought innovation to the treatment of Crohn's disease, rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, ulcerative colitis, pediatric Crohn's disease and psoriasis. The world leader in monoclonal antibody production and technology, Centocor has brought critical biologic therapies to patients suffering from debilitating immune disorders. Centocor, Inc. is a wholly owned subsidiary of Johnson & Johnson.

JOHNSON & JOHNSON DISCLOSURE NOTICE: This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could vary materially from Centocor's expectations and projections. Risks and uncertainties include general industry conditions and competition; economic conditions, such as interest rate and currency exchange rate fluctuations; technological advances and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approvals; domestic and foreign health care reforms and governmental laws and regulations; and trends toward health care cost containment. A further list and description of these risks, uncertainties and other factors can be found in Exhibit 99 of Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended December 31, 2006. Copies of this Form 10-K, as well as subsequent filings, are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. Centocor does not undertake to update any forward-looking statements as a result of new information or future events or developments.

About Schering-Plough

Schering-Plough is an innovation-driven, science-centered global health care company. Through its own biopharmaceutical research and collaborations with partners, Schering-Plough creates therapies that help save and improve lives around the world. The company applies its research-and-development platform to human prescription and consumer products as well as to animal health products. In November 2007, Schering-Plough acquired Organon BioSciences, with its Organon human health and Intervet animal health businesses, marking a pivotal step in the company's ongoing transformation. Schering-Plough's vision is to "Earn Trust, Every Day" with the doctors, patients, customers and other stakeholders served by its approximately 50,000 people around the world. The company is based in Kenilworth, N.J., and its Web site is www.schering-plough.com.

SCHERING-PLOUGH DISCLOSURE NOTICE: The information in this press release includes certain "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including statements relating to the timing of filing applications for golimumab. Forward-looking statements relate to expectations or forecasts of future events. Schering-Plough does not assume the obligation to update any forward-looking statement. Many factors could cause actual results to differ materially from Schering-Plough's forward-looking statements, including market forces, economic factors, product availability, patent and other intellectual property protection, current and future branded, generic or over-the-counter competition, the regulatory process, and any developments following regulatory approval, among other uncertainties. For further details about these and other factors that may impact the forward-looking statements, see Schering-Plough's Securities and Exchange Commission filings, including Part II, Item 1A. "Risk Factors" in the Schering-Plough's third quarter 2007 10-Q.

###

Created by 10K Wizard www.10KWizard.com