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P.E. 2/4/02



SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

**FORM 6-K**

**REPORT OF FOREIGN PRIVATE ISSUER  
PURSUANT TO RULE 13a-16 OR 15d-16 OF  
THE SECURITIES EXCHANGE ACT OF 1934**

Commission File Number - 1-15182

Report on Form 6-K

**DR. REDDY'S LABORATORIES LIMITED**  
(Name of Registrant)

7-1-27, Ameerpet  
Hyderabad, Andhra Pradesh 500 016, India  
+91-40-3731946

(Address of Principal Executive Offices)

FEB 04 2002



Indicate by check mark whether registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F  [X]

Form 40-F  [ ]

Indicate by check mark whether the registrant by furnishing the information contained in this form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes  [ ]

No  [X]

If "Yes" is marked, indicate below the file number assigned to registrant in connection with Rule 12g3 2(b).

Not applicable.

**PROCESSED**

FEB 11 2002

**THOMSON  
FINANCIAL**

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Exclusive License Agreement dated May 29, 2001 among Novartis Pharma AG, Dr. Reddy's Laboratories Limited, Reddy-Cheminor, Inc. and Reddy Netherlands B.V. redacted for confidentiality purposes pursuant to which a Confidential Treatment Request will be made to the Securities and Exchange Commission.

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## 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, thereunto duly authorized.

**Dr. Reddy's Laboratories Limited**

\_\_\_\_\_  
(Registrant)

Date: **February 1, 2002**

By: \_\_\_\_\_

(Signature)\*

\* Print the name and title of the signing officer under his signature.

**Santosh Kumar Nair**  
**Company Secretary**

**EXCLUSIVE LICENSE AGREEMENT**

This AGREEMENT is made as of this 29th day of May, 2001, by and between Novartis Pharma AG, a corporation organized and existing under the laws of Switzerland (hereinafter referred to as "Licensee" or "Novartis") and Dr. Reddy's Laboratories Limited, a corporation organized and existing under the laws of India, Reddy-Cheminor, Inc., a corporation organized and existing under the laws of the State of New Jersey, and Reddy Netherlands B.V., a corporation organized and existing under the laws of the Netherlands (each, a "Licensor Entity" and, collectively, "Licensor" or "Reddy").

**RECITALS**

WHEREAS, Licensor owns certain patent rights and valuable know-how relating to the Compound (as defined below);

WHEREAS, Licensor has full and exclusive rights to grant the License under Licensor Patent Rights and Licensor Know-How (as such terms are defined herein), and desires to grant to Licensee an exclusive license to these rights under the terms and conditions set forth herein; and

WHEREAS, Licensee desires to obtain a license under the Licensor Patent Rights and Licensor Know-How in accordance with the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the mutual covenants and agreements of the parties herein contained, the parties hereto, intending to be legally bound, do hereby agree as follows.

**ARTICLE I. Definitions**

Unless specifically provided otherwise, the terms in this Agreement with initial letters capitalized, whether used in the singular or plural, shall have the meaning set forth below, or the meaning as designated in places throughout this Agreement:

1.1 "Act" shall mean the United States Food, Drug and Cosmetic Act, as amended, and the regulations thereunder.

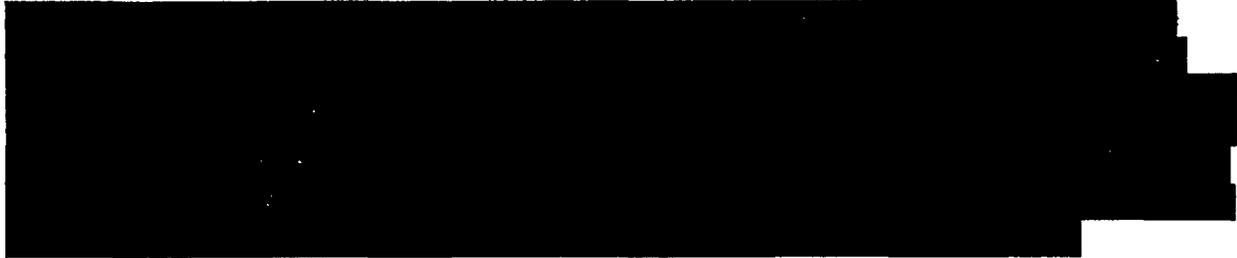
1.2 "Active Compound" shall have the meaning set forth in Section 7.1.

1.3 "Affiliate" shall mean, with respect to any specified Person, any other Person that directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with, such specified Person. "Control" (including the terms "controlled by" and "under common control with"), with respect to the relationship between or among two or more Persons, shall mean the possession, directly or indirectly or as trustee or executor, of the power to direct or cause the direction of the affairs or management of a Person, whether through the ownership of voting securities, as trustee or executor, by contract or otherwise, including, without limitation, the ownership, directly or indirectly, of securities having the power to elect a majority of directors or similar body governing the affairs of such Person.

1.4 "Agency" shall mean any governmental regulatory authority responsible for granting health or pricing approvals, registrations, import permits or other approvals required before Licensed Products may be tested or marketed in any country.

1.5 "Back-Up Compound" shall have the meaning set forth in Section 6.1.

1.6 "Back-Up Compound Intermediate" shall mean



1.7 "Bulk API" shall mean the Compound in bulk form.

1.8 "Bulk Product" shall mean any Licensed Product which is in finished dosage form and is ready to be administered, but excluding any packaging, labeling and any necessary inserts.

1.9 "Calendar Quarter" shall mean the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31.

1.10 "Calendar Year" shall mean each successive period of twelve (12) months commencing on January 1 and ending on December 31.

1.11 "Change of Control" shall mean any of the following events: (i) a Competitor is or becomes the "beneficial owner" (as defined in Rules 13d-3 and 13d-5 of the Securities Exchange Act of 1934, as amended, except that a Person shall be deemed to have "beneficial ownership" of all shares that any such Person has the right to acquire, whether such right is exercisable immediately or only after the passage of time), directly or indirectly, of 30% or more of the total voting power of all classes of capital stock then outstanding of any Licensor Entity normally entitled to vote in elections of directors; (ii) any Licensor Entity consolidates with or merges into another corporation or entity, or any corporation or entity consolidates with or merges into any Licensor Entity, in either event pursuant to a transaction in which 30% or more of the total voting power of all classes of capital stock then outstanding of such Licensor Entity normally entitled to vote in elections of directors is acquired by a Competitor; (iii) any Licensor Entity conveys, transfers or leases all or substantially all of its assets to a Competitor; or (iv) a number of members of the board of directors (or equivalent governing body) of any Licensor Entity constituting 30% or more of the total number of directors of such Licensor Entity shall have been elected to the board of directors of such Licensor Entity pursuant to the nomination by a Competitor (whether pursuant to contract or otherwise).

1.12 "Co-Detail Country" shall have the meaning set forth in Section 8.2.

1.13 "Co-Detailing Agreement" shall have the meaning set forth in Section 8.2.

1.14 "Competitor" shall mean any Person which, together with its Affiliates, had, as of the date of determination, consolidated sales of ethical pharmaceutical products in the

most recently completed fiscal year of such Person prior to such date of at least One Billion Dollars.

1.15 "Composition of Matter Claim"

[REDACTED]

1.16 "Compound" shall mean

[REDACTED]

1.17 "Co-Promotion Agreement" shall have the meaning set forth in Section 8.1.

1.18 "Co-Promotion Country" shall have the meaning set forth in Section 8.1.

1.19 "Dosage Unit" shall have the meaning set forth in Section 5.3.

1.20 "Effective Date" shall have the meaning set forth in Section 12.4.

1.21 "FDA" shall mean the United States Food and Drug Administration and any successor agency thereto.

1.22 "Field" shall mean the diagnosis, prevention and treatment of diseases in humans, including without limitation, the treatment of Type 2 diabetes (NIDDM), diabetic dyslipidemia, hypertension and obesity.

1.23 "First Commercial Sale" shall mean, with respect to a Licensed Product, the first sale for use or consumption by the public of such Licensed Product in a country after all required approvals, including any required marketing and pricing approvals, have been granted by the governing Agency of such country.

1.24 "FTC" shall mean the Federal Trade Commission.

1.25 "HSR Act" shall mean the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and the rules promulgated thereunder.

1.26 "IND" shall mean an Investigational New Drug application in the U.S. or the corresponding application for the investigation of Licensed Products in any other country or group of countries, as defined in the applicable laws and regulations and filed with the Agency of a given country or group of countries.

1.27 "Information Package" shall have the meaning set forth in Section 7.1.

1.28 "Initial Payment" shall have the meaning set forth in Section 3.1.

1.29 "Launch" shall mean, with respect to any country in the Territory, the first date of commercial sale of a Licensed Product to unaffiliated third parties in such country in such quantities as are customarily required for the general introduction of a pharmaceutical product in such country.

1.30 "Licensed Product" shall mean any product incorporating or comprising the Compound, in finished dosage pharmaceutical form (i) the manufacture, use, sale or offer for sale of which would, but for the license granted hereunder, constitute infringement of a Valid Claim of Licensor Patent Rights, or (ii) which incorporates or embodies Licensor Know-How.

1.31 "License" shall have the meaning set forth in Section 2.1.

1.32 "Licensee" shall have the meaning set forth in the Preamble.

1.33 "Licensee Technical Information and Patent Rights" shall mean all information and data, technical information, improvements, inventions, discoveries, trade secrets, specifications, instructions, processes, formulae, materials, expertise and other technology, whether or not patentable, made, developed, conceived or reduced to practice solely by Licensee, its Affiliates or others acting on its or their behalf in connection with any research, development or other work performed after the date hereof relating to Licensed Products and/or the Compound, or the development, manufacture or use of the same, and any patents, patent applications or other intellectual property rights based on the foregoing.

1.34 "Licensor" shall have the meaning set forth in the Preamble.

1.35 “Licensor Entity” shall have the meaning set forth in the Preamble.

1.36 “Licensor Know-How” shall mean all information and data, technical information, trade secrets, specifications, instructions, processes, formulae, materials, expertise and information relating to the Licensed Products and/or the Compound, processes for their manufacture, formulations containing them, compositions incorporating or comprising them, their manufacture, development, registration, use or marketing or methods of assaying or testing them, known to Licensor or an Affiliate thereof as of the date hereof or developed or acquired (other than from Licensee or any Affiliate thereof) by Licensor or an Affiliate thereof at any time during the term of this Agreement. Licensor Know-How shall also include Licensor’s or its Affiliates’ interest in any unpatented inventions jointly owned with Licensee to the extent provided in the last sentence of Section 11.1(c) hereof. Notwithstanding the foregoing, Licensor Know-How shall not include (i) know-how of any Person that becomes an Affiliate of Licensor after the date hereof to the extent that on the date such Person becomes an Affiliate of Licensor, such Person is subject to a pre-existing contractual obligation which would either (x) prevent such know-how from being included in Licensor Know-How or (y) if such know-how were included in Licensor Know-How, would have a material adverse effect upon such Person or Licensor and (ii) know-how which is licensed to Licensor or any Affiliate of Licensor after the date hereof to the extent that on the effective date of such license such know-how is subject to a pre-existing contractual obligation which would either (x) prevent such know-how from being included in Licensor Know-How or (y) if such know-how were included in Licensor Know-How, would have a material adverse effect upon Licensor or such Affiliate.

Such Licensor Know-How shall include, without limitation:

(i) all biological, chemical, pharmacological, biochemical, toxicological, pharmaceutical, physical and analytical, safety, quality control, manufacturing, preclinical and clinical data, instructions, processes, formulae, expertise and information, relevant to the manufacture, use or sale of and/or which may be useful in studying, testing, development, production, formulation or use of Licensed Products and/or the Compound, or intermediates for the synthesis thereof (it being acknowledged and agreed that, while the License granted hereunder includes the license of all such intermediates, such License of intermediates shall only be exclusive to the extent such intermediates are included within the definition of Compound); and

(ii) copies of any health registration documents and amendments or supplements thereto filed with respect to Licensed Products and/or the Compound with any Agency by or on behalf of Licensor or any Affiliate thereof and all correspondence to and from such Agency with respect to Licensed Products and/or the Compound.

1.37 “Licensor Patent Rights” shall mean all patent rights owned or controlled by or licensed to Licensor or an Affiliate thereof, as of the date hereof or at any time during the term of this Agreement, and claiming (i) Licensed Products and/or the Compound, (ii) formulations containing them, (iii) compositions incorporating or comprising them, (iv) their development, (v) processes for their manufacture, (vi) use of the Licensed Products and/or the Compound, (vii) methods of assaying or testing intermediates for making, using or developing the Compound or Licensed Products or assaying or testing the Licensed Products and/or the Compound or (viii) intermediates for the synthesis of the Licensed Products and/or the Compound (including the use and manufacture of such intermediates) (it being acknowledged and agreed that, while the License granted hereunder includes the license of all such

intermediates, such License of intermediates shall only be exclusive to the extent such intermediates are included within the definition of Compound). Licensor Patent Rights shall include all patents and patent applications, all divisionals, continuations, substitutions, continuations-in-part, re-examinations, reissues, additions, renewals, extensions, registrations, and supplemental protection or complementary certificates and the like of the foregoing. Licensor Patent Rights existing as of the date hereof are set forth on Exhibit B and Licensor Patent Rights obtained or acquired by, or licensed to Licensor or an Affiliate thereof at any time during the term of this Agreement shall automatically fall within the scope of this Agreement and shall be added from time to time to said Exhibit. Licensor Patent Rights shall also include Licensor's, or any Affiliate's, share of any patent rights jointly owned by Licensor or such Affiliate of Licensor, in the event that Licensor or such Affiliate does not have the right to license all joint owners' shares under such patent rights, and Licensor Patent Rights shall include Licensor's and any Affiliate's interest in any patent rights with respect to inventions jointly owned with Licensee to the extent provided in the last sentence of Section 11.1(c) hereof. Notwithstanding the foregoing, Licensor Patent Rights shall not include (i) patent rights of any Person that becomes an Affiliate of Licensor after the date hereof to the extent that on the date such Person becomes an Affiliate of Licensor, such Person is subject to a pre-existing contractual obligation which would either (x) prevent such patent rights from being included in Licensor Patent Rights or (y) if such patent rights were included in Licensor Patent Rights, would have a material adverse effect upon such Person or Licensor and (ii) patent rights which are licensed to Licensor or any Affiliate of Licensor after the date hereof to the extent that on the effective date of such license such patent rights are subject to a pre-existing contractual obligation which would either (x) prevent such patent rights from being included in Licensor Patent Rights or (y) if such patent rights were included in Licensor Patent Rights, would have a material adverse effect upon Licensor or such Affiliate.

1.38 "Manufacturing Agreement" shall have the meaning set forth in Section 5.3.

1.39 "Market Exclusivity" shall mean

[REDACTED]

1.40 "Method of Use Claim" shall mean

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

1.41 “Milestone Payments” shall have the meaning set forth in Section 3.2.

1.42 “NDA” shall mean a New Drug Application in the U.S. or the corresponding application for authorization for marketing of a Licensed Product in any other country or group of countries, as defined in the applicable laws and regulations and filed with the Agency of a given country or group of countries.

1.43 “Net Sales” shall mean the gross invoice price of a Licensed Product sold by Licensee, its Affiliates, designees or sublicensees to independent, third-party customers in bona fide, arm’s-length transactions, after deducting, if not previously deducted in the amount invoiced or received:

- (i) quantity and/or cash discounts actually allowed or taken;
- (ii) freight, postage and shipping insurance allocated in accordance with Licensee’s standard allocation procedure, or, in the absence of such allocation, a fixed deduction of two percent (2%) of Net Sales as defined herein, however, before deduction for freight, postage and shipping insurance.
- (iii) customs duties and taxes, if any, directly related to the sale;
- (iv) amounts repaid or credited by reason of rejections, return of goods, retroactive price reductions specifically identifiable as relating to such Licensed Product;
- (v) amounts incurred resulting from governmental (or an agency thereof) mandated rebate programs;
- (vi) third party rebates and chargebacks related to the sale of such Licensed Product to the extent actually allowed; and
- (vii) as agreed by the parties in writing, any other specifically identifiable amounts included in gross sales of such Licensed Product that were or ultimately will be credited and that are substantially similar to those listed herein above.

The amount of Net Sales for any period shall be determined on the basis of sales recorded in such period in accordance with Licensee’s standard accounting methods.

In the event that a Licensed Product is sold as a component of a multi-component product or service or combination product, and is not separately invoiced, then Net Sales shall be based on that portion of the total invoice price for the multi-component product or service or combination product which is fairly allocable to the Licensed Product in comparison with the other components. Such portion shall be set in good faith negotiations between the parties.

1.44 "Novartis" shall have the meaning set forth in the Preamble.

1.45 "Person" shall mean any individual, partnership, firm, corporation, association, trust, unincorporated organization or other entity, as well as any syndicate or group that would be deemed to be a person under Section 13(d)(3) of the Securities Exchange Act of 1934, as amended.

1.46 "Primary Compound" shall have the meaning set forth in the definition of Compound.

1.47 "Primary Compound Intermediate" shall mean

[REDACTED]

1.48 "Primary Trademark" shall mean any trademark used by Licensee to market the Licensed Products in the United States, the European Union or Japan.

1.49 "Product Committee" shall have the meaning set forth in Section 10.1.

1.50 "Proprietary Information" shall mean and include, without limitation, information and data of one party or its Affiliates provided to the other party or its Affiliates prior to or after the date hereof in connection with this Agreement, including Licensor Know-How, Licensee Technical Information and Patent Rights and Licensor Patent Rights and all other scientific, clinical, regulatory, marketing, financial, and commercial information or data, whether communicated in writing or orally or by other means.

1.51 "Proposed Transaction" shall have the meaning set forth in Section 7.1.

1.52 "Reddy" shall have the meaning set forth in the Preamble.

1.53 "Substitute" of a Licensed Product shall mean

[REDACTED]

1.54 "Territory" shall mean the world.

1.55 "Third Party License" shall have the meaning set forth in Section 21.5(a).

1.56 "USBC" shall have the meaning set forth in Section 21.3.

1.57 "Valid Claim" shall mean a claim of an issued and unexpired patent which has not been revoked or held invalid or unenforceable by a decision of a patent office, court or other government agency of competent jurisdiction, unappealable or unappealed within the time allowed for appeal.

## ARTICLE II. Scope of License

### 2.1 Grant of License.

(a) Subject to the terms of this Agreement, Licensor hereby grants to Licensee an exclusive license, with the right to sublicense, in the Territory, under the Licensor Patent Rights and Licensor Know-How, to import, export, make, have made, develop, have developed, use, promote, distribute, market, sell and offer to sell, Licensed Products and/or the Compound in the Field, whether through itself, its Affiliates, its sublicensees and/or its designees (hereinafter the "License"). For the avoidance of doubt, the parties expressly acknowledge that Licensor Patent Rights and Licensor Know-How have been or may be licensed to third parties or used by Licensor to develop or commercialize compounds or products which are not the Compound or Licensed Products.

(b) Licensee agrees that it will not, whether through itself, its Affiliates, sublicensees and/or its designees, use the Licensor Patent Rights or Licensor Know-How for any purpose other than to import, export, make, have made, develop, have developed, use, promote, distribute, market, sell and offer to sell, Licensed Products and/or the Compound in the Field, provided, however, that this restriction shall not apply to Licensor Patent Rights or Licensor Know-How which:

(i) is, at the time such use first commences (as such commencement is evidenced by prior written documents and, at Licensee's option, oral evidence), part of the public domain through no action of Licensee or its Affiliates;

(ii) was already known to Licensee or its Affiliates as evidenced by (A) prior written documents in its possession which were not furnished, directly or indirectly, by Licensor, a licensee of Licensor or their Affiliates and (B) at Licensee's option, oral evidence;

(iii) is disclosed to Licensee or its Affiliates, as evidenced by prior written documents and, at Licensee's option, oral evidence, by a third party who is both not a licensee of Licensor and who is not in breach or default of any confidentiality obligation to Licensor or its Affiliates; or

(iv) is independently discovered or developed, as evidenced by prior written documents and, at Licensee's option, oral evidence, by Licensee or its Affiliates without reference to Licensor Know-How provided, directly or indirectly, by Licensor, a licensee of Licensor or their Affiliates.

Notwithstanding the foregoing, it is further understood and agreed that this Section 2.1(b) shall not prohibit Licensee, its Affiliates, sublicensees and/or its designees from using Licensor Patent Rights or Licensor Know-How for any purpose permitted by a separate sublicense granted to Licensee or any Affiliate thereof by a licensee of Licensor, provided that said licensee of Licensor is entitled by its license from Licensor to sublicense for said purpose.

### ARTICLE III. Consideration

3.1 Certain Payments. As consideration for past research and development performed by Licensor regarding the Compound, Licensee shall pay to such Licensor Entity as is designated in writing by Dr. Reddy's Laboratories Limited the total sum of five million dollars (\$5,000,000) (the "Initial Payment") within thirty (30) days after the Effective Date.

3.2 Milestone Payments. In consideration of the granting of the License and other rights of Licensee hereunder, Licensee shall make lump-sum milestone payments to Licensor upon the occurrence of certain milestone events with respect to Licensed Products, as set forth in Table I herein below (the "Milestone Payments").

[REDACTED]	
[REDACTED]	[REDACTED]

(a) Licensee shall notify Licensor in writing within thirty (30) days after the occurrence of each milestone event. Licensor shall submit an invoice to Licensee substantially in the form of Exhibit C hereto with respect to the Milestone Payment therefor. Licensee shall make the applicable Milestone Payment within thirty (30) days after receipt of the invoice.

(b) Each Milestone Payment shall only be payable if this Agreement is in force at the time the corresponding milestone event occurs. For the avoidance of doubt, each Milestone Payment shall be payable even if this Agreement is terminated during either of the thirty (30)-day periods set forth in paragraph (a) above.

(c) None of the Milestone Payments shall be payable more than once.

3.3 Royalty Payments. In consideration of the granting of the License and other rights of Licensee hereunder, Licensee shall pay to such Licensor Entity as is designated in writing by Dr. Reddy's Laboratories Limited royalties at the royalty rates set forth below on aggregate Net Sales of each Licensed Product by Licensee and its Affiliates, sublicensees and designees in the Territory as follows:

[Redacted]

[Redacted]	[Redacted]
[Redacted]	[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted text block]

[Redacted text block]

[Redacted text block]

[Redacted text block]

[REDACTED]

(iii) [REDACTED]

(d) Patent Term Extension. For the avoidance of doubt, the parties acknowledge and agree for purposes hereof that the life of any Licensor Patent Rights in any country shall include such additional period (if any) for which the effective period of patent protection provided by such Licensor Patent Rights is extended by any patent term extension, prolongation or equivalent measure (such as a Supplemental Protection Certificate) in such country.

(e) Certain Exclusions; Application of Royalty Once. Sales between Licensee, its Affiliates, sublicensees and designees shall not be subject to royalties hereunder. Royalties shall be calculated on Net Sales of Licensee, its Affiliates, sublicensees and designees to independent, third party customers. Royalties shall be payable only once with respect to the same unit of Licensed Product. For the avoidance of doubt, the parties further acknowledge and agree that the same unit of Licensed Product shall be subject to royalty only once under Section 3.3(a), 3.3(b)(i)(A), 3.3(b)(i)(B), 3.3(b)(ii)(A), 3.3(b)(ii)(B), 3.3(c)(i), 3.3(c)(ii) or 3.3(c)(iii), as applicable, and the royalties payable under such Sections are not, as to any such unit, cumulative. In the event that more than one of such Sections would apply to the sale of a unit of Licensed Product, then, if such Sections would provide for different royalty rates, only the Section which provides for the higher royalty rate will apply. At such time as the Section which provides for a higher royalty no longer applies, then royalties, if any, payable under any other Section which still applies will be payable at the rate and for the duration specified in such other Section.

#### 3.4 Third Party Obligation.

(a) In the event Licensee is required to obtain a license from any unaffiliated third party or parties under any patent or other intellectual property right of such third party or parties and is obligated to pay a royalty to such third party or is liable for damages or other payments to such third party because Licensee's exercise of the license rights granted in Section 2.1 of this Agreement or Licensee's use of the Licensor Know-How provided to Licensee pursuant to Article VI or IX of this Agreement infringes or is alleged to infringe such patent or other intellectual property rights of such third party, then Licensee and Licensor shall [REDACTED] of the amount of such royalties, damages and other payments; *provided*, that Licensor's payment obligations under this Section 3.4(a) in any Calendar Year shall not exceed [REDACTED] of the aggregate royalties payable to Licensor in such Calendar Year (the "Agreed Limit"). For purposes of this Section 3.4(a), any damages or other payments which are not based on a percentage of Net Sales shall be amortized (including interest at the rate publicly announced from time to time by Citibank N.A. as its prime rate) over the remaining term of the Licensor Patent Rights covering the Compound and/or the Licensed Products in the United States for purposes of applying the Agreed Limit, following which, subject to the following sentence, Licensor shall not have any further liability for such damages or other payments. Notwithstanding the foregoing, [REDACTED] of such royalties, damages and/or other payments shall be borne by Licensor under circumstances in which Licensor has breached its representation and

warranty set forth in Section 12.2(a). Licensor shall not have any further liability to Licensee under this Agreement on account of the facts, events or occurrences with respect to such third party infringement claim which gives rise to such royalties, damages and/or other payments.

(b) In the event Licensee is required to obtain a license from any unaffiliated third party or parties under any patent or other intellectual property right of such third party or parties and is obligated to pay a royalty to such third party or is liable for damages or other payments to such third party because the use of the Licensee Technical Information and Patent Rights in connection with the development, commercialization, manufacture, use, sale or offer for sale of the Compound and/or Licensed Products infringes or is alleged to infringe such patent or other intellectual property rights of such third party, [REDACTED]

[REDACTED] For purposes of this Section 3.4(b), [REDACTED]

(c) Notwithstanding the foregoing, [REDACTED]

All such payments shall be made promptly by Licensor. Licensor will not be entitled to add such royalties due to third parties to the royalty rates set forth in Section 3.3.

(d) In connection with obtaining a license from any unaffiliated third party or parties as contemplated by subsection (a) or (b) above, Licensee shall in good faith seek to obtain the right to grant a sublicense under such license to Licensor for use of the licensed technology following a termination and reversion, in whole or in part, of this Agreement in the event that Licensor is entitled to and elects to receive such a sublicense pursuant to Section 21.5(a)(i) or (ii).

### 3.5 Reports; Payment of Royalty.

(a) Quarterly Royalty Obligations. Within sixty (60) days after the close of each Calendar Quarter during the term of this Agreement following the First Commercial Sale of a Licensed Product, Licensee shall furnish to Licensor a written report showing the Net Sales by Licensee, its Affiliates, sublicensees and its designees in each country during such Calendar Quarter and the royalties payable hereunder. Such report shall be accompanied by payment of the royalties for such Calendar Quarter. On a yearly basis, such report shall include Net Sales, gross sales and the following deductions from gross sales: (A) sales tax, (B) special selling expenses (freight, insurance), (C) value of goods estimated to be returned, and (D) credits, rebates and discounts. Licensee shall keep complete and accurate records in sufficient detail to enable the royalties payable hereunder to be determined. Licensee will provide to Licensor any additional non-confidential information reasonably requested by Licensor to determine Net Sales and royalties payable hereunder.

(b) Exchange Rates. In the case of Net Sales in currencies other than United States dollars, such Net Sales shall first be calculated in the foreign currency, then converted to Swiss Francs, on the basis of Novartis' account of sales which represents the conversion of all local currency sales year-to-date to Swiss Francs at a sales weighted average exchange rate for

the year-to-date in which the sales are recorded, and then converted to United States dollars, calculated on a monthly basis (as opposed to daily) using Novartis' monthly average exchange rates which it applies to all of its products. Novartis' monthly average exchange rates are currently calculated using the average of Reuters Daily Rates between 09:00 a.m. and 10:00 a.m. on the one hand and the official Frankfurt fixing of the German National Bank rates in the afternoon on the other hand.

(c) Calculation of Royalty Payments. All royalty payments due under this Agreement shall be paid in United States dollars and shall be calculated on the basis of Licensee's quarterly standard account of sales which represents the conversion of all local currency sales for a Calendar Quarter into Swiss francs and conversion of Swiss francs into United States Dollars as provided in paragraph (b) above.

(d) Taxes. All taxes levied on payment of royalties to Licensor under this Agreement shall be paid by Licensor. If applicable laws or regulations require withholding taxes by Licensee, Licensee shall deduct the taxes from royalty payments due to Licensor and shall pay such taxes to the appropriate government tax authority. The foregoing shall not limit the right of Licensor to seek applicable exemptions from the payment of such taxes or such withholding obligations, provided that such exemptions do not impose any liability or obligation on Licensee or any of its Affiliates.

### 3.6 Audits.

(a) Upon the written request of Licensor and not more than once in each Calendar Year, Licensee shall permit an independent certified public accounting firm of nationally recognized standing mutually acceptable to Licensor and Licensee, to have access during normal business hours to such records of Licensee as such accounting firm deems reasonably necessary to determine whether there has been an overpayment or underpayment of royalties pursuant to this Agreement for any Calendar Year ending not more than thirty-six (36) months prior to the date of such request. Licensee will provide such assistance to the accounting firm as is reasonably requested by such accounting firm in connection with the audit. Such accounting firm will be required to execute a confidentiality agreement with Licensee in the form attached hereto as Exhibit D (the "Confidentiality Agreement") prior to commencing any such audit. Such accounting firm shall report only on matters which in its reasonable judgment bear on whether the royalties paid by Licensee were determined and accurately calculated in accordance with this Agreement. These rights with respect to any Calendar Year shall terminate three (3) years after the end of such Calendar Year.

(b) If after consultation with both parties, such accounting firm concludes that there was an overpayment or underpayment, Licensee shall pay the additional royalties due to Licensor or Licensor shall return to Licensee any excess royalties paid, as the case may be, within thirty (30) days after the accounting firm's written report is delivered to both Licensor and Licensee, plus interest on such royalties from the date originally payable or from the date paid, in the case of any overpayment, at the rate publicly announced from time to time by Citibank N.A. as its prime rate.

Neither Licensor nor Licensee (nor their Affiliates) shall consult with such accounting firm in person or orally unless the other party is given reasonable

advance notice of and the opportunity to participate in such consultation; all communications made in writing shall be copied to the other party who may respond.

(c) The decision of the accounting firm shall be final and binding upon the parties, and not subject to further arbitration pursuant to Article XXVIII or otherwise. Should either party fail to comply with the decision, the cost of any proceeding brought to enforce same shall be at the sole expense of the non-complying party, who shall reimburse the complying party for its reasonable attorneys' fees and reasonable disbursements. Interest on said award shall be as provided in Section 3.6(b) above.

(d) Licensee shall require each of its sublicensees, agents and designees which are authorized to sell Licensed Products pursuant to this Agreement to provide sales reports to Licensee, to keep and maintain records of sales and to grant access to such records by Licensor's independent accountant to the same extent required of Licensee under this Agreement.

(e) Licensor shall treat all financial information subject to review under this Section 3.6 and any corresponding provisions contained in any said sublicense in accordance with the confidentiality provisions of this Agreement, and shall cause its accounting firm to enter into the Confidentiality Agreement with Licensee.

#### **ARTICLE IV. Development and Commercialization**

4.1 Development and Commercialization by Licensee. Licensee shall have the exclusive license, with the right to sublicense, hereunder to develop, have developed, promote, distribute, market, sell and offer to sell the Licensed Products and/or the Compound whether through itself, its Affiliates and/or its designees. Licensee shall use reasonable commercial efforts, consistent with the usual practice followed by Licensee in pursuing the development, commercialization and marketing of its other similar pharmaceutical products, to develop, commercialize and market Licensed Products. Subject to the foregoing, Licensee obligations under this Section may be suspended, in Licensee's sole discretion, for so long as there exists any material safety (including toxicity), efficacy, regulatory, medical, or legal issue. Subject to compliance with the foregoing, the development, commercialization and marketing of Licensed Products and the Compound shall be in Licensee's sole discretion.

#### 4.2 Licensee Abandonment.

(a) If Licensee determines, in its sole discretion, that it no longer intends to pursue the development, commercialization and marketing activities with respect to the Compound and Licensed Products, in their entirety, then Licensee shall provide written notice to Licensor of such intention, and, upon receipt of such notice, Licensor shall have the right to terminate this Agreement in accordance with Section 21.2.

(b) If all development, commercialization and marketing activities with respect to the Compound and Licensed Products have ceased for a [REDACTED] period due to the sole discretion of Licensee, and not due to a safety (including toxicity), efficacy, regulatory, manufacturing, medical or legal issue, or technical or commercial requirement, then, Licensor shall have the right to terminate this Agreement pursuant to Section 21.2, *provided*, that prior to such termination, at the request of either Licensor or Licensee, representatives of Licensee and Licensor will meet to discuss the status of Licensee's efforts with respect to the Compound and Licensed Products for a period of up to [REDACTED]. For the avoidance of doubt, Licensee's

cessation of all such development, commercialization and marketing activities with respect to the Compound and Licensed Products for such a nine-month period as aforesaid may not be cured by Licensee during such [REDACTED] discussion period.

4.3 Ownership of Regulatory Filings. All regulatory filings submitted in connection with obtaining Agency approval to test or market a Licensed Product, including, without limitation, all IND and NDA submissions, shall be owned by, and submitted by and in the name of, Licensee, its Affiliates or its designees; *provided, however*, that Licensor shall hold in its name such Drug Master Files and other regulatory filings as are required by law to be in Licensor's name to allow Licensor to manufacture Bulk API and Bulk Products for Licensee pursuant hereto.

## **ARTICLE V. Manufacture and Supply**

5.1 Manufacture by Novartis. Novartis shall have the exclusive license, with the right to sublicense, hereunder to make and have made the Licensed Products and the Compound; *provided, however*, that Novartis shall grant to Reddy a limited right to manufacture Licensed Products and the Compound for Novartis as provided in this Article V.

### 5.2 Manufacturing Know-How and Assistance.

(a) Reddy shall fully cooperate with and provide assistance to Novartis or its designee, through documentation, consultation, training and face-to-face meetings, to enable Novartis or its designee in an efficient and timely manner to proceed with development and manufacturing of the Compound and the Licensed Products, obtain all appropriate regulatory approvals for manufacturing (including qualification by the FDA or other applicable Agency of manufacturing sites), and thereafter conduct such manufacturing.

(b) Reddy shall make appropriate personnel available to assist Novartis or its designee at any time and from time to time as reasonably requested by Novartis, and shall provide Novartis' or its designee's appropriate personnel with access to the personnel and manufacturing and other operations of Reddy for such periods of time and in such manner as is reasonable in order to familiarize Novartis' or its designee's personnel with Licensor Know-How relating to the development and manufacture of the Compound and the Licensed Products and the application of the same. At Novartis' request, such assistance shall also be furnished at Novartis' or a third party manufacturer's facilities.

5.3 Limited Manufacture by Reddy. The following terms and conditions shall apply to the manufacture of Bulk API and Bulk Products. Novartis and Reddy shall enter into an agreement covering such terms and conditions related to the manufacture and supply of Bulk API and Bulk Products as are specifically provided in this Section 5.3 and covering other customary terms and conditions (the "Manufacturing Agreement"). The parties shall negotiate in good faith with a view to entering into the Manufacturing Agreement within 180 days of the Effective Date, or such other date as is mutually agreed by the parties. If the parties are unable to enter into the Manufacturing Agreement on or prior to such date, then the parties shall submit to arbitration in accordance with Article XXVIII. The parties agree that the arbitrators shall have the right to resolve any disputes relating to the Manufacturing Agreement and to supply any missing terms which are required for the performance of the Manufacturing Agreement.

(a) Supply for Clinical Studies. Novartis or its designee shall have the right to manufacture [REDACTED] of the Bulk Products required by Novartis for pre-Launch non-commercial use (including for use in clinical and animal toxicity studies and for NDA validation batches). Reddy shall manufacture and supply to Novartis, and Novartis shall purchase, [REDACTED] of Novartis' pre-Launch non-commercial requirements of Bulk API (including, without limitation, for the manufacture of Bulk Products for clinical and animal toxicity studies and for NDA validation batches). For purposes of Section 5.3 of this Agreement, "Novartis' requirements" or "Novartis' worldwide requirements," of Bulk API or Bulk Products, as the case may be, shall include the requirements of Novartis, its Affiliates, sublicensees and designees and shall not include the requirements of Reddy, its Affiliates, licensees or designees for any country with respect to which this Agreement has terminated and the applicable rights hereunder have reverted to Licensor in accordance with Article XXI.

(b) Supply for Commercial Use:

(i) Launch Quantities. Novartis or its designee shall have the right to manufacture [REDACTED] of Novartis' requirements of Bulk Products for Launch in any country. Novartis or its designee shall have the right to manufacture [REDACTED] of Novartis' requirements of Bulk API for the manufacture of such Launch quantities of Bulk Products. Reddy shall manufacture and supply to Novartis, and Novartis shall purchase, the other [REDACTED] of Novartis' requirements of Bulk API for the manufacture of such Launch quantities of Bulk Products.

(ii) Post-Launch Quantities. Novartis or its designee shall have the right to manufacture [REDACTED] of Novartis' worldwide requirements of Bulk Products (such worldwide requirements to include Launch quantities of Bulk Products manufactured by Novartis or its designee or, if requested by Novartis pursuant to Section 5.3(e)(ii), by Reddy). Reddy shall manufacture and supply to Novartis, and Novartis shall purchase, the other [REDACTED] of Novartis' worldwide requirements of Bulk Products. To the extent that Novartis purchases less than [REDACTED] of its worldwide requirements of Bulk Products from Reddy in any year as a result of a Launch in any country, the deficiency will be made up within [REDACTED] following the year of such Launch. Novartis or its designee shall have the right to manufacture [REDACTED] of Novartis' and Reddy's aggregate requirements of Bulk API for the manufacture of Bulk Products therefrom. Reddy shall manufacture and supply the other [REDACTED] of Novartis' and Reddy's aggregate requirements of Bulk API for the manufacture of Bulk Product therefrom.

(c) Supply Prices. The prices payable by Novartis to Reddy for supply of Bulk API and Bulk Products shall be as follows.

(i) Prior to Novartis' Launch of any Licensed Product in the Territory, the price for Bulk API to be used by Novartis or its designee in manufacturing Bulk Product for administration in clinical or animal toxicity studies, NDA validation batches or other non-commercial quantities shall be equal to Reddy's [REDACTED]. After Novartis' first Launch of any Licensed Product in the Territory, the price for Bulk API to be used by Novartis or its

designee in manufacturing Bulk Product for administration in clinical or animal toxicity studies, NDA validation batches or other non-commercial quantities shall be that set forth in Section 5.3(c)(ii) below. The price for Bulk Product, if any, supplied by Reddy to Novartis, at the request of Novartis, to be used by Novartis or its designee for administration in clinical or animal toxicity studies, NDA validation batches or other non-commercial quantities shall be equal to Reddy's

[REDACTED]

(ii) The price for Bulk API to be used by Novartis or its designee in manufacturing commercial supplies of Bulk Product shall be equal to Reddy's

[REDACTED]

(iii) Except as provided in Section 5.3(c)(i) above with respect to Bulk Products supplied by Reddy to Novartis for administration in clinical and animal toxicity studies, NDA validation batches or other non-commercial quantities, the prices for Bulk Products supplied by Reddy to Novartis shall be as set forth below.

[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]

[REDACTED]

[REDACTED]

(iv)

[REDACTED]

(d) Control Over and Responsibility For Certain Aspects of Manufacturing.

(i) Novartis shall have sole control over and shall direct all aspects of the manufacturing and supply of Compound and Licensed Products pursuant to this Agreement, whether such Compound and Licensed Products are manufactured by Novartis or Reddy. Without limiting the foregoing, Novartis shall be entitled to have personnel on-site at any facility utilized by Reddy to manufacture Compound and/or Licensed Products, which personnel shall have authority to supervise and direct all operations of such facility related to the manufacture or supply of Compound and/or Licensed Product, as the case may be.

(ii) All packaging, labeling and any necessary inserts for the Licensed Products shall be provided by Novartis.

(iii) Reddy shall be responsible for chemical, analytical and process development of the Compound at its sole cost and expense, subject to input, oversight and control by Novartis. Novartis shall select, in its sole discretion, the salts, polymorphs and physical properties of the Compound to be pursued and shall determine the specifications of the Compound selected. Novartis shall be responsible for all pharmaceutical development of the Compound into Licensed Products, and Novartis shall determine in its sole discretion all specifications for the Licensed Products, including but not limited to, Dosage Unit forms and dosage strengths.

(iv) Novartis shall provide Reddy with access to Licensee Technical Information and Patent Rights necessary or useful for, and for the sole purpose of allowing Reddy to use the same in, Reddy's manufacture under the Manufacturing Agreement of Bulk API and Bulk Products in conformance with Novartis' specifications. At the reasonable request of Reddy, Novartis shall make

appropriate personnel available to assist Reddy at any time and from time to time as reasonably requested by Reddy, and shall provide Reddy's appropriate personnel with access to the personnel and manufacturing operations of Novartis for such periods of time and in such manner as is reasonable in order to familiarize Reddy's personnel with Licensee Technical Information and Patent Rights relating to the manufacture of Bulk API and Bulk Products and the application of the same, in each case, for the sole purpose of allowing Reddy to use Licensee Technical Information and Patent Rights in Reddy's manufacture under the Manufacturing Agreement of Bulk API and Bulk Products in conformance with Novartis' specifications. At Reddy's reasonable request, such assistance shall also be furnished at Reddy's facilities. If Reddy arranges for a third party site in accordance with Section 5.3(e)(iv) below, then at Reddy's reasonable request, such access to Licensee Technical Information and Patent Rights and other assistance from Novartis shall be provided by Novartis to such third party or at such third party site, in the manner aforesaid for the sole purpose of allowing the third party to manufacture at such third party site Bulk API or Bulk Products, as the case may be, as provided in Section 5.3(e)(iv), in accordance with Novartis' specifications.

(v) After the applicable Reddy manufacturing sites are able to qualify, Novartis shall take such steps as are required by FDA or Agency requirements to be performed by Novartis to qualify Reddy's primary Bulk API manufacturing site and primary Bulk Products manufacturing site with the FDA or other applicable Agency on or prior to such time as Reddy is required to perform its manufacturing obligations under the Manufacturing Agreement, or such earlier time as reasonably requested by Reddy. In addition, if Novartis requests that Reddy arrange for a back-up Bulk API and/or a back-up Bulk Products manufacturing site, or if Reddy chooses at its option to arrange for same, as provided in Section 5.3(e)(iv), then, after the applicable Reddy manufacturing site is able to qualify, Novartis shall take such steps as are required by FDA or Agency requirements to be performed by Novartis to qualify such site(s) with the FDA or other applicable Agency.

(e) Standards.

(i) All Bulk API and Bulk Products manufactured and supplied by Reddy, and Reddy's manufacturing operations, shall conform to and be manufactured, stored, handled and shipped in accordance with Novartis' specifications, Novartis' established written standards and standard operating procedures (including but not limited to Novartis' established written standards for quality assurance and process control), Novartis' standards for health, safety and environmental ("HSE") protection, all Agency requirements (including without limitation the requirements of United States and European current Good Manufacturing Practice), ISO9000 and ICH Guidelines and all other applicable laws and regulations. At the reasonable request of Reddy, Novartis will adapt its HSE Global Standards to take into consideration local customary manufacturing practice; provided, however, that in no event will Novartis be required to modify such HSE Global Standards in any manner which would increase the level of risk to Novartis above that associated with its HSE Global Standards. In any event, Reddy shall be required to meet all customary standards and legal requirements

applicable in the country in which the applicable manufacturing site is located. To the extent that Novartis is manufacturing or has engaged a third party to manufacture Bulk API, Reddy shall not be required to meet any standard which Novartis does not enforce with respect to itself or any such third party manufacturer of Bulk API. To the extent that Novartis is manufacturing or has engaged a third party to manufacture Bulk Products, Reddy shall not be required to meet any standard which Novartis does not enforce with respect to itself or any such third party manufacturer of the Bulk Products. Reddy shall, at its sole cost and expense, make any capital improvements necessary to comply with this Section 5.3(e)(i). All Bulk Products manufactured by Reddy shall be bioequivalent to the Bulk Products manufactured by Novartis or its designees, as demonstrated in bioequivalence studies (in vitro or in vivo studies, as required by applicable laws and regulations) conducted by Novartis. Reddy shall maintain all regulatory approvals necessary for its manufacture of Bulk API and Bulk Products for Novartis.

(ii) Reddy shall maintain manufacturing capacity such that at all times after its primary Bulk API manufacturing site has been qualified by the FDA or other applicable Agency to manufacture Bulk API, Reddy is capable of producing at least [REDACTED] of the Bulk API required by Novartis (including Bulk API required by Reddy for manufacture of Bulk Products for Novartis) and at all times after its primary Bulk Products manufacturing site has been qualified by the FDA or other applicable Agency to manufacture Bulk Products, Reddy is capable of producing at least one hundred percent (100%) of the Bulk Products required by Novartis; and Reddy shall, from time to time at the request of Novartis, manufacture and supply such amounts of Bulk API and/or Bulk Products as are designated by Novartis in excess of its purchase obligations under the Manufacturing Agreement, up to a total of one hundred percent (100%) of its requirements therefor whether for clinical and animal toxicity studies, NDA validation batches or for commercial use (whether for Launch or post-Launch). Subject to Section 5.3(h), nothing herein shall limit Novartis' right to manufacture, or have a third party manufacture, any Bulk API or Bulk Products which Reddy is entitled but fails to manufacture under the terms of this Article V and the Manufacturing Agreement.

(iii) At all times after Reddy's primary Bulk Products manufacturing site has been qualified by the FDA or other applicable Agency to manufacture Bulk Products, Reddy shall maintain at its cost inventory of Bulk Products in such amounts as requested by Novartis up to an amount equal to the projected worldwide demand for the first six months of the following calendar year and with such expiration dating as requested by Novartis, provided that Reddy shall have a reasonable time after its primary Bulk Products manufacturing site has been qualified by the FDA or other applicable Agency to accumulate the requisite inventory of Bulk Products. At all times after Reddy's primary Bulk API manufacturing site has been qualified by the FDA or other applicable Agency to manufacture Bulk API, Reddy shall maintain at its cost inventory of Bulk API in such amounts as requested by Novartis up to an amount equal to the projected worldwide demand for the following calendar year and with such expiration dating as requested by Novartis, provided that Reddy shall have a reasonable time

after its primary Bulk API manufacturing site has been qualified by the FDA or other applicable Agency to accumulate the requisite inventory of Bulk API.

(iv) At Novartis' request, Reddy shall arrange, at its sole cost and expense, to have, in addition to its primary Bulk API manufacturing site and primary Bulk Products manufacturing site, a back-up Reddy Bulk API manufacturing site and a back-up Reddy Bulk Products manufacturing site at different locations from the primary Bulk API manufacturing site and primary Bulk Products manufacturing site, which back-up sites are qualified by the FDA or other applicable Agency and available at all times, and capable of manufacturing [REDACTED] of Novartis' requirements of Bulk API and Bulk Products. The foregoing will not preclude Reddy's arranging, at its option, for a back-up Reddy Bulk API manufacturing site and/or a back-up Reddy Bulk Products manufacturing site which satisfies the foregoing requirements. If and only if each of the primary and back-up Reddy manufacture sites for Bulk API and Bulk Products has been qualified by the FDA and has been capable of producing at least [REDACTED] of Novartis' requirements of Bulk API and Bulk Products, as the case may be, and both of such primary and back-up Reddy manufacture sites have failed to manufacture and supply substantially all of the Bulk API or Bulk Products, as the case may be, required to be supplied by Reddy in accordance with the Manufacturing Agreement, then Reddy may arrange for an additional back-up site for the manufacture of Bulk API or Bulk Products, as the case may be, which additional site is operated by a party other than Reddy, provided, that (A) such third party back-up site complies with all of the requirements of this Section 5.3, and (B) such third party site, its owner and operator must be approved in writing by Novartis, such approval not to be unreasonably withheld.

(v) Any changes in manufacturing site, processes, testing methods, quality or equipment for the manufacture of Bulk API or Bulk Products must be approved by Novartis in writing. The Product Committee shall adopt a procedure under which changes will be proposed by Reddy and considered by Novartis. With respect to immaterial proposed changes only, Novartis' approval shall not be unreasonably withheld.

(vi) Reddy shall fully cooperate with and provide assistance to Novartis or its third party manufacturer through documentation, consultation, training and face-to-face meetings, to enable Novartis or its third party manufacturer in an efficient and timely manner to proceed with manufacturing of Bulk API and/or Bulk Products. If the Manufacturing Agreement terminates at any time for any reason, or if at any time Reddy is unable to manufacture and supply Bulk Products and/or Bulk API in accordance with the Manufacturing Agreement, Reddy shall, at Novartis' request, provide all necessary assistance in qualifying with the FDA or other applicable Agency Novartis or a third party manufacturer to manufacture Bulk Products and/or Bulk API, as the case may be. If at any time any Reddy site utilized to manufacture and supply Bulk API and/or Bulk Products is unable to manufacture and supply such Bulk Products and/or Bulk API in accordance with the Manufacturing Agreement, and Reddy has remedied such inability or has arranged for another manufacturing site which is capable of manufacturing and supplying such Bulk Products and/or Bulk API in

accordance with the Manufacturing Agreement, and Reddy has the right under the Manufacturing Agreement to resume manufacturing and supplying to Novartis, then, after the applicable Reddy manufacturing site is able to qualify, Novartis shall take such steps as are required by FDA or Agency requirements to be performed by Novartis to re-qualify with the FDA or other applicable Agency such site or to qualify with the FDA or other applicable Agency another manufacturing site in order to permit Reddy to resume manufacturing and supplying Bulk API and/or Bulk Products in accordance with the Manufacturing Agreement.

(f) Term. [REDACTED]

(g) Termination. The Manufacturing Agreement shall contain customary termination provisions, subject to Section 5.3(h) below. In addition, Reddy shall have the right to terminate:

(i) its obligation to manufacture Bulk Product if, for any Calendar Year after the third (3rd) anniversary of the first Launch of Licensed Product in the Territory, Reddy's gross margin does not exceed [REDACTED] by providing Novartis with not less than three (3) years prior written notice of termination (for the avoidance of doubt, the earliest effective date of any termination by Reddy of the Manufacturing Agreement under this Section 5.3(g)(i) shall be six (6) years after such first Launch, provided, however, that the three (3) year notice period may be reduced if so agreed in writing by Novartis); or

(ii) its obligation to manufacture certain Bulk Products in dosage strengths intended for use other than in treating diabetes, pursuant to the last sentence of Section 5.3(c)(iii) hereof; or

(iii) its obligation to manufacture Bulk Products if at any time Reddy is supplying less than [REDACTED] of Novartis' annual worldwide requirements of Bulk Products.

In the event the Manufacturing Agreement is terminated for any reason, Reddy shall continue to manufacture and supply to Novartis until Novartis has established and satisfied all regulatory requirements for another manufacturing source; provided that Novartis shall diligently pursue

establishment of and satisfaction of all regulatory requirements for another manufacturing source. Reddy shall furnish all know-how and assistance to Novartis or its designee to achieve a smooth transition in a timely and efficient manner. In the event that the Manufacturing Agreement is terminated for any reason and Reddy has remaining inventory of Bulk API and/or Bulk Products, Novartis shall continue to purchase Bulk API and/or Bulk Products from Reddy in accordance with the forecasting and order placement procedures to be set forth in the Manufacturing Agreement until such time as all such inventory has been purchased, provided that such Bulk API and/or Bulk Products meet all requirements of Section 5.3(e)(i).

(h) Failure to Manufacture and Supply.

(i) If Reddy is unable for a period of less than [REDACTED] to manufacture and supply requisite quantities of Bulk Products and/or Bulk API in accordance with the requirements set forth in the Manufacturing Agreement (without utilizing the inventories provided for in Section 5.3(e)(iii)), after Reddy is able to, it shall have the right at any time to resume supplying to Novartis. If Reddy is unable for a period of at least nine months but not more than 24 months to manufacture and supply requisite quantities of Bulk Products and/or Bulk API in accordance with the requirements set forth in the Manufacturing Agreement (without utilizing the inventories provided for in Section 5.3(e)(iii)), then Novartis shall have the right to obtain such Bulk Products and/or Bulk API, as the case may be, from another supplier (which, at Novartis' option, may be Novartis, an Affiliate thereof, or a third party manufacturer), and Reddy shall provide all necessary assistance to Novartis, its Affiliate or third party manufacturer pursuant to Section 5.3(e)(vi) above. After Reddy is able to, it shall be entitled to resume its manufacturing in accordance with the Manufacturing Agreement subject to other manufacturing commitments reasonably made by Novartis in order to ensure that it has an uninterrupted supply of Bulk API and Bulk Products, which commitments may extend beyond the period of such non-performance by Reddy if reasonably necessary to ensure such uninterrupted supply. If Reddy is unable for a period of in excess of 24 months to manufacture and supply requisite quantities of Bulk Products and/or Bulk API in accordance with the requirements set forth in the Manufacturing Agreement (without utilizing the inventories provided for in Section 5.3(e)(iii)), then Novartis shall have the right to terminate the Manufacturing Agreement with respect to Bulk API and/or Bulk Products, as the case may be.

(ii) Notwithstanding the foregoing, if prior to Novartis' Launch of any Licensed Product in the Territory Reddy fails for a period of [REDACTED] to supply Bulk API in accordance with the requirements set forth in the Manufacturing Agreement, Novartis shall have the right to terminate the Manufacturing Agreement with respect to Bulk API.

(iii) The foregoing subsections (i) and (ii) shall not limit Novartis' right to damages for any breach by Reddy of the Manufacturing Agreement, subject to Sections 5.3(j) and 5.3(k) below.

(iv) If at any time Reddy is unable or has reason to believe it will be unable to meet its supply obligations under the Manufacturing Agreement without utilizing the inventories provided for in Section 5.3(e)(iii), Reddy shall

immediately provide written notice to Novartis specifying the details of such inability or anticipated inability to perform.

(i) **Dispute Resolution.** In the event that Reddy objects to any request made by Novartis pursuant to Section 5.3(d)(i) or Section 5.3(e)(i), on the grounds that such request is not consistent with the standards set forth in such sections, Reddy shall be entitled to appeal such request. Any such appeal shall be presented for resolution first to the Product Committee, and if the dispute is not satisfactorily resolved, then to a senior Novartis manufacturing executive and if the dispute is not satisfactorily resolved, then the matter shall be submitted to arbitration in accordance with Article XXVIII.

(j) **Indemnification.** The Manufacturing Agreement shall include customary mutual indemnification provisions with respect to claims by one party against the other for (x) its own damages (subject to Section 5.3(k)) and (y) damages incurred by a third party which are recoverable from a party hereto (except lost profits of the third party), including without limitation, in the case of both (x) and (y), for failure of Reddy to fulfill its supply obligations thereunder.

(k) **Damages.** This Section 5.3(k) relates to damages which may be recoverable by Reddy or Novartis as a result of such damages being incurred by it (and not by a third party) arising from a breach of the Manufacturing Agreement by the other party. The damages recoverable by Reddy for breach of the Manufacturing Agreement by Novartis shall be limited to those provided in Section 2-708(2) of the New York Uniform Commercial Code (the "NYUCC") (it being acknowledged and agreed that the prices set forth in Section 5.3(c) include reasonable overhead), including incidental damages as provided in Section 2-710 of the NYUCC. The damages recoverable by Novartis for breach of the Manufacturing Agreement by Reddy shall be limited to those provided in Sections 2-712(1) and (2) of the NYUCC, including incidental damages as provided in Section 2-715 of the NYUCC; provided, however, that if Novartis elects to supply Bulk Product or Bulk API which Reddy failed to supply by manufacturing such Bulk Product or Bulk API, as the case may be, itself or through its Affiliates, Novartis shall be entitled to recover the reasonable cost of manufacturing such Bulk Product or Bulk API, as the case may be (including reasonable start-up costs such as the cost of equipment, production scale-up and the establishment and qualification of the manufacturing site) less the price that Novartis would have paid to Reddy under the Manufacturing Agreement for such Bulk API or Bulk Product, as the case may be. Notwithstanding the foregoing, (i) in no event shall either party be entitled to recover consequential damages incurred by it as a result of the other party's breach, except to the extent that damages recoverable pursuant to Section 2-708(2) of the NYUCC constitute consequential damages, in the case of a breach of the Manufacturing Agreement by Novartis and (ii) this paragraph (k) shall not relieve either party of its obligation to mitigate its damages in the event of a breach by the other of the Manufacturing Agreement (including, without limitation, with respect to Novartis's election as to whether to supply Bulk Product or Bulk API which Reddy failed to supply by manufacturing the same itself or through its Affiliates or by purchasing the same from a third party).

(l) **Definition of Cost.** The term "fully absorbed manufacturing cost" shall be defined in the Manufacturing Agreement and shall include reasonable overhead. Such fully absorbed manufacturing cost shall be determined on an "open book" basis, which term shall also be defined in the Manufacturing Agreement.

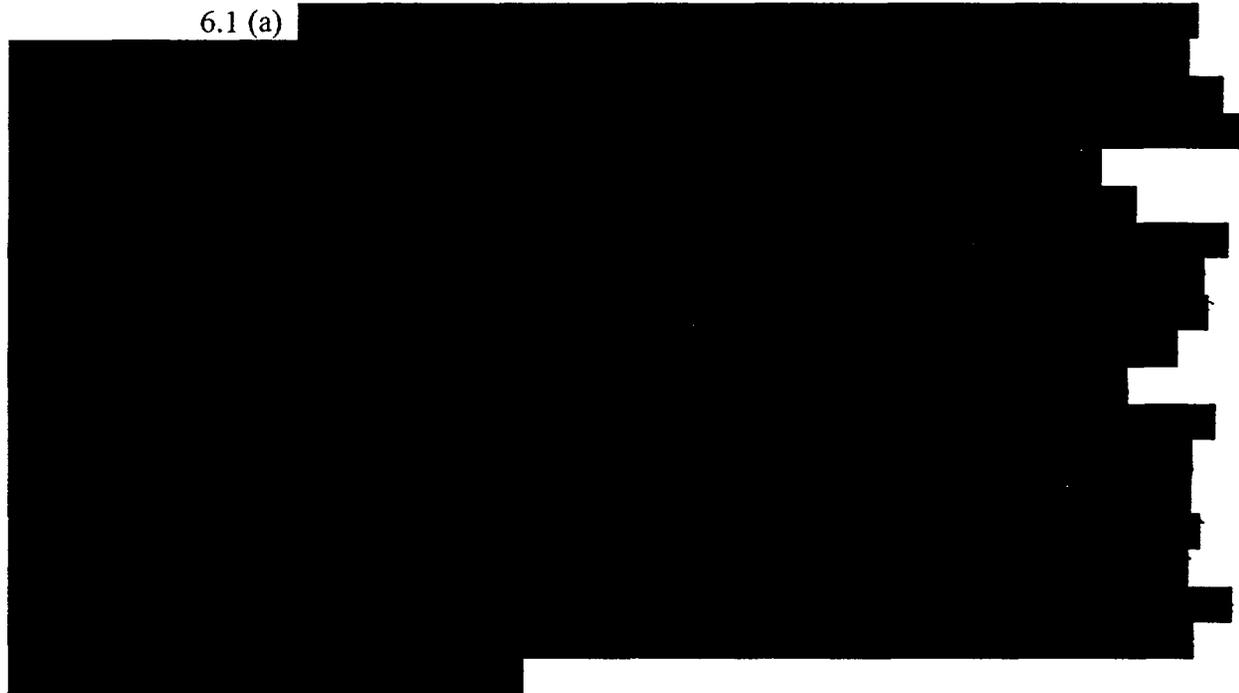
(m) Costs and Expenses. Except as expressly provided in this Article V, each of the parties shall bear its own costs and expenses (including but not limited to employee salaries and any out-of-pocket expenses) in connection with performing its obligations under Section 5.2 and the Manufacturing Agreement.

(n) Additional Terms. The Manufacturing Agreement shall also provide, among other things, for a system for Novartis' placing orders and providing forecasts for Bulk API and Bulk Products, delivery and acceptance of Bulk API and Bulk Products, quality control, inspection, customary insurance provisions and such other terms as may be agreed upon by the parties.

(o) The provision of this Section 5.3 shall remain in full force and effect during the term of this License Agreement until Novartis and Reddy enter into the Manufacturing Agreement. Upon the parties' entering into the Manufacturing Agreement, this Section 5.3 shall be of no further force and effect.

#### ARTICLE VI. Back-Up Compound

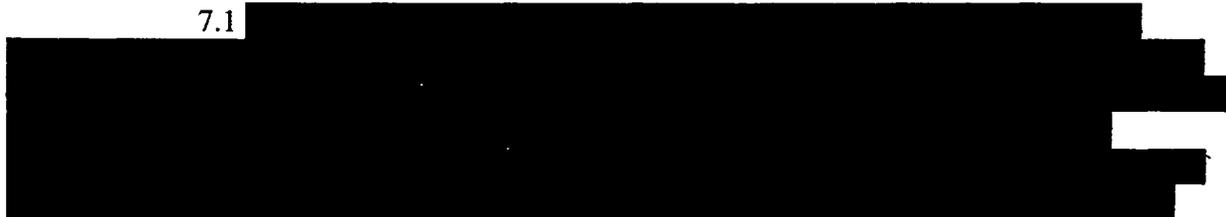
6.1 (a)



(b) The Back-Up Compound provided to Licensee in accordance with this Section 6.1 shall be included in the License, and shall be the "Back-Up Compound" referenced in the definition of Compound.

#### ARTICLE VII. Right of First Evaluation

7.1



[REDACTED]

Licensee shall have the right to evaluate and test samples of such Active Compound(s), provided, however, that Licensee shall not perform analytical studies on any such samples for purposes of determining the chemical structure thereof. Prior to conducting any tests on such samples, Licensee shall provide a notice to Licensor describing the tests which it intends to conduct, and Licensee shall, after completion of such tests, provide a copy of the results thereof to Licensor. Licensor shall not in any way discuss a Proposed Transaction with, provide information to, negotiate with, or enter into any agreement with any third party with respect to a Proposed Transaction involving such Active Compound at any time until after [REDACTED] following receipt by Licensee of the complete Information Package with respect to such Active Compound, or such earlier time as Licensee, in its sole discretion, indicates by written notice to Licensor that it is not interested in the Active Compound. For purposes hereof, a "Proposed Transaction" shall mean a license, purchase, co-promotion, co-development, co-marketing, co-detailing or any similar arrangement.

7.2 Licensee acknowledges that Licensor has no obligation hereunder to develop any Active Compound. However, any Active Compound which is developed by Licensor or any of its Affiliates and with respect to which Licensor or any of its Affiliates determines to propose to enter into a Proposed Transaction at any time within three (3) years after the execution of this Agreement shall be subject to this Article VII.

7.3 Notwithstanding the foregoing, with respect to [REDACTED], Licensor shall not be obligated to comply with Section 7.1; provided, however, that

(i) Licensor shall be obligated to provide Licensee with the same information package which was previously provided to third parties with respect to such compounds, together with samples of such compounds;

(ii) Licensee shall have the right to evaluate and test samples of such compounds; provided, further, however, that Licensee shall not perform analytical studies on any such samples for purposes of determining the chemical structure thereof and prior to conducting any tests on such samples, Licensee shall provide a notice to Licensor describing the tests which it intends to conduct, and Licensee shall, after completion of such tests, provide a copy of the results thereof to Licensor;

(iii) With respect to third parties who have not prior to the date hereof been provided with an information package with respect to such compounds, Licensor shall not in any way discuss a Proposed Transaction with, provide information to, negotiate with, or enter into any agreement with any third party with respect to a Proposed Transaction involving such compounds for a period of 120 days from Licensee's receipt of such information packages; and

(iv) With respect to third parties who prior to the date hereof have been provided with an information package with respect to such compounds, Licensor shall not enter into any agreement with any such third party with respect to a

Proposed Transaction involving such compounds for a period of 120 days from Licensee's receipt of such information packages.

7.4 Notwithstanding the foregoing, this Article VII shall not apply to any compound(s) or product(s) developed, in whole or in part, by a Person that becomes an Affiliate of Licensor after the date hereof to the extent that on the date such Person becomes an Affiliate of Licensor such Person is subject to a pre-existing contractual obligation which would either (x) prevent such compound or product from being subject to this Article VII or (y) if such compound or product were subject to this Article VII, would have a material adverse effect upon such Person or Licensor. In addition, this Article VII shall not apply to the license of the specific intermediate referenced in Section 12.4(b)(iii)(A) to the third party referenced in such Section.

7.5 The Information Package (including all compounds, products and related information) and any other information provided to Novartis pursuant to this Article VII shall be subject to the confidentiality provisions set forth in Article XIV which shall be effective immediately for that purpose.

### **ARTICLE VIII. Co-Promotion/Co-Detailing**

8.1 Co-Promotion. Licensee and Licensor shall negotiate in good faith to enter into a co-promotion agreement (the "Co-Promotion Agreement") pursuant to which Licensee will grant to Licensor certain rights to co-promote Licensed Products in India and Sri Lanka (collectively, the "Co-Promotion Countries") on such terms and conditions as may be mutually acceptable to Licensor and Licensee based, among other things, on the concept of sharing costs (including the costs of Phase IIIB and Phase IV clinical studies in the Co-Promotion Countries), expenses and profits and being responsible for details on a [REDACTED] basis. Licensee shall control, in its sole discretion, all aspects of the development, promotion, distribution, marketing and sale (including pricing and regulatory compliance) of such Licensed Products. In the event that the parties shall have used good faith efforts to reach agreement on the terms and conditions of a Co-Promotion Agreement but shall have failed to reach such agreement, they will not be obligated to enter into a Co-Promotion Agreement.

8.2 Co-Detailing. In the event that Licensee wishes to market or promote Licensed Products in any or all of the following countries: [REDACTED]  
[REDACTED] (the "Co-Detail Countries"), Licensee agrees to discuss in good faith granting Licensor rights to co-detail such Licensed Products in such Co-Detail Countries where Licensee wishes to market or promote Licensed Products. If the parties are able to reach agreement with respect to a mutually acceptable co-detailing arrangement in such Co-Detail Countries, they shall negotiate in good faith to enter into a co-detailing agreement (the "Co-Detailing Agreement") on such terms and conditions as may be mutually acceptable to Licensor and Licensee. Licensee shall control, in its sole discretion, all aspects of the development, promotion, distribution, marketing and sale (including pricing and regulatory compliance) of such Licensed Products. In the event that the parties shall have used good faith efforts to reach agreement on the terms and conditions of a Co-Detailing Agreement, but shall have failed to reach such agreement, they will not be obligated to enter into a Co-Detailing Agreement.

## **ARTICLE IX. Licensor Obligation to Furnish Know-How**

9.1 Initial Obligation. Within thirty (30) days following the Effective Date of this Agreement, Licensor shall provide to Licensee or its designated Affiliate all Licensor Know-How relating to the Compound or Licensed Products not already provided to Licensee, including Licensor Know-How which may be necessary or useful to Licensee to develop, manufacture, register, use or market the Compound and the Licensed Products and practice the license granted hereunder efficiently.

9.2 Continuing Obligation. Licensor shall have a continuing obligation to disclose and provide promptly and effectively to Licensee such additional Licensor Know-How as is developed or obtained by Licensor or its Affiliates during the term of this Agreement and which may be necessary or useful to Licensee to develop, manufacture, register, use or market the Compound and the Licensed Products and practice the license granted hereunder efficiently. Notwithstanding the foregoing, except as provided in Section 5.3(d)(iii), Licensor and its Affiliates shall have no obligation to develop such additional Licensor Know-How.

9.3 Notification of FDA. Within thirty (30) days following the Effective Date of this Agreement, Licensor shall provide a letter to the FDA and all other relevant Agencies transferring to Licensee sponsorship of all Licensor IND applications, if any, covering the Compound or Licensed Products in the Field.

9.4 Regulatory Filings. Licensor shall fully cooperate with and provide assistance to Licensee in connection with regulatory filings submitted or to be submitted by Licensee or its designee with any Agency relating to Licensed Products. Licensor shall provide Licensee and its designees with copies of any regulatory filings of Licensor and its Affiliates made with any Agency relevant to the Licensed Products and all documents required by Licensee for its regulatory filings (including but not limited to all documents relating to the Chemistry, Manufacturing and Controls Sections of such regulatory filings), and Licensee and its designees shall be entitled to use the information contained therein in their regulatory filings relating to the Licensed Products. Licensor shall grant or cause to be granted to Licensee and its designees cross-reference rights to any relevant Drug Master Files and other regulatory filings submitted by Licensor or its Affiliates with any Agency.

## **ARTICLE X. Product Committee.**

10.1 Product Committee. Licensor and Licensee shall establish a committee consisting of representatives of Licensor and Licensee (the "Product Committee"). The Product Committee shall meet periodically as mutually determined by Licensor and Licensee for the purpose of facilitating the exchange of information with respect to the technical development and manufacture of the Compound and/or Licensed Products. The Product Committee shall have no authority to make any decisions or take any action with respect to any activities undertaken pursuant to this Agreement. The existence of the Product Committee shall in no way alter the respective rights or obligations of the parties hereunder.

## **ARTICLE XI. Ownership of Inventions**

11.1 Ownership.

(a) Licensee shall own all right, title and interest in and to all Licensee Technical Information and Patent Rights.

(b) Licensor shall own all right, title and interest in and to all inventions, discoveries and other technology, whether or not patentable, and any patent applications, patents or other intellectual property rights based thereon made, developed, conceived or reduced to practice solely by Licensor, its Affiliates or others acting on its or their behalf, in connection with any research, development or other work relating to Licensed Products and/or the Compound performed after the date hereof. For the avoidance of doubt, it is further understood and agreed that Licensor, its Affiliates or others acting on its or their behalf, shall have the right to use Licensor Patent Rights and Licensor Know-How in connection with any research, development or other work related to Licensed Products and/or the Compound after the date hereof to make, develop, conceive or reduce to practice any invention, discovery or other technology, whether or not patentable, and to obtain any patent or other intellectual property based thereon ("Licensor Technology"). Licensor shall have the right to exploit or license its interest in Licensor Technology for any purpose without any obligation of accounting to, nor any obligation to obtain approval of, Licensee, except that Licensor shall not have the right under Licensor Technology to import, export, make, have made, develop, have developed, use, promote, distribute, market, sell and offer to sell, Licensed Products and/or the Compound in the Field in the Territory or to grant a license to any Person to do any of the same, which rights are included in the exclusive License granted to Licensee as defined in Section 2.1 (and subject to the payment of royalties in accordance with this Agreement).

(c) Licensee and Licensor shall jointly own the entire right, title and interest in and to all inventions, discoveries and other technology, whether or not patentable (and any patent applications, patents or other intellectual property rights based thereon) which are under the laws of inventorship deemed to be jointly made, developed, conceived or reduced to practice by Licensee, its Affiliates or others acting on its or their behalf, on the one hand, and Licensor, its Affiliates or others acting on its or their behalf, on the other hand, in connection with any research, development or other work relating to the Licensed Products and/or the Compound, performed under or in connection with this Agreement ("Jointly Owned Technology"). Subject to the next sentence, each party shall have the right to exploit or license its interest in the Jointly Owned Technology for any purpose without any obligation of accounting to, nor any obligation to obtain approval of, the other party. To the extent Jointly Owned Technology relates solely to Licensed Products and/or the Compound or Jointly Owned Technology relates to other products or compounds as well as the Licensed Products and/or the Compound, then Licensor's and its Affiliates' interest in the same (to the extent related to Licensed Products and/or the Compound) will be included in the exclusive License granted to Licensee hereunder (subject to the payment of royalties in accordance with this Agreement).

## **ARTICLE XII. Warranties and Covenants**

12.1 Representations and Warranties of Licensor and Licensee. Each of the Licensor Entities (jointly and severally) and Licensee represents and warrants to the other that:

(a) it is a corporation duly organized, validly existing, and in good standing under the laws of its jurisdiction of formation;

(b) it has full corporate power and authority to execute, deliver, and perform this Agreement, and has taken all corporate action required by law and its organizational documents

to authorize the execution and delivery of this Agreement and the consummation of the transactions contemplated by this Agreement;

(c) this Agreement constitutes a valid and binding agreement enforceable against it in accordance with its terms (except as the enforceability thereof may be limited by bankruptcy, bank moratorium or similar laws affecting creditors' rights generally and laws restricting the availability of equitable remedies and may be subject to general principles of equity whether or not such enforceability is considered in a proceeding at law or in equity);

(d) the execution and delivery of this Agreement and all other instruments and documents required to be executed pursuant to this Agreement, and the consummation of the transactions contemplated hereby do not and shall not (i) conflict with or result in a breach of any provision of its organizational documents, (ii) result in a breach of any agreement to which it is a party; or (iii) violate any law.

12.2 Representations and Warranties of Licensor. Each of the Licensor Entities, jointly and severally, represents and warrants on the date hereof and on the Effective Date:

(a) that (i) to the best of its knowledge, Licensee, its Affiliates, sublicensees, and/or designees may import, export, make, have made, develop, have developed, use, promote, distribute, market, sell and offer to sell, the Licensed Products and/or the Compound in the Field in the Territory without infringing any intellectual property or other rights of any Person (including, but not limited to, any Affiliate of Licensor), (ii) it is not aware that any Person is infringing the Licensor Patent Rights and (iii) it is not aware that any Person is using any Licensor Know-How which is a trade secret or proprietary to Licensor or its Affiliates (it being acknowledged by Licensee that, notwithstanding the foregoing clause (iii), Licensor Know-How has been licensed by Licensor to third parties, or used by Licensor, in each case to develop or commercialize compounds or products which are not the Compound or Licensed Products and the grant of any such license to a third party, the use thereof by the licensee thereof in accordance with such license or such use by Licensor, in each case, in and of itself, shall not constitute a breach of the representation and warranty in such clause (iii));

(b) that, (i) except as set forth on Schedule 12.2(b), Licensor owns or possesses all right, title and interest in and to the Licensor Patent Rights and the Licensor Know-How free and clear of all encumbrances, and has the right to convey to Licensee the License as provided in Section 2.1 free and clear of all encumbrances, and (ii) without limiting the generality of clause (i), none of the Licensor Patent Rights or Licensor Know-How have been pledged, assigned or otherwise conveyed, in whole or in part, to any Person (it being acknowledged by Licensee that, notwithstanding the foregoing clause (ii), Licensor Patent Rights and Licensor Know-How have been licensed by Licensor to third parties, or used by Licensor, in each case to develop or commercialize compounds or products which are not the Compound or Licensed Products and the grant of any such license to a third party, the use thereof by the licensee thereof in accordance with such license or such use by Licensor, in each case, in and of itself, shall not constitute a breach of the representation and warranty in such clause (ii)). Each of the Licensor Entities represents and warrants that Licensor and its Affiliates have not granted any interest in Licensor Patent Rights or Licensor Know-How which is inconsistent with this Agreement or the rights granted herein;

(c) that, to the best of its knowledge, none of the claims of any of the Licensor Patent Rights or the applications listed on Exhibit B, if issued, would not be valid and enforceable;

(d) that it has not entered into a government funding relationship that would result in rights to any of the Licensed Products or the Compound residing in the National Institutes of Health or other Agency or the U.S. or other government, and that the licenses granted hereunder are not subject to overriding obligations to the U.S. government as set forth in Public Law 96-517 (35 U.S.C. 200-204), as amended, or any similar obligations under the laws of any other country;

(e) that it has not commercialized or agreed to commercialize, nor has it licensed a third party to commercialize, any intermediate, or byproduct or impurity generated in the synthesis of the Compound for the diagnosis, prevention or treatment of Type 2 diabetes (for the avoidance of doubt, this subsection (e) shall not be construed to mean that Licensor has not developed or commercialized or licensed a third party to develop or commercialize for any purpose any compound or product which is not an intermediate or byproduct or impurity generated in the synthesis of the Compound, or any combination of the foregoing, but which utilizes any such intermediate, byproduct or impurity in the synthesis of such compound or product, provided, however, that such compound or product is not the Compound and/or a Licensed Product); and

(f) except as set forth on Schedule 12.2(b), Dr. Reddy's Research Foundation has assigned to Licensor any Licensor Patent Rights and Licensor Know-How which it had on the date hereof or may acquire in the future and has no rights whatsoever with respect to Licensor Patent Rights and Licensor Know-How.

12.3 Representations and Warranties of Licensee. (a) Licensee represents and warrants that, as of the date hereof, [REDACTED]

(b) Licensee represents and warrants, as of the date hereof, that neither it nor any of its Affiliates has breached the Confidentiality Agreement between Dr. Reddy's Research Foundation and Novartis Pharma AG signed by Dr. Reddy's Group on December 23, 1999 and signed by Novartis Pharma AG on January 3, 2000, and that neither Licensee nor any of its Affiliates has synthesized, tested, imported, exported, made, had made, developed, had developed, promoted, distributed, marketed, sold or offered to sell DRF-554158.

12.4 Covenants. (a) Covenants of Licensor and Licensee. Each of Licensor and Licensee covenants and agrees to prepare and make appropriate filings under the HSR Act relating to this Agreement and the transactions contemplated hereby as soon as reasonably practicable, but in any event within 30 days of the date of this Agreement (the "Filing Date"). The parties agree to cooperate in the antitrust clearance process and to furnish promptly to the FTC and the Antitrust Division of the Department of Justice any additional information reasonably requested by them in connection with such filings. Other than the provisions of this Section 12.4, and Sections 27.1, and 31.11 and Articles VII, XV and XXVIII hereof, the rights and obligations of Licensor and Licensee under this Agreement shall not become effective until

the waiting period provided by the HSR Act shall have terminated or expired without any action by any government agency or challenge to the transaction (the date of such termination or expiration, the "Effective Date"). Upon the occurrence of the Effective Date, all provisions of this Agreement shall become effective automatically without the need for further action by the parties. In the event that antitrust clearance from the FTC and Antitrust Division of the Department of Justice is not obtained within 90 days after the Filing Date, or such other date as the parties may mutually agree, this Agreement may be terminated by either party. In the event a provision of this Agreement needs to be deleted or substantially revised in order to obtain regulatory clearance of this transaction, the parties will negotiate in good faith in accordance with Article XXVI hereof.

(b) Covenants of Licensor. Each of the Licensor Entities, jointly and severally, covenants and agrees:

(i) that (A) except as set forth on Schedule 12.2(b), Licensor shall own or possess or continue to own or possess all right, title and interest in and to the Licensor Patent Rights and the Licensor Know-How free and clear of all encumbrances (other than this Agreement) and (B) without limiting the generality of clause (A), each of the Licensor Entities covenants and agrees that none of the Licensor Patent Rights or Licensor Know-How will be pledged, assigned or otherwise conveyed, in whole or in part, to any Person (it being acknowledged by Licensee that, notwithstanding the foregoing clause (B), Licensor Patent Rights and Licensor Know-How may be licensed in the future by Licensor to third parties, or used by Licensor, in each case to develop or commercialize compounds or products which are not the Compound or Licensed Products and the grant of any such license to a third party, the use thereof by the licensee thereof in accordance with such license or such use by Licensor, in each case, in and of itself, shall not constitute a breach of the covenant and agreement in such clause (B)). Each of the Licensor Entities covenants and agrees that Licensor and its Affiliates will not grant any interest in Licensor Patent Rights or Licensor Know-How which is inconsistent with this Agreement or the rights granted herein;

(ii) that Licensor will not enter into a government funding relationship that would result in rights to any of the Licensed Products or the Compound residing in the National Institutes of Health or other Agency or the U.S. or other government, and that the licenses granted hereunder are not subject to overriding obligations to the U.S. government as set forth in Public Law 96-517 (35 U.S.C. 200-204), as amended, or any similar obligations under the laws of any other country;

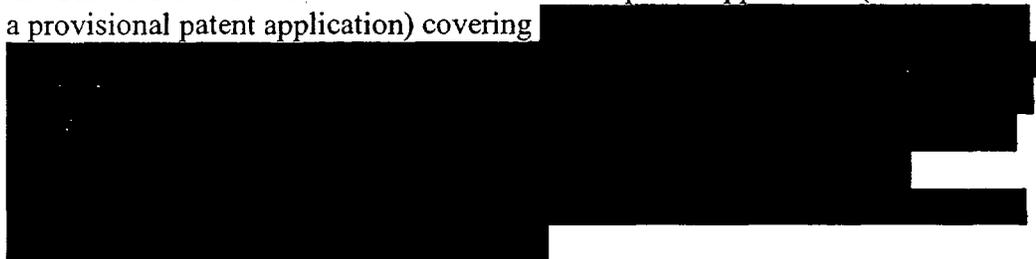
(iii) that it will not, nor will it license a third party to, develop or commercialize any intermediate or byproduct or impurity generated in the synthesis of the Compound, or any combination of the foregoing, for the diagnosis, prevention or treatment of Type II diabetes, except that (A)

[REDACTED]

and (B) for the avoidance of doubt, this clause (iii) shall not be construed to limit Licensor's rights to develop or commercialize or

license a third party to develop or commercialize for any purpose any compound or product which is not an intermediate or byproduct or impurity generated in the synthesis of the Compound, or any combination of the foregoing, but which utilizes any such intermediate, byproduct or impurity in the synthesis of such compound or product, provided, however, that such compound or product is not the Compound and/or a Licensed Product; and

(iv) that it will, within forty-five (45) days of the date hereof, file with the United States Patent and Trademark Office a patent application (which can be a provisional patent application) covering



(c) Covenants of Licensee. Licensee covenants and agrees that it will not (and will cause its Affiliates not to) sell the Compound (alone and not in the form of a Licensed Product) to any non-Affiliate other than for resale or distribution as a Licensed Product. (It is understood and agreed that the foregoing sentence shall not preclude Licensee or its Affiliates from engaging in contract manufacturing arrangements with manufacturers for the supply to Licensee or its Affiliates of the Compound and/or Licensed Products.)

#### **ARTICLE XIII. Adverse Event Reporting**

13.1 Adverse Reaction Reporting. Licensors and Licensee shall cooperate with respect to the exchange of adverse event and safety information relating to the Compound and Licensed Products. Details of the obligations of the parties with respect to handling and reporting such information to each other and related definitions, procedures and guidelines shall be set forth in an addendum to be agreed between the designated safety representatives of the parties following execution of this Agreement.

#### **ARTICLE XIV. Confidentiality**

14.1 Duty of Confidence. All Proprietary Information will be maintained in confidence and otherwise safeguarded by the recipient party, will be used by the recipient party only for the purposes of this Agreement and pursuant to the rights granted to the recipient party under this Agreement, and, without the prior written consent of the disclosing party, will not be disclosed by the recipient party to third parties and will be made available by the recipient party only to the employees or agents (including attorneys, consultants and insurers) of the recipient party or its Affiliates who need to know for purposes permitted under this Agreement. Each party shall hold as confidential such Proprietary Information of the other party or its Affiliates in the same manner and with the same protection as such party maintains its own confidential information. A party may disclose Proprietary Information of the other party or its Affiliates to a third party solely to the extent necessary for furthering the purposes of this Agreement provided that the third party is bound to maintain the confidentiality of the Proprietary Information in a manner consistent with the confidentiality provisions of this Agreement. The mutual obligations under this Section 14.1 shall not apply to any information to the extent that such information:

(a) is at the time of first disclosure or use by the recipient party (as such first disclosure or use is evidenced by prior written documents and, at the recipient's option, oral evidence) part of the public domain through no action of the recipient party or its Affiliates;

(b) was already known to the recipient party or its Affiliates as evidenced by (1) prior written documents in its possession which were not furnished, directly or indirectly, by the other party, its licensees or their Affiliates and (2) at the recipient party's option, oral evidence;

(c) is disclosed to the recipient party or its Affiliates, as evidenced by prior written documents and, at the recipient party's option, oral evidence, by a third party who is not a licensee of the disclosing party and which third party is not in breach or default of any confidentiality obligation to the party whose Proprietary Information is being disclosed or an Affiliate of such party; or

(d) is independently discovered or developed, as evidenced by prior written documents and, at the recipient party's option, oral evidence, by the recipient party or its Affiliates without reference to Proprietary Information provided, directly or indirectly, by the party whose Proprietary Information is being disclosed, its licensee or their Affiliates.

14.2 Disclosures Required by Law. In the event the recipient party is required by law to disclose Proprietary Information of the disclosing party to a government health regulatory agency to obtain regulatory approval for any Licensed Product and/or the Compound, or is required to disclose Proprietary Information in connection with bona fide legal process, the recipient party may do so only if it limits disclosure to that purpose, after giving the disclosing party prompt written notice of any instance of such a requirement in reasonable time for the disclosing party to attempt to object to or to limit such disclosure. In the event of disclosures required by law, the recipient party shall cooperate with the disclosing party as reasonably requested thereby.

14.3 Licensors Know-How. Licensor shall maintain in confidence and otherwise safeguard Licensor Know-How related to the Compound or Licensed Products, and shall not, without the prior written consent of Licensee, disclose or furnish the same to any Person other than Licensee or its Affiliates and designees, or use the same except to manufacture Licensed Products for Licensee as provided herein. Notwithstanding the foregoing, Licensor may license or disclose to third parties (subject to reasonable confidentiality requirements) or use, without the consent of Licensee, Licensor Know-How other than in connection with the Compound and/or Licensed Products.

## **ARTICLE XV. Publications and Publicity**

15.1 Publications. Any proposed oral public disclosures or written publications of Licensor relating to a Licensed Product and/or the Compound shall require Licensee's written consent prior to their release; provided, that the foregoing shall not apply to information which is not of a scientific or technical nature and which is in the public domain.

15.2 Publicity. Each party agrees not to issue any press release or other public statement, whether oral or written, disclosing the existence of this Agreement, the terms hereof or any information relating to this Agreement without the prior written consent of the other party, provided however, that neither party will be prevented from complying with any duty of

disclosure it may have pursuant to law or governmental regulation or pursuant to and as provided in Section 14.2. In the event of a disclosure required by law or governmental regulation, the parties shall coordinate with each other with respect to the timing, form and content of such required disclosure and, if so requested by the other party, the party subject to such obligation shall use reasonable best efforts to obtain an order protecting to the maximum extent possible the confidentiality of such provisions of this Agreement as reasonably requested by the other party. If the parties are unable to agree on the form or content of any required disclosure, such disclosure shall be limited to the minimum required by law or governmental regulation.

#### **ARTICLE XVI. Trademarks**

16.1 Licensee shall be entitled, in its sole discretion, to select the trademarks and tradenames for all Licensed Products which trademarks and tradenames for any Licensed Product may vary by country or within a country, in Licensee's sole discretion. Licensee shall own all right, title and interest in and to such trademarks and tradenames, and, except as expressly provided in Section 21.5(b), Licensor shall have no rights with respect to any such trademarks and tradenames.

#### **ARTICLE XVII. Indemnification**

17.1 Indemnification of Licensee. The Licensor Entities shall, jointly and severally, indemnify and hold Licensee and its Affiliates, and their respective officers, directors, employees, independent contractors, agents, and assigns, harmless from and against any and all liability, damage, loss, cost or expense, including reasonable attorneys' fees, resulting from (i) any claims made or suits brought against Licensee or any of the foregoing Persons or (ii) any claims brought directly by Licensee against Licensor, which, in either case, arise or result from:

(a) Licensor's or its agents', sublicensees' or designees' negligence or willful misconduct in connection with this Agreement or the development, commercialization, manufacture (but only in the event of manufacture following termination in whole or in part of this Agreement and the reversion of the applicable rights hereunder to Licensor in accordance with Article XXI and not pursuant to Article V and the Manufacturing Agreement) or sale of the Compound and/or Licensed Products;

(b) Licensor's material breach of any of the covenants, warranties and representations made to Licensee under this Agreement; or

(c) Licensor's or its agents', sublicensees' or designees' violation of any applicable law or regulation in connection with this Agreement or the development, commercialization, manufacture or sale of the Compound and/or Licensed Products.

Licensor shall only be obligated to so indemnify and hold Licensee harmless to the extent that such liability, damage, loss, cost or expense does not arise from the negligence or willful misconduct of Licensee or from any of the reasons set forth under Section 17.3 below.

17.2 Mitigation of Infringement. In the event that any of the Licensed Products and/or the Compound (or uses thereof) are alleged to infringe a third party's intellectual property rights, such infringement is alleged to arise from the exercise by Licensee of the license rights granted in Section 2.1 of this Agreement or Licensee's use of the Licensor Know-How provided to Licensee pursuant to Article VI or IX of this Agreement and there is a significant possibility

that such allegation may be upheld in a litigation, then, at Licensee's request, Licensor shall use its reasonable best efforts to promptly procure for Licensee and its Affiliates, sublicensees, designees, suppliers, contractors, end users and customers the right to continue using the Licensed Products and/or the Compound free of any liability for infringement. The royalties and other payments associated with any such license and any other damages or payments provided in Section 3.4 shall be allocated in accordance with Section 3.4, and Licensor shall not have any further liability to Licensee under this Agreement on account of the facts, events or occurrences with respect to such third party infringement claim which gives rise to such royalties, damages and/or other payments.

17.3 Indemnification of Licensor. Licensee shall indemnify and hold Licensor and its Affiliates, and their respective officers, directors, employees, independent contractors, agents, and assigns, harmless from and against any and all liability, damage, loss, cost or expense, including reasonable attorneys' fees, resulting from (i) any claims made or suits brought against Licensor or any of the foregoing Persons or (ii) any claims brought directly by Licensor against Licensee, which, in either case, arise or result from:

(a) Licensee's or its agents', sublicensees' or designees' negligence or willful misconduct in connection with this Agreement or the development, commercialization, manufacture or sale of the Compound and/or Licensed Products;

(b) Licensee's material breach of any of the covenants, warranties and representations made to Licensor under this Agreement; or

(c) Licensee's or its agents', sublicensees' or designees' violation of any applicable law or regulation in connection with this Agreement or the development, commercialization, manufacture or sale of the Compound and/or Licensed Products.

Licensee shall only be obligated to so indemnify and hold Licensor harmless to the extent that such liability, damage, loss, cost or expense does not arise from the negligence or willful misconduct of Licensor or from the reasons set forth under Section 17.1 above.

#### 17.4 Indemnification Procedures.

(a) Any party hereto or any of its Affiliates seeking indemnification hereunder (the "indemnified party") shall notify the other party (the "indemnifying party") in writing reasonably promptly after the assertion against the indemnified party of any claim or allegation by a third party (a "Third Party Claim") in respect of which the indemnified party intends to base a claim for indemnification hereunder, but the failure or delay so to notify the indemnifying party shall not relieve the indemnifying party of any obligation or liability that it may have to the indemnified party except to the extent that the indemnifying party demonstrates that its ability to defend or resolve such Third Party Claim is adversely affected thereby.

(b) (i) Subject to the provisions of Section 17.4(d) below, the indemnifying party shall have the right, upon written notice given to the indemnified party within thirty (30) days after receipt of the notice from the indemnified party of any Third Party Claim to assume the defense or handling of such Third Party Claim, at the indemnifying party's sole expense, in which case the provisions of Section 17.4(b)(ii) below shall govern.

(ii) The indemnifying party shall select counsel reasonably acceptable to the indemnified party in connection with conducting the defense or handling of such Third Party Claim, and the indemnifying party shall defend or handle the same in consultation with the indemnified party, and shall keep the indemnified party timely apprised of the status of such Third Party Claim. The indemnifying party shall not, without the prior written consent of the indemnified party, agree to a settlement of any Third Party Claim which could lead to liability or create any financial or other obligation on the part of the indemnified party for which the indemnified party is not entitled to indemnification hereunder. The indemnified party shall cooperate with the indemnifying party and shall be entitled to participate in the defense or handling of such Third Party Claim with its own counsel and at its own expense. Notwithstanding the foregoing, in the event the indemnifying party fails to conduct the defense or handling of any Third Party Claim in good faith after having assumed such defense or handling, then the provisions of Section 17.4(c)(ii) below shall govern.

(c) (i) If the indemnifying party does not give written notice to the indemnified party, within thirty (30) days after receipt of the notice from the indemnified party of any Third Party Claim, of the indemnifying party's election to assume the defense or handling of such Third Party Claim, the provisions of Section 17.4(c)(ii) below shall govern.

(ii) The indemnified party may, at the indemnifying party's expense, select counsel in connection with conducting the defense or handling of such Third Party Claim and defend or handle such Third Party Claim in such manner as it may deem appropriate, provided, however, that the indemnified party shall keep the indemnifying party timely apprised of the status of such Third Party Claim and shall not settle such Third Party Claim without the prior written consent of the indemnifying party, which consent shall not be unreasonably withheld. If the indemnified party defends or handles such Third Party Claim, the indemnifying party shall cooperate with the indemnified party and shall be entitled to participate in the defense or handling of such Third Party Claim with its own counsel and at its own expense.

(d) If the indemnified party intends to seek indemnification hereunder, other than for a Third Party Claim, then it shall notify the indemnifying party in writing promptly after its discovery of facts upon which it intends to base its claim for indemnification hereunder, but the failure or delay so to notify the indemnifying party shall not relieve the indemnifying party of any obligation or liability that it may have to the indemnified party except to the extent that the indemnifying party demonstrates that the indemnifying party's ability to defend or resolve such claim is adversely affected thereby.

(e) For the avoidance of doubt, this Article XVII is not intended to apply to the parties' obligations in or claims arising under Article V or the Manufacturing Agreement and the provisions of this Article XVII shall neither expand nor limit the rights and obligations of the parties relating to indemnification to be included in the Manufacturing Agreement.

### **ARTICLE XVIII. Patent Infringement**

18.1 Notification. Each party hereto shall promptly inform the other party of any infringement of the Licensor Patent Rights of which it has knowledge.

## 18.2 Right to Bring Action.

(a) Licensee shall have the right to initiate, prosecute and control legal action (whether by suit, proceeding or otherwise) in respect of any infringement by a third party of any claim of Licensor Patent Rights which relates solely to the Compound and/or a Licensed Product; provided, however, that if, within three (3) months of receiving written notice of an infringement and a request by Licensor that it take action with respect thereto, or if within twenty-one (21) days after Licensee and/or Licensor have received notification of patent certification as set forth under Section 20.6 below, Licensee fails to terminate such infringement or to commence action to such end, then thereafter Licensor shall have the right to initiate, prosecute and control action against such an infringement.

(b) In the case of any infringement by a third party of any claim of Licensor Patent Rights which does not relate solely to the Compound and/or a Licensed Product, Licensor and Licensee shall have the right to jointly initiate, prosecute and control legal action (whether by suit, proceeding or otherwise) in respect of such infringement. All decisions regarding any such legal action shall be made by the parties jointly and expeditiously. For the purpose of facilitating discussions between the parties regarding such legal action, the parties shall form an infringement committee (the "Infringement Committee"), consisting of an equal number of representatives of Licensee and Licensor, which shall meet periodically as mutually determined by Licensor and Licensee and the parties shall reasonably cooperate in any such action.

18.3 Right to Join. In any action against an infringement brought in accordance with this Article XVIII, the party taking such action shall have the right to join the other party as a party to such action and each party shall reasonably cooperate with the other in regard to the same. In addition, each party shall have the right to join in any action against infringement brought in accordance with this Article XVIII if necessary in order to assert the damages incurred by such party as a result of the alleged infringement, provided, that (i) the foregoing shall not limit or restrict in any way the rights of the party controlling such action as determined in accordance with Section 18.2 from exercising such control in its discretion and (ii) notwithstanding the foregoing, any monetary recovery in connection with such infringement action shall be allocated in accordance with Section 18.4.

18.4 Costs and Expenses; Recovery. The costs and expenses (including attorneys' fees) of any action against an infringement brought in accordance with this Article shall be borne by the party controlling the infringement action, in the case of an action referenced in Section 18.2(a), and equally by Licensee and Licensor, in the case of an action referenced in Section 18.2(b). Any monetary recovery in connection with such infringement action shall first be applied to reimburse Licensor and Licensee for their out-of-pocket expenses (including reasonable attorneys' fees) in taking such infringement action. Once the parties have been reimbursed for their out-of-pocket expenses, the remainder will be apportioned in proportion to damages actually incurred by the parties. The party(ies) controlling the infringement action shall use reasonable efforts to have the court or arbitrator issue findings as to the actual damages incurred by each of Licensor and Licensee.

## **ARTICLE XIX. Certain Licensor Obligations with Respect to Patents**

19.1 Updating. Licensor shall promptly advise Licensee of any additions to, or deletions from the list of Licensor Patent Rights set forth in Exhibit B, and shall otherwise promptly and fully keep Licensee apprised of the general subject matter of the Licensor Patent

Rights set forth in Exhibit B and apprised with respect to the status of filing, prosecution, and maintenance of Licensor Patent Rights set forth in Exhibit B, including, but not limited to, the issuance of patents upon any patent applications included therein. Licensor shall offer to provide to Licensee and shall, at Licensee's option, provide to Licensee (i) a copy of any patent application within Licensor's Patent Rights added to Exhibit B which relates specifically to Licensed Products and/or Compound; and (ii) copies of all papers disclosing references and acts submitted to a Patent Office as part of a duty of disclosure and references cited by a Patent Office associated with the patent applications referred to in clause (i) including copies of any documents cited.

19.2 Maintenance. Licensor shall, at its expense, diligently take all steps necessary to procure and to maintain the Licensor Patent Rights in full force and effect, including but not limited to a duty to diligently file and pursue patent applications as well as, if applicable, any reissues and re-examinations. If Licensor shall elect not to procure or to maintain any of the Licensor Patent Rights, it shall promptly (and in any event not less than one month prior to the deadline for taking appropriate action with respect to such Licensor Patent Rights) notify Licensee of that election and shall, at Licensee's request, assign to Licensee or its designee all right, title and interest in and to such Licensor Patent Right involved, in which case, if such Licensor Patent Right is the only Licensor Patent Right covering a particular Licensed Product in a country, then the payment of a patent royalty hereunder shall cease with respect to sales of such Licensed Product in the country involved.

#### **ARTICLE XX. Drug Price Competition and Patent Term Restoration Act**

20.1 The parties agree to cooperate in an effort to avoid loss of any rights which may otherwise be available to the parties hereto under the provisions of the Drug Price Competition and Patent Term Restoration Act of 1984 or comparable laws outside the United States.

20.2 Licensor shall provide relevant patent information to Licensee so that Licensee, as NDA applicant, may inform the FDA or other applicable Agency.

20.3 Licensor shall grant Licensee cross-reference rights to relevant Drug Master Files and pre-clinical, clinical or other regulatory files.

20.4 The parties shall cooperate in determining, if applicable, which of Licensor Patent Rights shall be extended.

20.5 Licensor agrees that applications for patent extension are to be made by Licensee in the sixty (60) day period following NDA approval; consequently, the parties agree that preparation for such application shall begin upon FDA's issuance of an "Approvable Letter" and Licensor shall execute such documents in connection with such application as may be reasonably requested by Licensee.

20.6 Notice of any "patent certification" filed by a third party FDA application which references to a U.S. patent licensed hereunder shall be immediately provided to the other party.

20.7 No actions or agreements which interfere with the above activities shall be undertaken or entered into after the Effective Date.

20.8 The parties shall cooperate with each other in obtaining patent term restoration or supplemental protection certificates or their equivalents in any country and region in the Territory where applicable to the Licensor Patent Rights, at Licensor's cost. Licensor shall provide all reasonable assistance to Licensee, including permitting Licensee to proceed with applications for such in the name of Licensor, if so required, but at the cost of Licensor.

#### ARTICLE XXI. Termination

21.1 Termination by Licensee. Licensee may terminate this Agreement in its sole discretion at any time during the term hereof:

(a) on not less than thirty (30) days prior written notice to Licensor for any reason or no reason;

(b) immediately, upon notice to Licensor, in the event of a Change of Control of Licensor;

(c) on not less than ten (10) days prior written notice to Licensor, in whole or on a country-by-country basis, in the event of a significant regulatory, medical, efficacy, safety or legal issue such that Licensee determines that there is an adverse effect on Licensee's ability to market and sell the Licensed Products and/or the Compound or an adverse effect on the competitiveness of the Licensed Product and/or the Compound; or

(d) on not less than thirty (30) days prior written notice to Licensor, in the event that

[REDACTED]

21.2 Termination by Licensor. Licensor may terminate this Agreement pursuant to Section 4.2 immediately by written notice to Licensee which shall be provided by Licensor not later than 30 days after (i) in the case of termination pursuant to Section 4.2(a), Licensor receives written notice from Licensee that it no longer intends to pursue development, commercialization and marketing activities with respect to the Compound and Licensed Products, in their entirety, or (ii) in the case of termination pursuant to Section 4.2(b), expiration of the [REDACTED] discussion period set forth therein.

21.3 Termination by Either Party.

(a) In the event either party shall be in breach of any material obligation hereunder, the non-breaching party may give written notice to the breaching party specifying the claimed particulars of such breach, and in the event such material breach is not cured, or effective steps to cure such material breach have not been initiated or are not thereafter diligently pursued within sixty (60) days following the date of such written notification, in addition to any other damages or remedies available to the non-breaching party, the non-breaching party shall have the right thereafter to terminate this Agreement by giving not less than thirty (30) days prior written notice to the breaching party to such effect. Any termination by any party under this

Section 21.3(a) shall be without prejudice to any damages or remedies to which it may be entitled from the other party.

(b) Either party may terminate this Agreement without notice if the other party becomes insolvent, makes or has made an assignment for the benefit of creditors, is the subject of proceedings in voluntary or involuntary bankruptcy instituted on behalf of or against such party (except for involuntary bankruptcies which are dismissed within ninety (90) days), or has a receiver or trustee appointed for substantially all of its property.

Licensee's rights under this Agreement shall include, without limitation, those rights afforded by 11 U.S.C. § 365(n) of the United States Bankruptcy Code (the "USBC") and any successor thereto, if applicable. If the bankruptcy trustee of Licensor as a debtor or debtor-in-possession rejects this Agreement under 11 U.S.C. § 365(o) of the USBC, Licensee may elect to retain its rights licensed from Licensor hereunder (and any other supplementary agreements hereto) for the duration of this Agreement and avail itself of all rights and remedies to the full extent contemplated by this Agreement and 11 U.S.C. § 365(n) of the USBC, and any other relevant laws.

#### 21.4 Effect of Termination on License; Certain Reversion Rights.

(a) Upon termination of this Agreement by Licensee pursuant to Section 21.1(a), 21.1(c) or 21.1(d), and upon termination of this Agreement by Licensor pursuant to Section 21.2, 21.3(a) or 21.3(b), all rights and obligations under this Agreement shall terminate and all license rights shall revert to Licensor and Licensee shall return to Licensor all Licensor Proprietary Information, except that a copy of such Proprietary Information may be retained by Licensee in segregated files for archival purposes, and except that in regard to termination of this Agreement pursuant to Section 21.1(c) with respect to a particular country, the rights and obligations under this Agreement with respect to such country shall terminate and license rights with respect to such country shall revert to Licensor.

(b) In the case of termination by Licensee pursuant to Section 21.1(b) or 21.3(b), all rights of Licensee shall survive, and all rights of Licensor shall terminate other than Licensor's rights under Articles III, IV, V, XI, XIII, XIV, XV, XVII, XVIII, XX, XXI, XXVIII and XXIX.

(c) In the case of termination by Licensee pursuant to Sections 21.3(a), all rights of Licensee shall survive, and all rights of Licensor shall terminate other than Licensor's rights under Articles III, IV, XI, XIII, XIV, XV, XVII, XVIII, XX, XXI (except Section 21.5), XXVIII and XXIX.

(d) In the event that Licensee has obtained requisite governmental approvals to market and sell Licensed Products in any country in the Territory and thereafter determines not to market and sell Licensed Products in such country for any reason (other than Licensee's determination in its sole discretion (but subject to the second sentence of Section 4.1) that the marketing or sale of Licensed Products in such country could have an adverse effect on Net Sales in any of the United States, the European Union or Japan), then Licensee shall give Licensor written notice and Licensee's rights and obligations hereunder with respect to the Compound and Licensed Products in such country shall terminate and such rights shall revert to Licensor.

(e) In the event that Licensee determines not to develop and seek requisite governmental approvals to market and sell Licensed Products in the United States, the European Union or Japan, then Licensee shall give Licensor written notice and Licensee's rights and obligations with respect to the Compound and Licensed Products in the United States, the European Union or Japan, as the case may be, shall terminate and such rights shall revert to Licensor.

#### 21.5 Use of Data and Trademarks Upon Termination.

##### (a) Use of Data Upon Termination.

(i) In the event of termination of this Agreement by Licensee pursuant to Section 21.1(a), 21.1(c), 21.1(d), 21.4(d) or 21.4(e) or by Licensor pursuant to Section 21.2 or 21.3(b), Licensor shall be granted (A) a license (with the right to sublicense) under Licensee Technical Information and Patent Rights (including, without limitation, all data (including clinical data) developed by Licensee relating to the Compound and/or the Licensed Products), and (B) to the extent Licensor so elects, a sublicense (with the right to sublicense) of any license to third party patent or other intellectual property rights granted to Licensee prior to the date of such termination pursuant to Section 3.4(a) or (b) or Section 17.2 (a "Third Party License"), but only to the extent permitted under the terms of such Third Party License and subject to the terms and conditions thereof, provided, that in the case of clause (A) and (B), such license or sublicense, as the case may be, shall be solely to make, use and sell the Compound and/or Licensed Products; provided, further, that in the case of termination on a country-by-country basis pursuant to Section 21.1(c), 21.4(d) or 21.4(e), Licensor shall only be entitled to the foregoing insofar as it relates to the country with respect to which the License is being terminated. Upon any such termination, Licensee shall assign to Licensor all regulatory filings with Agencies, including all INDs, NDAs and the like with respect to the Compound and/or the Licensed Products; provided, however, that in the case of termination on a country-by-country basis pursuant to Section 21.1(c), 21.4(d) or 21.4(e), Licensor shall only be entitled to assignment of the foregoing insofar as they relate to the country with respect to which the License is being terminated. In the event that, following such termination, Licensor or an Affiliate of Licensor commercializes a Licensed Product, Licensor shall pay to Licensee a royalty equal to [REDACTED] of net sales (determined in a manner consistent with the determination of Net Sales hereunder and subject to reporting obligations and audit rights consistent with Sections 3.5(a) and 3.6) of such Licensed Product. In the event that Licensor commercializes a Licensed Product through a third party (whether by license or otherwise), Licensor shall pay to Licensee a royalty equal to [REDACTED] of all royalty and other payments Licensor or any Affiliate thereof receives from such third party in respect of such Licensed Product. Notwithstanding the foregoing, in no event shall the payments to be made by Licensor to Licensee under this Section 21.5(a)(i) exceed the aggregate amount (such amount, the "Reimbursement Cap") of (i) all development costs incurred by Licensee with respect to the Compound and the Licensed Products and all Milestone Payments paid by Licensee to Licensor hereunder, plus (ii) if Licensor elects to receive a sublicense under any Third Party License, all costs incurred by Licensee in connection with obtaining and performing under such Third Party License (including, without limitation,

license fees, milestone payments, royalties, damages or other payments), less any portion of such costs previously borne by Licensor pursuant to Section 3.4. When such payments to Licensee under this Section 21.5(a)(i) shall have reached the Reimbursement Cap, the licenses granted under this Section 21.5(a)(i) shall be paid up, subject, in the case of a sublicense of a Third Party License, to the next sentence. Notwithstanding the foregoing, following any such termination of this Agreement, if Licensor elects to receive a sublicense under any Third Party License, all costs (such as future royalties) with respect to such Third Party License arising after the date of termination and relating to the Compound and/or Licensed Products or the manufacture, use or sale thereof shall be borne by Licensor.

(ii) In the event of termination of this Agreement by Licensor prior to Launch anywhere in the Territory pursuant to Section 21.3(a), Licensor shall be granted (A) a paid-up license (with the right to sublicense) under Licensee Technical Information and Patent Rights (including, without limitation, all data (including clinical data) developed by Licensee relating to the Compound and/or the Licensed Products), and (B) if Licensor so elects, a sublicense (with the right to sublicense) of any Third Party License, but only to the extent permitted under the terms of such Third Party License and subject to the terms and conditions thereof, provided, that in the case of clause (A) and (B), such license or sublicense, as the case may be, shall be solely to make, use and sell the Compound and/or Licensed Products. Upon any such termination, Licensee shall assign to Licensor all regulatory filings with Agencies, including all INDs, NDAs and the like with respect to the Compound and/or the Licensed Products. Licensor's sole and exclusive remedy in the event of such a termination shall be Licensee's performance of its obligations under this Section 21.5(a)(ii), and Licensor shall not be entitled to pursue any other remedy at law or in equity. Notwithstanding the foregoing, following any such termination of this Agreement, if Licensor elects to receive a sublicense under any Third Party License, all costs (such as future royalties) with respect to such Third Party License arising after the date of termination and relating to the Compound and/or Licensed Products or the manufacture, use or sale thereof shall be borne by Licensor.

(iii) In the event of termination of this Agreement by Licensor after Launch anywhere in the Territory pursuant to Section 21.3(a), Licensor shall not be entitled to any license under Licensee Technical Information and Patent Rights, any sublicense of any Third Party License or any rights to any regulatory documents or filings but instead will be entitled to monetary damages arising from the breach giving rise to the right of termination.

(b) Use of Trademarks Upon Termination. In the event of termination of this Agreement after Launch anywhere in the Territory pursuant to Section 21.1(a) or 21.1(c) (with respect to the entire Territory) or by Licensor pursuant to Section 21.2 or 21.3(b), at the written request of Licensor, Licensor and Licensee shall enter into an agreement providing for a royalty-free license (with the right to sublicense) to Licensor to use the Primary Trademark in connection with the marketing and sale of the Licensed Products for a period of one year after the effective date of such termination and containing customary terms and conditions. For the avoidance of doubt, said royalty free license shall be without up-front cost or any other cost to Licensor. At

the written request of Licensor, the parties shall during Phase III Clinical Trials with respect to the first Licensed Product developed hereunder negotiate in good faith the form of an agreement which would provide for such license. In the event of any such termination, at the written request and at the sole option of Licensor, Licensee and Licensor shall negotiate in good faith to enter into an agreement providing for a royalty-bearing license to Licensor to use the Primary Trademark in connection with the marketing and sale of the Licensed Products after the expiration of such one year period and containing customary terms and conditions.

(c) No Additional Rights. In the event of termination of this Agreement (whether in its entirety or in any country), except as provided in Section 21.5(a) or Section 21.5(b), Licensor shall not be entitled to any license under Licensee Technical Information and Patent Rights, sublicense of Third Party Licenses, rights to any regulatory documents or filings, use of the Primary Trademark or use of any trademarks of Licensee or its Affiliates.

(d) Combination Products. Notwithstanding anything in this Section 21.5 to the contrary, if at the time of any termination and reversion of rights which gives rise to Licensor's rights provided in Section 21.5(a) and (b), Licensee is developing or commercializing a Licensed Product which is a combination product which includes both the Compound and any other active pharmaceutical ingredient, then, in such event, Licensor's rights to use any data, Licensee Technical Information and Patent Rights, regulatory documents or filings or the Primary Trademark shall be limited to that which relates solely to the Compound or Licensed Products which incorporate the Compound as the sole active pharmaceutical ingredient.

## **ARTICLE XXII. Term of Agreement**

22.1 Unless sooner terminated pursuant to Article XXI hereof, this Agreement shall continue in full force and effect until Licensee is no longer obligated to pay royalties hereunder.

22.2 For each country, upon expiration of Licensee's obligation to pay royalties hereunder, Licensee shall have a fully paid-up, royalty-free, transferable, perpetual and irrevocable exclusive license, with the right to sublicense, under and to the Licensor Patent Rights and Licensor Know-How, to import, export, make, have made, develop, have developed, use, promote, distribute, market, sell and offer to sell, Licensed Products and the Compound in the Field, in said country, whether through itself, its Affiliates or designees (it being understood that such license under any Licensor Patent Rights shall become non-exclusive upon the expiration of such Licensor Patent Rights).

22.3 In the event Licensee has a fully paid-up license in any country pursuant to Section 22.2, Licensee shall have the right to make, have made, develop and have developed, Licensed Products and the Compound anywhere in the world for use or sale, royalty-free, in said country.

## **ARTICLE XXIII. Survivability**

23.1 Expiration or termination of this Agreement shall not relieve the parties of any obligation accruing prior to such expiration or termination. Without limiting the foregoing, the obligations pursuant to Articles XV, XVII, XXVII and XXVIII and Sections 11.1, 13.1, 21.4, 21.5, 31.3, 31.10 and 31.11 shall survive termination of this Agreement.

23.2 The provisions of Sections 14.1 and 14.2 shall survive the termination or expiration of this Agreement for a period of ten (10) years.

#### **ARTICLE XXIV. Assignment**

24.1 Unless consent in writing is first obtained from the other party, this Agreement and the rights and obligations granted herein shall not be assignable by either party hereto, except to a successor to all or substantially all of its business, subject to Section 21.1(b). Notwithstanding the foregoing, each of Licensee and Licensor may assign its rights and obligations under this Agreement or any part hereof to one or more of its Affiliates without the consent of the other party. Any permitted assignee shall assume all obligations of its assignor under this Agreement, and no permitted assignment shall relieve the assignor of liability hereunder. Any attempted assignment in contravention of the foregoing shall be void.

#### **ARTICLE XXV. Extension to Affiliates**

25.1 Each party shall have the right to extend the rights and immunities granted in this Agreement to one or more of its Affiliates. All applicable terms and provisions of this Agreement, except this right to extend, shall apply to any such Affiliate to which this license has been extended to the same extent as such terms and provisions apply to the party extending such rights and immunities.

#### **ARTICLE XXVI. Severability**

26.1 Should one or more of the provisions of this Agreement become void or unenforceable as a matter of law, then this Agreement shall be construed as if such provision were not contained herein and the remainder of this Agreement shall be in full force and effect, and the parties will use their best efforts to substitute for the invalid or unenforceable provision a valid and enforceable provision which conforms as nearly as possible with the original intent of the parties.

#### **ARTICLE XXVII. Governing Law**

27.1 This Agreement shall be governed by and construed in accordance with the laws of the State of New York without regard to the conflicts of law provisions thereof.

#### **ARTICLE XXVIII. Arbitration**

28.1 If any controversy, claim or dispute arises under this Agreement, the parties shall negotiate in good faith to resolve such dispute. If the parties are unable to resolve the dispute to their mutual satisfaction within sixty (60) days after any party gives written notice to such effect to the other party, then any party may submit the dispute to arbitration for final settlement, which arbitration shall be conducted in accordance with the following procedures:

28.2 Any controversy, claim or dispute arising out of or relating to this Agreement shall be settled by arbitration in accordance with the Rules of Conciliation and Arbitration (the "ICC") of the International Chamber of Commerce (the "ICC Rules"), by three (3) arbitrators to be selected in accordance with such ICC Rules, provided, that each party shall choose one arbitrator and the two chosen arbitrators shall choose the third arbitrator. Notwithstanding the foregoing, for purposes of any arbitration pursuant to Section 5.3 the three (3) arbitrators shall consist of one individual with experience in manufacturing pharmaceutical

products selected by each of Licensor and Licensee and one attorney selected by the two arbitrators selected by the parties in accordance with the foregoing. The arbitrators shall be United States residents and shall be qualified by education, experience and training to decide the issues to be arbitrated.

28.3 Any such arbitration shall be conducted in English in London, England. The decision of the arbitrators shall be final, binding and conclusive upon the parties.

28.4 In connection with any such controversy, claim or dispute, each party shall be entitled to undertake and compel discovery with respect to such controversy, claim or dispute in the manner provided by and to the extent permitted by Rules 26-37 of the United States Federal Rules of Civil Procedure (as interpreted by the United States District Court for the Southern District of New York and the United States Court of Appeals for the Second Circuit or the Federal Circuit, whichever appellate court would have jurisdiction over appeals of the applicable controversy, claim or dispute taken from the United States District Court for the Southern District of New York) which Rules shall be fully applicable to and enforceable in all respects in such arbitration proceeding.

28.5 The arbitrators shall have the authority to grant any interim award and to order any interim or permanent relief as they may deem necessary or advisable under the circumstances, including, but not limited to, a grant of injunctive relief or an order of specific performance.

28.6 The parties shall bear equally the costs and expenses of arbitration, and each such party shall bear the costs and expenses of its own counsel, technical advisors and expert witnesses, unless the decision of the arbitrators shall otherwise direct.

28.7 If in connection with any controversy, claim or dispute under this Agreement, the ICC fails to give effect to any of the provisions of Sections 28.2, 28.3, 28.4, 28.5 or 28.6, then this Article XXVIII shall not apply to such controversy, claim or dispute.

28.8 Any arbitration award or any interim relief or award rendered in accordance with this Article XXVIII shall be satisfied promptly and without the need for the prevailing party to seek enforcement, which may be sought in any court having competent jurisdiction. In the event resort to enforcement proceedings are required for any interim or final award or decision, the party which has not complied with the arbitral award or decision, whether interim or final, shall be responsible for both parties' reasonable attorneys' fees and all costs in the enforcement proceeding.

#### **ARTICLE XXIX. Force Majeure**

29.1 Neither party shall be responsible to the other for any failure or delay in performing any of its obligations under this Agreement or for other nonperformance hereunder if such delay or nonperformance is caused by strike, stoppage of labor, lockout or other labor trouble, fire, flood, accident, act of God or of the government of any country or of any State or local Government, or of the public enemy of either, or by cause unavoidable or beyond the control of any party hereto. In such event, the party affected will use reasonable commercial efforts to resume performance of its obligations.

## ARTICLE XXX. Amendments

30.1 No provision of this Agreement may be amended or modified other than by a written document signed by authorized representatives of each party.

## ARTICLE XXXI. Miscellaneous

31.1 Intentionally Omitted.

31.2 Relationship of the Parties. Nothing contained in this Agreement shall be deemed to constitute a partnership, joint venture, or legal entity of any type between Licensor and Licensee, or to constitute one as the agent of the other. Both parties shall act solely as independent contractors, and nothing in this Agreement shall be construed to give either party the power or authority to act for, bind, or commit the other party.

31.3 Licensor Obligations. All obligations of Licensor under this Agreement shall be joint and several obligations of the Licensor Entities.

31.4 Entire Agreement. This Agreement, together with the Exhibits and Appendices hereto, sets forth the entire agreement and understanding of the parties as to the subject matter hereof and supersedes all proposals, oral or written, and all other communications between the parties with respect to such subject matter, including but not limited to the Letter of Intent (the "Letter of Intent") dated December 20, 2000 between Licensor and Licensee and the Confidentiality Agreement between Dr. Reddy's Research Foundation and Novartis Pharma AG signed by Dr. Reddy's Group on December 23, 1999 and signed by Novartis Pharma AG on January 3, 2000, as modified by the Letter of Intent (the "Confidentiality Agreement"). The foregoing shall not relieve any party from liability resulting from the breach of the Letter of Intent or the Confidentiality Agreement prior to the Effective Date.

31.5 Trademarks and Tradenames. This Agreement does not confer any right to use the trademarks except as provided in Section 21.5 or, except as may be required by applicable law, the name, of either party.

31.6 Interpretive Rules.

(a) References to dollars or "\$" in this Agreement mean United States dollars.

(b) As the context requires, the terms defined herein include the singular as well as the plural.

(c) Words of inclusion shall not be construed as terms of limitation herein, so that references to "included" matters shall be regarded as non-exclusive, non-characterizing illustrations.

(d) The use of a pronoun of one gender is deemed to include a pronoun of the appropriate gender.

(e) The headings of Articles and Sections of this Agreement are for convenience of reference only and shall not affect the meaning or interpretation of this Agreement in any way.

31.7 Successors and Assigns. This Agreement shall be binding upon and inure to the benefit of the parties hereto and their respective successors and permitted assigns.

31.8 Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

31.9 No Waiver. The failure of either party to assert a right hereunder or to insist upon compliance with any term or condition of this Agreement shall not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition by the other party.

31.10 Notices. All notices, consents, waivers, and other communications under this Agreement must be in writing and will be deemed to have been duly given when (a) delivered by hand (with written confirmation of receipt), (b) sent by telecopier (with written confirmation of receipt), provided that a copy is sent by a nationally recognized overnight delivery service (receipt requested), or (c) when received by the addressee, if sent by a nationally recognized overnight delivery service (receipt requested), in each case to the appropriate addresses and telecopier numbers set forth below (or to such other addresses and telecopier numbers as a party may designate by notice to the other parties):

If to Licensor:

Dr. Reddy's Laboratories Limited  
7-1-27 Ameerpet  
Hyderabad - 500016  
India  
Fax: 91 40 373 1955  
Attention: Mr. K. Satish Reddy, Managing Director and Chief Operating Officer

Reddy-Cheminor, Inc.  
66 South Maple Avenue  
Ridgewood, New Jersey 07450  
Fax: (201) 444-1456  
Attention: Cameron Reid, President

Reddy Netherlands B.V.  
34, Koningslaan  
1075 AD Amsterdam  
Fax: 31 20 7747747  
Attention: Dr. K. Anji Reddy, Managing Director

with a copy to:

If to Licensee:

Novartis Pharma AG  
Lichtstrasse 35  
Post Office Box 4002  
Basle, Switzerland  
Attn.: Legal Department  
Fax: 41-61-324-7399

with a copy to:

Novartis Pharma AG  
Lichtstrasse 35  
Post Office Box 4002  
Basle, Switzerland  
Attn: Head, Business Development and Licensing

31.11 Expenses. Each of the parties hereto shall bear its own expenses (including, without limitation, all compensation and expenses of counsel, financial advisors and consultants) incurred in connection with the preparation and execution of this Agreement and the consummation of the transactions contemplated hereby.

31.12 Further Assurances. Licensee and Licensor hereby covenant and agree without the necessity of any further consideration, to execute, acknowledge and deliver any and all such other documents and take any such other action as may be reasonably necessary to carry out the intent and purposes of this Agreement.

IN WITNESS WHEREOF, the parties intending to be bound have caused this Agreement to be executed by their duly authorized representatives, as of the date first above written.

DR. REDDY'S LABORATORIES LIMITED

By: /s/

Name: K. Satish Reddy

Title: Managing Director & Chief Operating Officer

REDDY-CHEMINOR, INC.

By: /s/

Name: Dr. K. Anji Reddy

Title: Director

REDDY NETHERLANDS B.V.

By: /s/

Name: Dr. K. Anji Reddy

Title: Managing Director

NOVARTIS PHARMA AG

By: /s/

Name: Subhanu Saxena

Title: Global Head, BD&L – Primary Care

By: /s/

Name: Herbert Gut

Title: General Counsel

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**EXHIBIT A-1**  
**The Primary Compound**

Redacted

**EXHIBIT A-2**

**Syntheses of the Primary Compound**

Redacted

**EXHIBIT B**  
**Licensors Patent Rights**

Redacted

**EXHIBIT C**

Sample Invoice

[Licensor Letterhead]

[Date]

Novartis Pharma AG  
Zentraler Faktoreneingang  
Attn: Ms. M. Gnehm  
Lichtstrasse 35  
CH - 4002  
Basle, Switzerland

Dear Ms. Gnehm,

Re: License Agreement

This is an invoice requesting payment in connection with the above-captioned Agreement between Licensor and Novartis Pharma AG.

Novartis Contract Code N°: [will be assigned within Novartis following execution]

Novartis Cost Centre: [will be assigned within Novartis]

SPECIFICATION: [PLEASE SPECIFY THE EVENT FOR WHICH THE INVOICE IS DUE, AND ADD ANY COPIES OF INVOICES FROM THIRD PARTIES IN CASE REIMBURSEMENT FOR THIRD PARTY WORK IS AGREED TO]

Amount and Currency: [self-explanatory]

Bank address and Account No.: [insert the name and address of the bank to which the payment should be sent and the account number to which it should be credited]

Sincerely yours,

Licensor

Reddy Novartis License Agreement Redacted

EXHIBIT D

CONFIDENTIALITY AGREEMENT

THIS AGREEMENT is made and entered into this \_\_\_\_ day of \_\_\_\_\_, \_\_\_\_\_, by and between Novartis Pharma AG, Lichtstrasse 35, Post Office Box 4002, Basle, Switzerland (hereinafter referred to as "Novartis") and \_\_\_\_\_, \_\_\_\_\_ (hereinafter referred to as "Recipient").

WITNESSETH:

WHEREAS, Novartis possesses certain confidential and proprietary information and is willing to disclose such confidential and proprietary information to Recipient, subject to Recipient's agreement to the terms and conditions herein set forth.

NOW, THEREFORE, Recipient agrees as follows:

1. Novartis will disclose to Recipient certain confidential and proprietary information in connection with that certain License Agreement (the "License Agreement") between Novartis and Dr. Reddy's Laboratories Limited, Reddy-Cheminor, Inc. and Reddy Netherlands B.V. (collectively, "Reddy") dated as of May \_\_, 2001 (hereinafter "Confidential Information") for the purpose of allowing Recipient to determine whether there has been an overpayment or underpayment of royalties pursuant to the License Agreement and to determine whether the royalties paid by Licensee were determined and accurately calculated in accordance with the License Agreement.

2. In consideration of Novartis' disclosure of the Confidential Information, Recipient agrees that it shall make no use of any of the Confidential Information except for the aforementioned purpose and shall prevent disclosure of the Confidential Information to third parties (including Reddy, except as provided in Paragraph 5 below). These restrictions shall not apply to Confidential Information which:

(a) at the time of disclosure is available to the public through no fault of Recipient;

(b) Recipient can demonstrate by written records, was known to, or was otherwise in the possession of, Recipient prior to the receipt of such Confidential Information from Novartis or its Affiliates; or

(c) Recipient can demonstrate by prior written records was obtained by Recipient from a source other than Novartis or its Affiliates and other than one who would be

breaching a commitment of confidentiality to Novartis or its Affiliates by disclosing the Confidential Information to Recipient.

3. Recipient shall limit disclosure of the Confidential Information received hereunder to only those of its employees who are directly concerned with the purpose stated above. Recipient shall advise its employees upon disclosure of any Confidential Information to them of the confidential nature of the Confidential Information and the terms and conditions of this Agreement and shall use all reasonable safeguards to prevent unauthorized disclosure by such employees. In any event, Recipient shall be liable hereunder for any unauthorized disclosure by such employees.

4. Recipient agrees to return to Novartis all Confidential Information (including copies and excerpts) upon the request of Novartis.

5. Notwithstanding the foregoing, Recipient shall be entitled to submit a written report to Reddy based on its review of the Confidential Information and consultations with Reddy and Novartis personnel (such review and consultations to be in accordance with the License Agreement) which in Recipient's reasonable judgment bear on whether the royalties paid by Licensee were determined and accurately calculated in accordance with the License Agreement, *provided* that a copy of such report shall also be provided to Novartis.

6. Should Recipient receive judicial process, court order or administrative request seeking the production of information disclosed to Recipient hereunder, then Recipient shall so notify Novartis in sufficient time as to allow Novartis a reasonable opportunity to seek a protective order.

7. The failure of Novartis to require performance of any of the provisions of this Agreement shall in no manner limit Novartis' right to enforce such provisions at a later time.

8. Recipient acknowledges and expressly agrees that any disclosure of Confidential Information in violation of this Agreement would be detrimental to Novartis' business. In accordance with applicable law and in addition to any other rights and remedies available to Novartis, Novartis shall be entitled to secure equitable relief by way of injunction or otherwise and Recipient will immediately return all Confidential Information and materials received pursuant to this Agreement.

9. This Agreement shall be construed in accordance with the laws of the State of New York.

10. This Agreement shall be assignable by Novartis to one or more of its affiliates, or to a successor or assign of the business to which this Agreement relates, to the same extent as, and only in connection with, assignment by Novartis of its rights under the License Agreement. As used herein, the word "affiliates" shall mean corporations, partnerships or other business entities, and the employees and agents thereof which, directly or indirectly, are controlled by, control, or are under common control with, Novartis. Otherwise, this Agreement shall not be

assignable by either party without the prior express written consent of the other party. Any assignment or attempt at same in contravention of the foregoing shall be void and without effect. For the purposes of this paragraph, a transfer of all or substantially all of the stock or assets of Recipient shall be deemed an assignment.

11. This Agreement constitutes the entire understanding between the parties relating to the subject matter hereof, and no amendment or modification to this Agreement shall be valid or binding upon the parties unless made in writing and signed by each party.

IN WITNESS WHEREOF, the parties hereto have entered into this Agreement as of the day and year first above written.

NOVARTIS:

Novartis Pharma AG

By \_\_\_\_\_  
Name \_\_\_\_\_  
Title \_\_\_\_\_

RECIPIENT:

[\_\_\_\_\_]

By \_\_\_\_\_  
Name \_\_\_\_\_  
Title \_\_\_\_\_

Exhibit E

Redacted

Schedule 7.1



Schedule 12.2(b)

[REDACTED]

[REDACTED]

[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]

[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

---

<sup>1</sup> Unofficial application serial no.