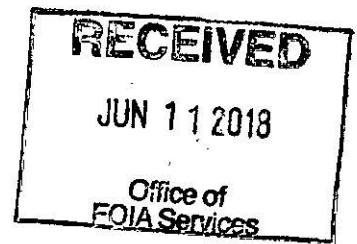


18-04678-E

ktMINE
940 West Adams
Suite 100
Chicago, IL 60607

June 11, 2018

U.S. Securities & Exchange Commission
Office of FOIA Services
100 F Street NE
Mail Stop 2465
Washington, DC 20549



Hello,

Under the Freedom of Information Act (FOIA), please send the confidential portions (i.e. unredacted documents) corresponding to the expiration of the Confidential Treatment Order submitted under Rule 24b-2 of the following company:

Exhibit 10.43 to the form 10-Q/A filed by Pharmaceutical Resources Inc. on January 11, 2002.

We authorize \$0 for search and review fees, as these documents have been previously requested. Please contact me if search will require additional fees beyond the above mentioned. I can be reached via email at julia.justusson@ktmine.com.

Thank you,

A handwritten signature in black ink, appearing to read "Julia Justusson". The signature is fluid and cursive, with a long horizontal stroke at the end.

Julia Justusson
Research Analyst



UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
STATION PLACE
100 F STREET, NE
WASHINGTON, DC 20549-2465

Office of FOIA Services

June 13, 2018

Ms. Julia Justusson
ktMINE
940 West Adams, Suite 100
Chicago, IL 60607

RE: Freedom of Information Act (FOIA), 5 U.S.C. § 552
Request No. 18-04678-E

Dear Ms. Justusson:

This letter is in response to your request, dated June 11, 2018 and received in this office on June 11, 2018, for Exhibit 10.43 to the Form 10-Q/A filed by Pharmaceutical Resources Inc. on January 11, 2002.

The search for responsive records has resulted in the retrieval of 31 pages of records that may be responsive to your request. They are being provided to you with this letter.

If you have any questions, please contact me at luetkenhausj@sec.gov or (202) 551-8352. You may also contact me at foiapa@sec.gov or (202) 551-7900. You also have the right to seek assistance from Aaron Taylor as a FOIA Public Liaison or contact the Office of Government Information Services (OGIS) for dispute resolution services. OGIS can be reached at 1-877-684-6448 or Archives.gov or via e-mail at ogis@nara.gov.

Sincerely,

A handwritten signature in black ink that reads "Jason Luetkenhaus".

Jason Luetkenhaus
FOIA Lead Research Specialist

Enclosures

Execution Copy

Dated December 11, 2001
ELAN CORPORATION PLC.
AND
PAR PHARMACEUTICAL, INC.

DEVELOPMENT, LICENSE AND SUPPLY AGREEMENT
INDEX

RECEIVED
OFFICE OF THE SECRETARY
2002 FEB -1 PM 3:02

THIS AGREEMENT is made on December 11, 2001.

BETWEEN:

- (1) ELAN CORPORATION, PLC., a company incorporated in Ireland having its registered office at Lincoln House, Lincoln Place, Dublin 2, Ireland; and
- (2) PAR PHARMACEUTICAL, INC., a company organized under the laws of New Jersey, with offices at One Rain Ridge Road, Spring Valley, New York 10977, United States of America

RECITALS:

A. Elan is beneficially entitled to the use of various patents which have been granted or are pending under the International Convention in relation to the development and production of drug specific dosage forms for pharmaceutical products and processes.

B. In each of the following 5 years, Par wishes for Elan to develop a formulation of two of the Compounds (as agreed between Par and Elan) and thereafter for Par to market the same, on the terms and conditions set out herein.

C. Accordingly, Par wishes to enter into this Agreement to obtain the right to utilize the Elan Intellectual Property to import, use, offer for sale and sell the Products in the Territory.

NOW IT IS HEREBY AGREED AS FOLLOWS:

CLAUSE 1 PRELIMINARY

1.1. Definitions:

"AB Rateable" shall have the meaning as defined and accepted by the FDA.

"Affiliate" shall mean any corporation or entity controlling or controlled or under common control with Elan or Par, as the case may be. For the purposes of this Agreement, "control" shall mean the direct or indirect ownership of more than 50% of the issued voting shares or other voting rights of the subject entity to elect directors or the governing body, or if not meeting the preceding criteria, any entity owned or controlled by or owning or controlling at the maximum control or ownership right permitted in the country where such entity exists.

"ANDA" shall mean an abbreviated new drug application filed with the FDA, including any supplements or amendments thereto which may be filed.

"CGCP, CGMIP, CGLP" shall mean respectively current Good Clinical Practice, current Good Manufacturing Practice and current Good Laboratory Practice as defined in the U.S. Federal Food,

Drug and Cosmetic Act and the regulations promulgated thereunder, as may be amended from time to time.

"CFW" shall mean the US Code of Federal Regulations 21, as amended from time to time.

"CMC Section" shall mean the chemistry, manufacturing, and controls section of the Regulatory Application as defined in CFR Section 314.50 (1), as may be amended from time to time.

"Competing Product" shall mean a product AB Rateable to any Product

"Compound" shall mean one of the active drug products listed in Schedule 2, all of which are AB Rateable to another product, which Schedule may be added to by mutual agreement of the parties, provided that any such additions shall be AB Rateable to another product.

"Development Costs" shall mean the fully allocated cost of developing the Products calculated in accordance with Elan's normal accounting practice and in a manner consistent with expenses and overhead allocated to other controlled release products developed by Elan. Development Costs shall include the total costs of developing the Products which is the sum total of all direct (including external contracted activities, biostudies, API etc.) and indirect costs including attributable overheads.

"DNW" shall mean Drug Master File, as defined in the CFR Section 314.420 and/or its equivalent in the other countries of the Territory.

"Effective Date" shall mean the date of this Agreement.

"Elan" shall mean Elan Corporation, plc., a public limited company incorporated under the laws of Ireland.

"Elan Improvements" shall mean any and all improvements to the Elan Patents, the Elan Know-How and/or the Elan Technology and/or the Product that have been conceived, created, developed and/or otherwise invented by Elan and/or Par under the R&D Program, or otherwise pursuant to this Agreement.

"Elan Intellectual Property" shall mean the Elan Know-How, the Elan Patents, the Elan Technology and the Elan Improvements.

For the avoidance of doubt, Elan Intellectual Property shall exclude inventions, patents and know-how owned, licensed or controlled by the Excluded Entities.

"Elan Know-How" shall mean any and all rights owned, licensed or controlled by Elan to any scientific, pharmaceutical or technical information (including information in the CMC Section), data, discovery, invention (whether patentable or not), know-how, substances, techniques, processes, systems, formulations, designs and expertise relating to controlled release formulation or other Elan Technology (as defined in the R&D Program).

For the avoidance of doubt, Elan Know-How shall exclude any know-how owned, licensed or controlled by one or more of the Excluded Entities.

In the event that Elan acquires or merges with a third party entity, Elan Know-How shall not include any know-how to the extent that such know-how relates to a product containing the same active ingredient as a Product which has been approved for marketing or is in development by the said third party entity at the time of such acquisition or merger. For the avoidance of doubt, the occurrence of any such acquisition or merger shall not affect the license of the Elan Know-How granted to Par hereunder.

"Elan Patents" shall mean any and all rights under any and all patent applications and/or patents, now existing, currently pending or hereafter, filed or obtained or licensed by Elan relating to controlled release formulations as set forth in Schedule 1, or to other Elan Technology (as defined in the R&D Program) and any foreign counterparts thereof and all divisionals, continuations, continuations-in-part, any foreign counterparts thereof and all patents issuing on any of the foregoing, and any foreign counterparts thereof, together with all registrations, reissues, re-examinations, supplemental protection certificates, or extensions thereof, and any foreign counterparts thereof.

For the avoidance of doubt, Elan Patents shall exclude any patents owned, licensed or controlled by one or more of the Excluded Entities.

In the event that Elan acquires or merges with a third party entity, Elan Patents shall not include any know-how to the extent that such know-how relates to a product containing the same active ingredient as a Product which has been approved for marketing or is in development by the said third party entity at the time of such acquisition or merger. For the avoidance of doubt, the occurrence of any such acquisition or merger shall not affect the license of the Elan Patents granted to Par hereunder.

"Elan Technology" shall have the meaning defined in the R&D Program for a Nominated Compound.

"Excluded Entities" shall mean The Liposome Company, Inc. and its subsidiaries; Athena Neurosciences Finance LLC; Axogen Limited; Neuralab Limited; Dura Pharmaceuticals, Inc. and its subsidiaries; Quadrant Healthcare PLC; Delsys; Elan Pharmaceuticals Research Corporation and its subsidiaries; and Affiliates (present or future) of Elan Corp within the division of Elan Corp carrying on business as Elan Pharmaceuticals which incorporates, inter alia, EPIL (only to the extent that it is the owner of patents, know-how or other intellectual property or technology invented and/or developed within the division of Elan Corp carrying on business as Elan Pharmaceuticals), Athena Diagnostics Inc., Athena Neurosciences, Inc., Elan Pharmaceuticals, Inc. and Elan Europe Limited and its subsidiaries.

"Elan's Facility" shall mean Elan's manufacturing facility at Athlone, Ireland, or such other facility as Elan may from time to time specify.

"Ex Works" shall have the meaning as such term is defined in the ICC Incoterms, 2000, International Rules for the Interpretation of Trade Terms, ICC Publication No. 560.

"FDA" shall mean the United States Food and Drug Administration or any other successor agency whose approval is necessary to market the Product in the USA.

"First Commercial Sale" shall mean in respect of a Product the first sale under this Agreement in an arm's length transaction to an independent third party. Par will provide Elan with written notice of the date of such sale.

"Force Majeure" shall mean causes beyond a party's reasonable control, including, without limitation, acts of God, fires, strikes, acts of war, or intervention of a Governmental Authority or non-availability of raw materials.

"Gross Profit" in respect of a Product shall mean Net Sales of that Product less Product Manufacturing Cost.

"Governmental Authority" shall mean and include all governmental and regulatory bodies, agencies, departments or entities, whether or not located in the Territory, which regulate, direct or control commerce in or with the Territory.

"In Market" shall mean the sale of the Product in the Territory by Par and/or its Affiliates, or where applicable by a permitted sub-licensee, to an unaffiliated third party such as (i) the end-user consumer of the Product; or (ii) a wholesaler, distributor, managed care organization, hospital or pharmacy or other unaffiliated third party which effects the final commercial sale to the end-user consumer of the Product, and shall exclude the transfer pricing of the Product by Par to an Affiliate or a permitted sub-licensee.

"Launch Stocks" shall mean the quantities of stocks of a Product required by Par to support the commercial introduction of that Product following Regulatory Approval.

"Marketing Committee" shall mean the committee to be established pursuant to Clause 10.

"Net Sales" shall mean in the case of Product sold by Par or an Affiliate or a permitted sub-licensee, that sum determined by deducting from the aggregate gross In Market sales proceeds billed for the Product by Par or, its Affiliate or a permitted sub-licensee, as the case may be, in accordance with generally accepted accounting principles:

- (i) customs duties or other taxes (excluding income or corporation tax), directly related to the sale of the Product which are paid by Par or its Affiliate or permitted sub-licensees as the case may be;
- (ii) a discount from the gross sales proceeds to cover such normal costs as are incurred by Par or its Affiliates or permitted sub-licensees, as the case may be, in respect of (A) returns, rebates (including Medicaid rebates), cash discounts (including discounts attributable to lowered prices due to the introduction of less expensive competitive products), advertising costs that are mutually

agreed to by the Marketing Committee, and allowances offered to, and actually taken by, third parties in the ordinary course of business, (B) applicable freight and shipping costs, and (C) applicable insurance costs, in each case directly related to the sale of the Product.

"Nominated Compound" shall mean a Compound nominated pursuant to Clause 3.2.

"Par" shall mean Par Pharmaceutical, Inc., a company organized under the laws of New Jersey, with offices at One Ram Ridge Road, Spring Valley, New York 10977, United States of America, and its Affiliates.

"Product" shall mean an active pharmaceutical form of a Nominated Compound that was created using or incorporates the Elan Intellectual Property.

"Product Manufacturing Cost" shall mean the fully allocated cost which is the sum total of all production related costs, packaging and labeling for the Product (direct labor, direct materials, facility overhead, other overhead and expenses, including but not limited to manufacturing charges for material adjustments, handling losses, physical adjustments, salvage and start-up costs, QA/QC and analytical charges, packaging and regulatory compliance costs for the Product including, but not limited to, stability and FDA fees), together with insurance costs accounted for in accordance with United States Generally Accepted Accounting Principles and in manner consistent with expenses and overhead allocated to other products manufactured by Elan.

"Product Specifications" shall mean in relation to a Product, the specifications set forth in the R&D Program or the Regulatory Application, such specifications as may from time to time be established by the applicable regulatory authorities, including without limitation, cGCPs, eGMPs and cGLPs, and such additional specifications for the Product as may be agreed by the parties in writing

"Regulatory Application" shall mean any regulatory application or any other application for marketing approval for the Product, which Elan will file in the Territory, including any supplements or amendments thereto which Elan will file.

"Regulatory Approval" shall mean the final approval to market the Product in the Territory, including pricing and reimbursement approval and any other approval which is required to launch the Product in the normal course of business.

"Technological Competitor" shall mean a person or entity listed in Schedule 3, and divisions, subsidiaries and successors thereof, or any additional broadbased technological competitor of Elan added to such Schedule from time to time upon mutual agreement of Par and Elan.

"Term" shall mean the term of this Agreement, as set out in Clause 14.

"Territory" shall mean the United States of America, its territories, protectorates and possessions.

"\$" shall mean United States Dollars.

1.2. Further Definitions:

In addition, the following definitions have the meanings in the Clauses corresponding thereto, as set forth below.

Definition	Clause
"Confidential Information"	17.1.1
"Due Date"	12.4
"Elan License"	2.1
"First Approval"	8.1.1
"Initial Period"	14.1
"Joined Party"	4.2.6
"Monthly Sales Estimate"	12.1
"Non-Joined Party"	4.2.6
"R&D Program"	6.1
"Statement"	12.1

1.3. Interpretation: In this Agreement:

1.3.1 the singular includes the plural and vice versa, the masculine includes the feminine and vice-versa and references to natural persons include corporate bodies, partnerships and vice versa.

1.3.2 any reference to a Clause or Schedule, unless otherwise specifically provided, shall be respectively to a Clause or Schedule of this Agreement..

1.3.3 the headings of this Agreement are for ease of reference only and shall not affect its construction or interpretation

1.3.4 the expressions "include" and "including" shall be construed without limitation.

CLAUSE 2 THE LICENSE

2.1. License to Par:

2.1.1 Subject to the terms of this Agreement, Elan hereby grants to Par for the Term an exclusive license (the "%Ian License") to the Elan Intellectual Property for the sole purpose of, and to the extent necessary for, importing, using, offering for sale and selling the Products in the Territory, subject (in respect of each Product) to any contractual obligations that Elan has as of the date on which the Compound in question becomes a Nominated Compound. For the avoidance of doubt (a) nothing in this Agreement shall prevent Elan or Par from entering into agreements and/or negotiations with third parties in respect of any Compound unless and until such time as that Compound becomes a Nominated Compound, and (b) Par acknowledges and understands that Elan makes no representations or warranties regarding Elan's freedom from contractual obligations to develop any of the Compounds.

2.1.2 Elan shall possess all rights including, without limitation, the right to research, develop, experiment with, manufacture, sell, license or otherwise market the Products outside the Territory.

2.2. Sub-licensing by Par:

2.2.1 Par shall be entitled, subject to the prior written consent of Elan which shall not be unreasonably withheld or delayed, to grant sublicenses in respect of the intellectual property rights licensed by Elan to Par under Clause 2. 1, provided that Par shall grant one sub-license only per Product and Par shall not grant a sub-license to a Technological Competitor.

2.2.2 Any sub-license granted hereunder shall be in the same terms mutatis mutandis as the terms of this Agreement insofar as they are applicable, but excluding the right to grant a further sub-license.

2.2.3 For the avoidance of doubt, Par shall ensure that Elan shall have the same rights of audit and inspection vis-à-vis a sub-licensee, as Elan has pursuant to this Agreement concerning Par.

2.2.4 Par shall be liable to Elan for all acts and omissions of any sublicensee as though such acts and omissions were by Par but only to the extent that Par would have been liable for such acts and omissions.

2.2.5 Where a sub-license has been granted under Clause 2.2. 1, such sublicense shall automatically terminate if this Agreement terminates.

2.2.6 Par shall not disclose any Confidential Information of Elan in its dealings with permitted sub-licensees without the prior written consent of Elan, which consent shall not be unreasonably withheld or delayed.

2.2.7 For the avoidance of doubt:

2.2.7.1 the parties agree that any sub-license granted pursuant to this Clause 2.2 shall not be capable of surviving the termination of this Agreement and Par shall promptly notify any sub-licensee of the termination of this Agreement; and

2.2.7.2 In Market sales of the Products by the sub-licensee shall be included in calculating Net Sales for the purposes of this Agreement.

CLAUSE 3 SELECTION OF COMPOUNDS

3.1. At any given time or at least in the fourth calendar quarter of each of the first 5 calendar years of the Term, authorized representatives of the parties shall meet and discuss in good faith, having regard to the prevailing market conditions and their then existing contractual obligations and market strategies:

3.1.1 which two of the Compounds (and in the case of the second to fifth calendar years, whether two of the Compounds) shall be selected for the commencement of development work in the following calendar year; and

3.1.2 whether, and if so how, the list of Compounds ought to be revised.

3.2. Pursuant to such discussions, unless otherwise agreed, the parties shall select in writing two Compounds for development pursuant to this Agreement during the following calendar year. Such discussions shall take into account whether the Compound is subject to contractual obligations of Elan or Par which would restrict the conduct of the R&D Program, the scope of the Elan License or the ability of Par to market the Product.

3.3. For the avoidance of doubt, during the first 5 calendar years of the Term, Elan shall not be obliged to commence development work in respect of a third or subsequent Compound unless Elan expressly agrees to do so.

3.4. The parties may by mutual written agreement abandon development of a Product at any time. In that event the Compound in question shall cease to be a Nominated Compound, but without prejudice to Elan's right to payment for the work conducted prior to that date, and Par shall have no further Elan License rights to such Product. Par shall reimburse Elan for work conducted within 60 days of that date.

CLAUSE 4 INTELLECTUAL PROPERTY

4.1. Ownership of Intellectual Property:

Elan shall be the owner of the Elan Intellectual Property.

4.2. Infringements and Misappropriation:

4.2.1 As the holder of the Regulatory Approval for a Product, Elan shall be responsible for making any required certifications under Section 505(b) of the U.S. Federal Food, Drug and Cosmetic Act ("Certification"). Elan will not make such Certification without first notifying, consulting and reaching mutual agreement with Par. If Par does not agree within 30 days of Elan's notification, the Product will be deemed abandoned pursuant to Clause 3.4. Par agrees to cooperate with Elan in all respects including providing any prior art or other information known to Par that is relevant to the Certification. If Elan elects to use outside counsel in connection with the Certification, such outside counsel shall be mutually agreed to by the parties and neither party shall unreasonably withhold its agreement to same. The parties shall share equally the cost of such outside counsel, including costs associated with patent review and invalidity and infringement analyses.

4.2.2 Par and Elan shall promptly inform the other in writing of any Defense Infringement or Enforcement Infringement (as those terms are defined below) of which it shall become aware in the Territory. The Party with such knowledge shall provide the other Party with any available evidence of alleged infringement or misappropriation. "Defense Infringement" shall mean any alleged

infringement or misappropriation by the filing of the ANDA or by the Product of a third party's intellectual property rights. "Enforcement Infringement" shall mean any alleged infringement or misappropriation by a third party of any rights within the Elan Intellectual Property or any affirmative challenge by a third party of the validity or enforceability of the Elan Intellectual Property.

4.2.3 In the event of any alleged Enforcement Infringement, Elan shall be entitled to institute, carry on and control proceedings (in its own name and/or that of Par) for Enforcement Infringement, including any counterclaims that may be raised in Defense Infringement. Elan shall pay the litigation costs and expenses of Enforcement Infringement, unless such proceeding is a counterclaim raised in Defense Infringement, in which case the parties shall share equally the litigation costs and expenses and also share equally in any recovery from such proceeding.

4.2.4 In the event of any alleged Defense Infringement, the following provisions shall apply. If a third-party institutes proceedings against Par and/or Elan separately, the party named in such proceeding will name the other party as co-defendant if permitted by the court or, if required by the court, will not oppose and will support a motion to intervene by the other party. Whether or not such third party institutes proceedings, and regardless of whether Par is joined or not, Par shall control the Defense Infringement but Par shall not engage in communications with the plaintiff that could adversely impact Elan nor shall Par settle the Defense Infringement without first consulting and reaching mutual agreement with Elan. Outside counsel used in the Defense Infringement shall be mutually agreed to by the parties and neither party shall unreasonably withhold its agreement to same. Either party may elect to have separate legal representation. The Parties shall share equally the litigation costs and expenses in defending such an action (including the reasonable legal costs and expenses incurred by a Party who elects to have separate legal representation), including reasonable attorney fees, experts fees etc. In the event that Par decides in writing that it does not wish to conduct such defense, Elan may at its option elect to do so instead of Par, without prejudice to Elan's rights and Par's obligations under 4.2.5. For the avoidance of doubt, after consultation with Par, Elan shall decide whether to bring a counterclaim for Enforcement Infringement raised in Defense Infringement and Elan shall have sole control over such proceedings.

4.2.5 Par shall bear all and any liability to one or more third parties for Defense Infringement (including a claim, court order or judgment for a lump sum, ongoing royalties or a settlement to one or more third parties) and shall indemnify and keep indemnified Elan against any claim, judgment or court order made against Par or Elan in respect of the same; provided however Par has the sole right to decide whether to launch a particular Product.

4.2.6 In each case where only one of the Parties (the "Joined Party") is a party to proceedings, whether in respect of an alleged Enforcement Infringement or an alleged Defense Infringement, the Joined Party shall provide to the other Party (the "Non-Joined Party"):

- (i) updates as to its progress on a regular basis; and
- (ii) such other information concerning the litigation as the Non-Joined Party may reasonably request, subject always to the Non-Joined Party having provided undertakings as to confidentiality and the non-waiver of privilege to the reasonable satisfaction of the Joined Party

PROVIDED THAT the Joined Party shall be under no obligation to disclose to the Non-Joined Party any advice of outside attorneys. Furthermore the Joined Party shall discuss litigation strategy at reasonable times with the Non-Joined Party (but shall not be bound to follow any recommendation of the Non-Joined Party) and shall keep the Non-Joined Party informed of any actual or proposed change in outside counsel used in respect of the said litigation.

4.2.7 The Non-Joined Party shall provide all reasonable co-operation in the litigation, including without limitation Product technical expertise to the other Party to support any Defense Infringement litigation or Enforcement Infringement litigation (including complying with requests for orders for discovery and depositions). Any expenses incurred by Elan or Par in providing such Product technical expertise shall be included in the total patent review and legal expenses, in accordance with Clause 4.2.4.

4.2.8 Costs which are shared pursuant to Clauses 4.2.1, 4.2.3 and 4.2.4 shall be paid in the first instance by Elan. Par shall pay its share of such costs to Elan as and when sufficient Profit becomes available to it to discharge such share PROVIDED THAT in the event of (i) the termination of this Agreement, howsoever arising; or (ii) Par not having effected full scale commercial launch of the Product in the Territory on or before the Date For Launch (whether or not Elan exercises its right of termination in respect of the same), the entire balance of Par's share of such costs shall become immediately due and payable.

4.3. Trademarks:

4.3.1 Par may market, sell and/or distribute each Product under any trademark or trademarks and trade dress as Par or its customers may from time to time select. Such trademarks shall remain the sole property of Par or its customers as the case may be, and Elan shall not use any such trademark(s) whether during the term or thereafter, and whether in the Territory or outside the Territory, without the prior written consent of Par.

4.3.2 For the term of this Agreement Par shall grant Elan a royalty-free non-exclusive license to the applicable Par trademarks solely to enable Elan to fulfill its obligations pursuant to the terms of this Agreement.

4.4. Cessation of Development or Manufacture:

Without prejudice to any other remedy it may have hereunder, Elan shall be entitled to cease development and/or manufacture of the Product at any time where a matter comes to its attention such that, in Elan's reasonable opinion, the development and/or manufacture of the Product would constitute a material risk of the infringement of the intellectual property rights of any third party.

CLAUSE 5 NON-COMPETITION

Par shall not develop, market or sell any Competing Product in the Territory during the term of the Agreement as it relates to the Product in question (and for one year after such termination of this Agreement if the Agreement is terminated solely due to Par's default of its obligations hereunder

beyond any applicable cure period). The parties may develop, market or sell any Compound that was the subject of a Product abandoned pursuant to Clause 3.4.

CLAUSE 6 DEVELOPMENT OF EACH PRODUCT

6.1. In respect of each Nominated Compound, Elan shall prepare a development plan, setting out inter alia milestones, time lines and specification of the Product in question (the "R&D Program"). Such development plan shall take into account the reasonable comments of Par, but shall otherwise be in Elan's sole discretion.

6.2. Elan shall use reasonable commercial efforts to develop the Product in accordance with the R&D Program.

6.3. Elan and Par shall undertake their respective obligations under the R&D Program on a collaborative basis. Accordingly, the parties shall co-operate in good faith particularly with respect to unknown problems or contingencies and shall perform their respective obligations in a commercially reasonable, diligent and workmanlike manner.

6.4. In the event that Elan believes that significant additional work and/or additional costs are required over and above that set out in the R&D Program, Elan shall so inform Par. Before any further work is done, the parties shall mutually agree regarding such additional work, the necessary changes to the R&D Program and/or increased costs as the case may be.

6.5. Elan will have no liability to Par as a result of any failure or delay of the Product to achieve the Product Specifications or one or more of the milestones set out in the R&D Program and/or to obtain the Regulatory Approval in one or more of the countries of the Territory.

6.6. Unless the parties agree otherwise, Elan will maintain raw material, clinical supply and analytical samples in storage for a time period based upon Elan's sample retention policy, or such longer period of time as Par may reasonably request. Elan agrees to maintain Product batch production and control records and associated test results until the marketing application is approved by the FDA or discontinuation of its Regulatory Application in respect of the same.

CLAUSE 7 REGULATORY MATTERS

7.1. Elan shall be responsible for the compilation and filing of the Regulatory Applications in respect of the Product with the FDA and shall be the holder of any Regulatory Approvals granted for the Product and the party principally responsible for interaction with the FDA.

7.2. Elan shall notify Par of the date of submission of any Regulatory Application for the Product in the Territory and shall also notify Par in writing of the Regulatory Approval as soon as is reasonably possible following said Regulatory Approval. Elan shall notify Par in writing as soon as possible of any notification received by Elan from the FDA to conduct an inspection of its manufacturing, clinical or other facilities as directly related to the Product. Copies, of all correspondence with the FDA with respect to the Product post its acceptance for filing shall be provided to the other Party; such correspondence shall be subject to redaction by Elan to the extent

that such correspondence relates to the confidential portions of the CMC Section relating to formulation and manufacturing processes. On or after the date of First Commercial Sale, Elan shall provide Par with a status update with regard to any audit or inspection conducted by FDA which relates directly to the Product.

7.3. Par shall be responsible for obtaining all applicable state and local regulatory approvals for the distribution of the Product in the Territory. Elan shall co-operate with Par in obtaining such approvals.

7.4. It is hereby acknowledged that there are inherent uncertainties involved in the registration of pharmaceutical products with the FDA and equivalent bodies in relation to achieving the Product Specifications and obtaining the Regulatory Approvals and such uncertainties form part of the business risk involved in undertaking the form of commercial collaboration outlined in this Agreement.

Accordingly, Elan and Par shall have no liability to the other as a result of any failure of a Product to obtain Regulatory Approval.

CLAUSE 8 FORECASTS, ORDERS AND SUPPLY

8.1 In order to permit Elan to allocate its manufacturing capacity and to assist Par with its sales and marketing, Par shall provide Elan with bona fide written forecasts of its requirements of each Product as follows:

8.1.1 within 120 days of submission of an ANDA for the Product, a forecast broken down on a monthly basis, for the period beginning with the first anticipated Regulatory Approval ("First Approval");

8.1.2 thereafter every three months until First Approval, an updated forecast prepared on the same basis;

8.1.3 within 15 days of First Approval, and thereafter each calendar month not later than 23rd of the month, a 12 month forecast, broken down on a month-by-month basis, for the period commencing at the beginning of the following month; and

8.1.4 not later than 1 August in each year, a 5 year forecast, broken down on an annual basis.

8.2. The first four months of each of the forecasts referred to in Clause 8.1.3 (five months in the case of Launch Stocks) shall be binding on Par and shall be formalized by a firm purchase order from Par to Elan. Forecasts shall not otherwise be binding on either party.

8.3. In respect of each Product, Elan shall notify Par of a minimum batch size for commercial manufacture and supply.

8.4. For the avoidance of doubt, Elan shall have no obligation to supply Product in excess of Par's properly forecast requirements.

8.5. Save as otherwise provided in this Agreement, Elan shall use commercially reasonable efforts to produce and supply to Par (even if in excess of Par's previously forecasted amounts) its entire requirements of each Product, for the purposes of both development and commercial supply, within (in the case of Product for commercial supply) the time for delivery set out in the relative firm purchase orders. Elan shall be the sole and exclusive supplier of each Product to Par in the Territory and Par will purchase each Product exclusively from Elan in the Territory.

8.6. All Product shall be supplied:

8.6.1 in accordance with Par's firm purchase orders pursuant to Clause 8.2;

8.6.2 in tablet or capsule form as specified in the R&D Program;

8.6.3 Ex Works Elan's Facility;

8.6.4 free from any liens or encumbrances;

8.6.5 in accordance with Product Specifications;

8.6.6 manufactured in accordance with all prevailing legislative and regulatory requirements of the country where it is manufactured, including (where the Product is intended for commercial supply) CGMP;

8.6.7 not adulterated or misbranded; and

8.6.8 in suitable packaging, in particular as may be required pursuant to any Regulatory Approval and so as to permit safe storage and transport.

8.7. After receipt of a Product shipment, Par shall visually inspect the Product shipment. The parties agree that Par's visual inspection consists of (i) comparing the applicable order against the documentation accompanying the shipment to verify that the delivery date, identity, quantity and exterior shipment labeling comply with the order and (ii) visually inspecting the exterior of the Product shipment to verify that the shipment appears to be in good condition.

8.8. Elan shall be responsible for the packaging of the Product into final market packaging based on Par's instructions.

8.9. The terms of this Agreement are hereby incorporated by reference into each order of Product submitted by Par and accepted by Elan. In the event of any conflict between an order or other written instructions and this Agreement, the terms of this Agreement shall prevail.

8.10. Product supplied otherwise than for commercial supply shall be used by Par solely for research and development purposes, including but not limited to stability studies, packaging studies, and for clinical trials. Subject to the prior written consent of Elan, which shall not be unreasonably withheld or delayed, and subject further to the other applicable provisions of this

Agreement, validation batches may be used towards Launch Stocks and subsequent commercial supply.

8.11. In the event Par wishes to supply active pharmaceutical ingredient ("API") for a Product, the ' parties agree to discuss in good faith Elan sourcing such API from Par, but Elan shall be under no obligation to do so.

CLAUSE 9 SPECIFICATION AND DISPUTES

9.1. All claims for failure of any delivery of Product to conform to Product Specifications must be made by Par to Elan, in writing within 45 days following delivery except in the case of latent defects. Claims for latent defects, not discovered during the routine testing protocol (to be agreed by Par and Elan) shall be made in writing within 30 days of discovery. Failure to make timely claims in the manner prescribed shall constitute acceptance of the delivery.

9.2. If Product has been delivered and has been shown within the period designated in Clause 9.1 not to conform to Product Specifications, or is otherwise adulterated, misbranded or defective, then unless such non-conformity is the result of the negligent acts or omissions of Par:

9.2.1 it shall be replaced at the cost of Elan within 90 days of the receipt by Elan of notification of non-conformity or other failure hereunder; and

9.2.2 Elan shall also be responsible for all costs incurred by Par in relation to any testing, handling processing, destruction or return of the defective Product.

9.3. In the event of an unresolved dispute as to conformity of the Product with the Product Specifications, the parties shall within 30 days appoint an independent laboratory, mutually acceptable to the parties, to undertake the relevant testing and its findings shall be conclusive and binding upon the parties. All costs relating to this process shall be borne solely by the unsuccessful party.

CLAUSE 10 MARKETING AND PROMOTION OF THE PRODUCT

10.1. No later than January 2002 the Parties shall establish a Marketing Committee consisting of at least one representative from each Party who shall act as liaison between the Parties to ensure that Elan is up to date on the prevailing market conditions and Par's efforts at marketing and selling the Products.

10.2. Within 90 days of the filing of the Regulatory Application in the Territory with respect to each Product, Par will outline to Elan the structure of the promotional activities to be carried out by Par for the period up to the First Commercial Sale of the Product and annually thereafter.

10.3. Par shall both prior to and subsequent to the launch of the Product communicate with Elan at meetings of the Marketing Committee regarding its objectives for and performance of such Product in the Territory. At such meetings, Par shall report on the ongoing sales performance of the Product in the Territory, including marketing approaches, educational campaigns, promotional and

advertising materials and campaigns, sales plans and results, performance against competitors, its objectives for the Product and its plans for the next year of the Agreement. In addition the Marketing Committee shall review the quarterly royalty statements.

10.4. Unless otherwise agreed by the Parties, the Marketing Committee shall meet at least once each calendar quarter, such meetings to continue until 2 years after launch of the last Product or such later time as may be agreed. Thereafter, the Parties shall meet on an annual basis. The Marketing Committee shall meet alternately at the offices of Elan and Par or as otherwise agreed by the Parties. Each Party shall bear the cost of its own travel expenses.

10.5. Par shall control and shall be responsible for all decisions regarding the pricing policies and strategies with respect to the marketing and sales of each Product. Par shall control the format of the promotional campaign to be submitted to the FDA, but shall inform Elan thereof and provide to Elan a copy of each such promotional material for submission, at latest concurrent with its submission to the FDA. Par shall use reasonable efforts to obtain approval by the FDA of the promotional campaign for each Product and will provide to Elan any FDA correspondence thereto.

10.6. Par shall use reasonable commercial efforts consistent with its normal business practices to market and promote each Product throughout the

Territory to all appropriate classes of trade and in doing so, shall use the same level of effort as with other similar products of similar sales potential which it markets.

10.7. Par covenants that it shall not use the Product as a "loss leader" in its marketing programs and shall at all times use its reasonable efforts in marketing the Product.

10.8. Par shall submit layout and designs for all trade packaging, cartons and labels and other printed materials to Elan at least 6 months prior to First Commercial Sale of the Product. Elan shall provide label and insert copy in the Regulatory Application to the FDA in accordance with current FDA requirements PROVIDED ALWAYS that the provisions of this Clause 10.8 shall be without prejudice to the obligations and responsibilities of Par under Clause 10.5 and for the avoidance of doubt, Par shall indemnify and hold harmless Elan against all claims, damages, losses, liabilities and expenses (including reasonable attorneys' fees) to which Elan may become liable relating to the activities described in this Clause 10.

10.9. To the extent permitted by law, such materials shall include due acknowledgment that the Product is developed and manufactured by Elan. Such acknowledgment shall take into consideration regulatory requirements and Par's commercial requirements.

10.10. Par shall mark or have marked all relevant patent number(s) (if any) on all relevant packaging and labeling of the Product, subject to FDA control and regulations of all packaging copy, or otherwise reasonably communicate to the trade the existence of any patents of Elan for the Territory in such a manner as to ensure compliance with, and enforceability under, applicable laws in the Territory.

10.11. Par shall effect the full scale commercial launch of each Product in the Territory as expeditiously as practical when allowed by law, subject to the receipt of Launch Stocks of the Product and in any event within 120 days of Regulatory Approval in respect of that Product (the 'Date For Launch'). For the avoidance of doubt, it shall be Par's responsibility to order Launch Stocks in sufficient time to allow launch within such period.

CLAUSE 11 FINANCIAL PROVISIONS

11.1. Development Royalties:

The parties agree to the following regarding Development Costs:

- (a) Par shall pay to Elan up to \$1.5 million per calendar year for development of each Product. Such payments will continue each calendar year until the earlier of total repayment of all Development Costs to Elan or the launch of the Product. Elan will invoice Par on a monthly basis an amount of \$125,000 from the date of commencement of the R&D Program until the earlier of total repayment of all Development Costs to Elan or the launch of the Product.
- (b) The annual payments of \$1.5 million per Product will be aggregated and the Development Costs in any given calendar year for all Products that Par is obligated to pay Elan will not exceed such aggregated amount in any calendar year. Elan may offset Development Costs expenditure in excess of \$1.5 million in any calendar year on any individual projects against projects on which Development Costs expenditure is less than \$1.5 million in any calendar year.
- (c) Upon launch, all outstanding Development Costs will be repaid to Elan out of Par's Gross Profit. Par's Gross Profit shall first be allocated to re-payment to Elan until all outstanding amounts are satisfied. For the avoidance of doubt, Elan shall be entitled to repayment of all outstanding Development Costs incurred by Elan on any R&D Program, whether or not that R&D Program resulted in launch of a Product.

11.2. Price of Product:

11.2.1 Elan shall supply each Product to Par at the Product Manufacturing Cost in respect of that Product in accordance with the terms of this Agreement.

11.2.2 Subject to Clause 11.2.3, the Product Manufacturing Cost of each Product may be reviewed by Elan once per annum and may be adjusted for the following calendar year solely to reflect actual changes in Product Manufacturing Cost. Elan shall provide Par with written notice and reasonable backup documentation of any such increase in the Product Manufacturing Cost 60 days before the end of each calendar year to take effect in the following calendar year.

11.2.3 Any increases or decreases in the cost of the active ingredient or any other components used in the Product in excess of 3% from the then current base are to be passed on in the Product Manufacturing Cost manufactured from the effective date of use of such active ingredient or any other component.

11.3. Royalty on Sales:

In consideration of the license of the Elan Patents granted to Par under this Agreement, Par shall pay to Elan a royalty equal to 40% of Gross Profit.

11.4. Bundling:

In the event that Par or any Affiliate of Par shall sell the Product together with other products of Par to third parties (by the method commonly known in the pharmaceutical industry as "bundling"), Par shall not conduct such bundling in such a manner as to discount the Product at a greater proportion than the other products bundled by Par.

11.5. Method of calculation of royalties and fees:

The parties acknowledge and agree that the methods for calculating the fees and payments hereunder are for the purposes of the convenience of the parties, are freely chosen and not coerced.

CLAUSE 12 PAYMENTS, REPORTS AND AUDITS

12.1. Records:

Par shall keep true and accurate records of gross sales of the Product, the items deducted from the gross amount in calculating the Net Sales, the Net Sales and the royalties payable to Elan under Clause 11. Par shall deliver to Elan a written statement (the "Statement") thereof within 30 days following the end of each calendar quarter, (or any part thereof in the first or last calendar quarter of this Agreement) for such calendar quarter. The Statement shall outline the calculation of the Net Sales from gross revenues during that calendar quarter, the applicable details of deductions incurred, and a computation of the sums due to Elan. In addition, Par shall deliver to Elan a written monthly sales estimate (the "Monthly Sales Estimated") within 30 days in advance of each month setting forth its best estimate of Product sales for such month. The parties' financial officers shall agree upon the precise format of the Statement and the Monthly Sales Estimate.

12.2 Taxes:

Any income or other taxes which Par is required by law to pay or withhold on behalf of Elan with respect to royalties and any other monies payable to Elan under this Agreement shall be deducted from the amount of such Net Sales payments, royalties and other monies due. Par shall furnish Elan with proof of such payments. Any such tax required to be paid or withheld shall be an expense of and borne solely by Elan. Par shall promptly provide Elan with a certificate or other documentary evidence to enable Elan to support a claim for a refund or a foreign tax credit with respect to any such tax so withheld or deducted by Par. The parties will reasonably cooperate in completing and filing documents required under the provisions of any applicable tax treaty or under any other applicable law, in order to enable Par to make such payments to Elan without any deduction or withholding.

12.3 Mode of Payment:

12.3.1 Payment for development royalties under Clause 11. 1 shall be due and owing on date of invoicing and in any event payable within 30 days of the date of invoice.

12.3.2 Payment for Product under Clause 1 1.2 shall be made within 30 days of the date of the delivery of the Product.

12.3.3 Payment of royalties under Clause 11.3 shall be made once in each calendar quarter within 45 days after the expiry of the relevant calendar quarter.

12.3.4 All payments due hereunder shall be made in U.S. Dollars.

12.3.5 All payments due hereunder shall be made to the designated bank account of Elan in accordance with such timely written instructions as Elan shall from time to time provide.

12.4 Interest:

Par shall pay interest to Elan on sums not paid to Elan on the date on which payment should have been made pursuant to the applicable provisions of this Agreement ("Due Date") over the period from the Due Date until the date of actual payment (both before and after judgment) at the Prime Rate publicly announced by Morgan Guaranty Trust Company of New York at its principal office on the Due Date (or next to occur business day, if such date is not a business day) plus 5%, such interest to payable on demand from time to time and compounded monthly/quarterly.

12.5 Audit:

12.5.1 For the 180 day period following the close of each calendar year of the Agreement, Elan and Par will, in the event that the other party reasonably requests such access, provide each other's independent certified accountants (reasonably acceptable to the other party) with access, during regular business hours and subject to the confidentiality provisions as contained in this Agreement, to such party's books and records relating to the Products, solely for the purpose of verifying the accuracy and reasonable composition of the calculations hereunder for the calendar year then ended.

12.5.2 In the event of a discovery of a discrepancy which exceeds 5% of the amount due or charged by a party for any period (and provided that the amount of the discrepancy exceeds \$25000), the cost of such accountants shall be borne by the audited party; otherwise, such cost shall be borne by the auditing party.

12.6 Inspection:

At such time as shall be agreed with Elan, such agreement not to be unreasonably withheld, Elan shall make (and where relevant shall procure that Elan's subcontractor shall make) that portion of its manufacturing, testing or storage facility where Product is manufactured, tested or stored, including all record and reference samples relating to the Product available for inspection by Par's

duly qualified employee, or by a duly qualified consultant, contractor or agent of Par with the consent of Elan, which consent shall not be unreasonably withheld or delayed, or by the relevant governmental or regulatory authority. The investigation shall be limited to determining whether there is compliance with the requirements of this Agreement.

CLAUSE 13 ADVERSE EVENTS AND PRODUCT RECALL

13.1. Each party shall give the other immediate notice, which shall be promptly confirmed in writing, of any occurrence that involves:

13.1.1 any material complaint about the safety or effectiveness of the Product, including a claim for death or injury following administration of the Product (that is plausibly related to the administration of the Product); and

13.1.2 any other matter arising out of this Agreement that must be reported to a Governmental Authority.

13.2. The parties agree that within sixty (60) days following the Effective Date representatives of each party with responsibility for the safety surveillance and pharmacovigilance of the Product shall meet to develop detailed procedures regarding the format, timing and content of the safety information to be exchanged between the parties, and shall meet periodically thereafter to update the procedures.

13.3. If a party:

13.3.1 is notified by a Governmental Authority that a recall of the Product is required, requested or otherwise advisable as being probably needed; or

13.3.2 establishes a need to recall the Product for non-conformities with the Product Specifications-

it shall promptly give to the other party written notice of the same with full details.

13.4 Unless otherwise agreed, Par shall take the lead / co-ordinating role in the recall in a commercially reasonable manner and Elan shall afford all reasonable assistance. A joint recall administration team shall be established with an equal number of nominated individuals from both parties participating. A final report shall be completed by the recall administration team and delivered promptly to each party.

13.5 If the parties are unable to agree as to whether the Product complies with Product Specifications, or as to whether Par or Elan is responsible for any agreed or established non-conformity, the dispute shall be settled as set forth in Clause 9.

13.6 The costs of a recall of the Product, including the cost of replacement quantities of Product, shall be borne as follows:

13.6.1 in the event that the principal reason for the recall under this Clause 13 is Par's negligence or willful misconduct, its failure to supply Compound conforming to Compound Specifications, its failure to handle or store the Product in conformity with the Product Specifications, or Par's failure to comply with applicable laws or regulations, by Par;

13.6.2 in the event that the principal reason for the recall under this Clause 13 of the Product in question is Elan's negligence or willful misconduct, its failure to supply Product conforming to the Product Specifications, or Elan's failure to comply with applicable laws or regulations, by Elan;

13.6.3 in the event that the reason that the recall of the Product under this Clause 13 was legally required is not one of those set forth in Clauses 13.6. 1 or 13.6.2 by the parties equally.

CLAUSE 14 DURATION AND TERMINATION

14.1. This Agreement shall be deemed to have come into force on the Effective Date and, subject to the rights of termination outlined in this Clause 14 will expire on a Product by Product basis:

14.1.1 on the 15th anniversary of First Commercial Sale of that Product; or

14.1.2 upon the expiration of the life of the last to expire patent included in the Elan Patents;

whichever date is later to occur (the "Initial Period").

14.2. At the end of the Initial Period, the Agreement shall continue automatically for rolling 3 year periods thereafter, unless the Agreement has been terminated by either of the parties by serving 2 years' written notice on the other immediately prior to the end of the Initial Period or any additional 3 year period provided for herein.

14.3. In addition to the rights of termination provided for elsewhere in this Agreement, either party will be entitled forthwith to terminate this Agreement by written notice to the other party if-

14.3.1 that other party commits any material breach of any of the provisions of this Agreement, and in the case of a breach capable of cure, fails to cure the same within 60 days after receipt of a written notice giving full particulars of the breach and requiring it to be remedied;

14.3.2 that other party goes into liquidation (except for the purposes of amalgamation or reconstruction and in such manner that the company resulting therefrom effectively agrees to be bound by or assume the obligations imposed on that other party under this Agreement);

14.3.3 an encumbrancer takes possession or a receiver is appointed over any of the property or assets of that other party; or

14.3.4 any proceedings are filed or commenced by that other party under bankruptcy, insolvency or debtor relief laws or anything analogous to any of the foregoing under the laws of any jurisdiction occurs in relation to that other party.

14.4. For the purposes of Clause 14.3. 1, a breach will be considered capable of cure if the party in breach can comply with the provision in question in all respects other than as to the time of performance.

14.5. In further addition to the rights and termination provided for elsewhere in this Agreement, and in addition to any other remedy it may have, Elan shall be entitled to terminate this Agreement in the event that:

14.5.1 (in respect of a Product) Par notifies Elan that it does not wish to commercialize that Product or fails to launch it by the Date For -Launch; or

14.5.2 (in respect of a Product) Par does not agree in writing to increased costs and/or a change to the R&D Program, as the case may be, proposed by Elan under Clause 6.4 within thirty (30) days of delivery of Elan's proposal; or

14.5.3 there is a change in ownership or control of more than 40% of the voting rights in Par; or

14.5.4 a Technological Competitor of Elan or a company with a Competing Product acquires 20% or more of Par's voting stock or where 20% or more of such company's voting stock is acquired by Par; or

14.5.5 (in respect of a Product) the net price payable to Elan (that is the price of that Product and the percentage of Profit relating thereto) is less than Product Manufacturing Cost plus 10% for a period of one year.

CLAUSE 15 CONSEQUENCES OF TERMINATION

15.1. Upon exercise of those rights of termination specified in Clause 14 or elsewhere in this Agreement, this Agreement shall, subject to the provisions of the Agreement which survive the termination of the Agreement and Clause 15.2 automatically terminate forthwith and be of no further legal force or effect.

15.2. Upon termination of the Agreement by either party, in toto or in respect of a particular Product, the following shall be the consequences in respect of all Products or that Product, as applicable:-

15.2.1 any sums that were due from Par to Elan under the provisions of Clause I or otherwise howsoever prior to the exercise of the right to terminate this Agreement as set forth herein shall be paid in full within 30 days of termination of this Agreement and Elan shall not be liable to repay to Par any amount of money paid or payable by Par to Elan up to the date of the termination of this Agreement;

15.2.2 all representations and warranties shall insofar are appropriate remain in full force and effect;

15.2.3 the rights of inspection and audit shall continue in force for the period referred to in the relevant provisions of this Agreement; and

15.2.4 for the avoidance of doubt, Elan shall be entitled to research, develop and commercialize the Product in question for its own benefit.

CLAUSE 16 WARRANTY AND INDEMNITY

16.1. Elan represents and warrants to Par as of the Effective Date, as follows:

16.1.1 Elan has the right to grant the Elan License, subject to Clause 2. 1. 1;

16.1.2 it will inform Par if there are any agreements between Elan and any third party that conflict with the Elan License at such time as a Compound becomes a Nominated Compound;

16.1.3 each Product supplied by Elan to Par under this Agreement will conform to the Product Specifications therefor, and regulations governing the conduct of clinical trials and stability requirements, and shall not be adulterated or misbranded within the meaning of the US Food, Drug and Cosmetics Act.

EXCEPT AS SET FORTH IN TI-HS CLAUSE 16.1, ELAN IS GRANTING THE ELAN LICENSE HEREUNDER ON AN "AS IS" BASIS WITHOUT REPRESENTATION OR WARRANTY WHETHER EXPRESS OR IMPLIED INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR INFRINGEMENT OF THIRD PARTY RIGHTS, AND ALL SUCH WARRANTIES ARE EXPRESSLY DISCLAIMED TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAWS.

16.2. Par represents and warrants to Elan as of the Effective Date, as follows:

16.2.1 Par has the right to enter into this Agreement.

16.2.2 there are no agreements between Par and any third party that conflict with this Agreement.

16.2.3 this Agreement does not require any filings under the Hart-Scott Rodino Antitrust Improvements Act of 1976, as amended, and the rules promulgated thereunder (16 C.F.R. 80 1.1 et seq.);

16.2.4 in storing, transporting, marketing, promoting and selling each Product hereunder, Par will exercise all due skill, care and diligence in conducting such activities; and Par will comply with the provisions of this Agreement, all Regulatory Approvals, and in all material respects all applicable laws and regulations.

16.3. Each of Elan and Par represents and warrants to the other that:

16.3.1 it has such permits, licenses and authorizations of governmental or regulatory authorities as are necessary to own its respective properties, conduct its business and consummate the transactions contemplated hereby;

16.3.2 it is not currently debarred, suspended or otherwise excluded by any United States governmental agency from receiving Federal contracts.

16.4. Each of the parties shall indemnify and hold harmless the other party against all claims, damages, losses, liabilities and expenses (including reasonable attorneys' fees) to which the other party may become liable insofar as they arise out of any breach by the first party of any of its obligations or warranties under this Agreement.

16.5. Par shall indemnify Elan against all and any claims (whether successful or not), damages, losses, liabilities, or expenses (including reasonable attorneys' fees) made or brought seeking damages for personal injury (including death) and/or for the costs of medical treatment, caused or attributed to a Product or a Nominated Compound, except to the relative extent that the same is attributable to Elan's gross negligence or breach of the provisions of this Agreement.

16.6. With reference to Clause 2.2, Par shall indemnify and hold harmless Elan to the extent that any claims, damages, losses, liabilities, or expenses arise out of any such acts or omissions of any sub-licensee.

16.7. The party seeking an indemnity shall:

16.7.1 fully and promptly notify the other party of any claim or proceedings, or threatened claim or proceedings;

16.7.2 permit the indemnifying party to take full control of such claim or proceedings, with counsel of the indemnifying party's choice, provided that the indemnifying party shall reasonably and regularly consult with the indemnified party in relation to the progress and status of such claim or proceedings;

16.7.3 co-operate in the investigation and defense of such claim or proceedings;

16.7.4 not acknowledge the validity of, compromise or otherwise settle any such claim or proceedings without the prior written consent of the indemnifying party, which consent shall not be unreasonably withheld or delayed; and

16.7.5 take all reasonable steps to mitigate any loss or liability in respect of any such claim or proceedings.

16.8. WITHOUT PREJUDICE TO THE PROVISIONS OF CLAUSES 4.2.5 (DEFENSE INFRINGEMENT LIABILITY) AND 16.5 (PRODUCT LIABILITY FOR PERSONAL INJURY), NOTWITHSTANDING ANYTHING TO THE CONTRARY IN THIS AGREEMENT, ELAN AND PAR SHALL NOT BE LIABLE TO THE OTHER BY REASON OF ANY REPRESENTATION OR WARRANTY, CONDITION OR OTHER TERM OR ANY DUTY OF

COMMON LAW, OR UNDER THE EXPRESS TERMS OF THIS AGREEMENT, FOR ANY CONSEQUENTIAL, SPECIAL OR INCIDENTAL OR PUNITIVE LOSS OR DAMAGE (WHETHER FOR LOSS OF CURRENT OR FUTURE PROFITS, LOSS OF ENTERPRISE VALUE OR OTHERWISE) AND WHETHER OCCASIONED BY THE NEGLIGENCE OF THE RESPECTIVE PARTIES, THEIR EMPLOYEES OR AGENTS OR OTHERWISE.

16.9. Elan and Par shall maintain comprehensive general liability insurance, including product liability insurance on each Product respectively in such prudent amount (but not less than \$15 million) as shall be specified in the R&D Program for the duration of this Agreement and for a period of 5 years thereafter.

Each party shall provide the other party with a certificate from the insurance company verifying the above and shall notify the other party in writing at least 30 days prior to the expiration or termination of such coverage.

16.10. Where this Agreement provides for the indemnification of a party to this Agreement or for the limitation of a party's liability, such indemnification and/or limitation (as the case may be) shall also apply for the benefit of such party's Affiliates and the employees, officers, directors and agents of any of them.

PROVIDED HOWEVER, for the avoidance of doubt, that such indemnification and/or limitation (as the case may be) shall not apply for the benefit of a sub-licensee of a party hereunder.

CLAUSE 17 MISCELLANEOUS PROVISIONS

17.1. Confidentiality:

17.1.1 The parties agree that it will be necessary, from time to time, to disclose to each other confidential and proprietary information, including without limitation, inventions, trade secrets, specifications, designs, data, know-how and other proprietary information relating to the Product, processes, services and business of the disclosing party. The foregoing shall be referred to collectively as "Confidential Information". For the avoidance of doubt, Elan's Confidential Information shall include the Elan Intellectual Property.

17.1.2 Any Confidential Information disclosed by the disclosing party shall be used by the receiving party exclusively for the purposes of fulfilling the receiving party's obligations under this Agreement and for no other purpose.

17.1.3 Save as otherwise specifically provided herein, and subject to Clauses 17.2 and 17.3, each party shall disclose Confidential Information of the other party only to those employees, representatives and agents requiring knowledge thereof in connection with fulfilling the party's obligations under this Agreement, and not to any other third party.

Each party further agrees to inform all such employees, representatives and agents of the terms and provisions of this Agreement relating to Confidential Information and their duties hereunder and to obtain their agreement hereto as a condition of receiving Confidential Information.

Each party shall exercise the same standard of care as it would itself exercise in relation to its own confidential information (but in no event less than a reasonable standard of care) to protect and preserve the proprietary and confidential nature of the Confidential Information disclosed to it by the other party.

Upon termination or expiration of this Agreement, each party shall promptly, upon request of the other party, return all documents and any copies thereof containing Confidential Information belonging to, or disclosed by, such other party, save that it may retain one copy of the same solely for the purposes of ensuring compliance with the obligations set out in this Clause 17.

17.1.4 Any breach of this Clause 17 by any person informed by one of the parties is considered a breach by the party itself.

17.1.5 Confidential Information shall be deemed not to include:

17.1.5.1 information which is in the public domain;

17.1.5.2 information which is made public through no breach of this Agreement;

17.1.5.3 information which is independently developed by a party, as evidenced by such party's records;

17.1.5.4 information that becomes available to a receiving party on a non-confidential basis, whether directly or indirectly, from a source other than the other party hereto, which source did not acquire this information on a confidential basis.

17.1.6 The provisions relating to confidentiality in this Clause 17 shall remain in effect during the term of this Agreement, and for a period of 7 years following the expiration or earlier termination of this Agreement.

17.1.7 The parties agree that the obligations of this Clause 17 are necessary and reasonable in order to protect the parties' respective businesses, and each party agrees that monetary damages would be inadequate to compensate a party for any breach by the other party of its covenants and agreements set forth herein.

The parties agree that any such violation or threatened violation shall cause irreparable injury to a party and that, in addition to any other remedies that may be available, in law and equity or otherwise, each party shall be entitled to seek injunctive relief against the threatened breach of the provisions of this Clause 17, or a continuation of any such breach by the other party, specific performance and other equitable relief to redress such breach together with damages and reasonable counsel fees and expenses to enforce its rights hereunder.

17.2. Announcements:

17.2.1 Subject to Clause 17.2.2 and Clause 17.3, no announcement or public statement concerning the existence, subject matter or any term of this Agreement shall be made by or on behalf of any party hereto without the prior written approval of the other party or parties.

The terms of any such announcement shall be agreed in good faith by the parties.

17.2.2 For the purpose of demonstrating to third parties the benefits of the Elan Technology, Elan shall be entitled, without the prior written consent of Par, to disclose to third parties the numerical values underlying the Compound Data and other relevant data provided that Elan does not disclose Par's name.

17.3. Required Disclosures:

17.3.1 A party (the "Disclosing Party") will be entitled to make an announcement or public statement concerning the existence, subject matter or any term of this Agreement, or to disclose Confidential Information that the Disclosing Party is required to make or disclose pursuant to:

17.3. 1.1 a valid order of a court or Governmental Authority; or

17.3.1.2 any other requirement of law or any securities or stock exchange;

provided that if the Disclosing Party becomes legally required to make such announcement, public statement or disclosure hereunder, the Disclosing Party shall give the other party or parties hereto prompt notice of such fact to enable the other party or parties hereto to seek a protective order or other appropriate remedy concerning any such announcement, public statement or disclosure.

The Disclosing Party shall fully co-operate with the other party or parties hereto in connection with that other party's or parties' efforts to obtain any such order or other remedy.

If any such order or other remedy does not fully preclude announcement public statement or disclosure, the Disclosing Party -shall make such announcement, public statement or disclosure only to the extent that the same is legally required.

17.3.2 Each party shall notify the other party or parties hereto of any request by an Governmental Authority for disclosure of any Confidential Information required in connection with a Regulatory Application, provided that such party shall not disclose the Confidential Information to the Governmental Authority, without the prior written consent of the other party or parties hereto, which shall not be unreasonably withheld or delayed.

17.4. Assignments/ Sub-contracting:

This Agreement shall not be assigned by any party hereto without the prior written consent of the other party or parties hereto, save that any party may assign this Agreement in whole or in part and delegate its duties hereunder to its Affiliate or Affiliates without such consent provided that such

assignment or delegation has no material adverse tax implications for the other party or parties hereto. Elan shall also have the right to subcontract and/or delegate all or any portion of the development, manufacturing or packaging of one or more of the Products to one or more third parties (including Affiliates). Each Party shall be responsible for the acts and/or omissions of its respective Affiliates and subcontractors.

17.5. Parties bound:

This Agreement shall be binding upon and inure for the benefit of parties hereto, their successors and permitted assigns.

17.6. Severability:

If any provision in this Agreement is deemed to be, or becomes invalid, illegal, void or unenforceable under applicable laws:

17.6.1 such provision will be deemed amended to conforming to applicable laws so as to be valid and enforceable; or

17.6.2 if it cannot be so amended without materially altering the intention of the parties, it will be deleted the validity, legality and enforceability of the remaining provisions of this Agreement shall not be impaired or affected in any way.

17.7. Force Majeure:

Neither party to this Agreement shall be liable for failure or delay in the performance of any of its obligations hereunder if such failure or delay results from Force Majeure , but any such failure or delay shall be remedied by such party as soon as practicable.

17.8. Relationship of the parties:

17.8.1 Nothing contained in this Agreement is intended or is to be construed to constitute any of the parties hereto as partners or members of a joint venture or any party as an employee of another party.

17.8.2 No party hereto shall have any express or implied right or authority to assume or create any obligations on behalf of or in the name of any other party or to bind another party to any contract, agreement or undertaking with any third party.

17.9. Amendments:

No amendment, modification or addition hereto shall be effective or binding on any party hereto unless set forth in writing and executed by a duly authorized representative of all parties hereto.

17.10. Waiver:

No waiver of any right under this Agreement shall be deemed effective unless contained in a written document signed by the party charged with such waiver, and no waiver of any breach or failure to perform shall be deemed to be a waiver of any future breach or failure to perform or of any other right arising under this Agreement.

17.11. Entire agreement /No effect on other agreements:

17.11.1 This Agreement sets forth all of the agreements and understandings between the parties with respect to the subject matter hereof, and supersedes and terminates all prior agreements and understandings between the parties with respect to the subject matter hereof. There are no agreements or understandings with respect to the subject matter hereof, either oral or written, between the parties other than as set forth in this Agreement.

17.11.2 No provision of this Agreement shall be construed so as to negate, modify or affect in any way the provisions of any other agreement between the parties unless specifically referred to, and solely to the extent provided, in any such other agreement.

17.12. Governing law and jurisdiction:

17.12.1 This Agreement shall be governed by and construed in accordance with the laws of the State of New York.

17.12.2 For the purposes of this Agreement the parties submit to the exclusive jurisdiction of the Federal and State courts located in New York.

17.13. Notice:

17.13.1 Any notice to be given under this Agreement shall be sent in writing in English by registered or recorded delivery post reputable overnight courier or fax to:

Elan at

Elan Corporation, plc.
c/o Elan International Services Ltd.
102 St. James Court
Flatts
Smiths FL04
Bermuda
Attn: Secretary
Fax no. +1441292 2224

Par at

Par Pharmaceuticals
One Ram Ridge Road
Spring Valley, New York 10977
USA
Attention: Office of the President
Fax: +1845 425 7922

or to such other address(es) and fax numbers as may from time to time be notified by either party to the other hereunder.

17.13.2 Any notice sent by mail shall be deemed to have been delivered within 7 working days after dispatch or delivery to the relevant courier and any notice sent by fax shall be deemed to have been delivered upon confirmation of receipt. Notice of change of address shall be effective upon receipt.

17.14. Further assurances:

At the request of any of the parties, the other party or parties shall (and shall use reasonable efforts to procure that any other necessary third parties shall) execute and do all such documents, acts and things as may reasonably be required subsequent to the signing of this Agreement for assuring to or vesting in the requesting party the full benefit of the terms hereof.

17.15. Counterparts:

17.16. Set-off:

Each of the parties will be entitled but not obliged to set-off against any amount of money payable to by the other party hereunder, any amount of money payable by it to the other party hereunder.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement.

SIGNED

for and on behalf of

Elan Corporation, plc.

By: /s/ Kevin Insley

Name: _____

Title: _____

SIGNED

for and on behalf of

Par Pharmaceutical, Inc.

By: /s/ Scott Tarriff

Name: _____

Title: President and Chief Financial Officer