18-03798-E

Debra Smetana
ktMINE
940 West Adams
Suite 100
Chicago, IL 60607

U.S. Securities & Exchange Commission
Office of FOIA and Privacy Act Operations
100 F Street, NE
Mail Stop 2465
Washington, DC 20549-5100

Dear Sir or Madam:

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 10.1 to 10-Q filed on 11/07/2006 by Shire Plc

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. My daytime phone number is (312) 667-0267

Sincerely,

Debra Smetana

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

Office of FOIA Services

May 1, 2018

Ms. Debra Smetana
ktMINE
940 West Adams, Suite 100
Chicago, IL 60607

RE: Freedom of Information Act (FOIA), 5 U.S.C. § 552
Request No. 18-03798-E

Dear Ms. Smetana:

This letter is in response to your request, dated and received in this Office on April 6, 2018, for Exhibit 10.1 to the Form 10-Q filed on November 7, 2006 by Shire Plc.

The search for responsive records has resulted in the retrieval of 36 pages of records that may be responsive to your request. They are being provided to you with this letter.

As shown on the enclosed invoice, the processing fee is $61.00 in accordance with our fee schedule. You may use our new *Online Payment* option to pay by debit or credit card. If paying by mail, checks or money orders should be made payable to the SEC and a copy of the invoice should be mailed to our payment address: Enterprise Services Center, HQ Bldg., Room 181, AMZ-341, 6500 South MacArthur Boulevard, Oklahoma City, OK 73169. Please refer to the following link for detailed instructions on how to remit payments. http://www.sec.gov/about/offices/ofm.htm

If you have any questions, please contact me directly at andersonc@sec.gov or (202) 551-8315. You may also contact me at foiapa@sec.gov or (202) 551-7900. You also have the right to seek assistance from Ray J. McInerney 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,

Clarissa Anderson

Clarissa Anderson
FOIA Research Specialist

Enclosures

EXECUTION COPY

SETTLEMENT AGREEMENT

THIS SETTLEMENT AGREEMENT, (this "Settlement Agreement") dated as of this 14th day of August, 2006, is hereby entered into by and between Shire Laboratories Inc., a Delaware corporation with offices located at 725 Chesterbrook Boulevard, Wayne, PA 19087 ("Shire"), and Barr Laboratories, Inc., a Delaware corporation with offices located at 400 Chestnut Ridge Road, Woodcliff Lake, NJ 07677 ("Barr"). Each of Shire and Barr is sometimes referred to herein, individually, as a "Party" and, collectively, as the "Parties."

RECITALS

WHEREAS, Shire is the owner of New Drug Application ("NDA") No. 21-303, which was approved by the Food and Drug Administration ("FDA") for the manufacture and sale of a pharmaceutical composition containing mixed amphetamine salts for the treatment of Attention Deficit Hyperactivity Disorder, which Shire sells under the trademark Adderall XR (collectively, "Shire Product");

WHEREAS, Barr submitted an Abbreviated New Drug Application ("ANDA") No. 76-536 ("Barr's ANDA") to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §355(j)) with a paragraph IV certification seeking approval to engage in the commercial manufacture, use, and sale of product asserted to be bioequivalent to Shire Product;

WHEREAS, the filing of such an ANDA by Barr can be an act of infringement of any patent which claims the drug or the use of such drug under 35 U.S.C. § 271(e)(2)(A);

WHEREAS, as of August 14, 2006 Barr's ANDA has failed to receive either tentative or final marketing approval by the FDA;

WHEREAS, on February 24, 2003, after receiving a paragraph IV notice letter from Barr regarding United States Patent No. 6,322,819 (the "'819 Patent"), Shire sued Barr for infringing the '819 Patent in a civil action in the United States District Court for the Southern District of New York and Barr has asserted certain affirmative defenses and brought certain counterclaims that action, case no. 03-CV-1219 (collectively, the "'819 Case");

WHEREAS, on September 2, 2003, after receiving a paragraph IV notice letter from Barr regarding United States Patent No. 6,605,300 (the "'300 Patent), Shire sued Barr for infringing the '300 Patent in a civil action in the United States District Court for the Southern District of New York and Barr has asserted certain affirmative defenses and brought certain counterclaims in that action, case no. 03-CV-6632 (collectively, the "'300 Case").

WHEREAS, the '819 Case and the '300 Case (collectively referred to as "Litigation #1") were consolidated for trial on December 15, 2003 in the Southern District of New York before United States District Judge P. Kevin Castel ("Court #1").

WHEREAS, Shire has also sued Barr for a declaratory judgment finding the product to be sold under Barr's ANDA would infringe U.S. Patent No. 6,913,768 (the "'768 Patent") in a civil action, Civil Action No. 05-CV-8903 ("Litigation #2")("Litigation #2 together with

Litigation #1, the "Pending Litigations"), also in the United States District Court for the Southern District of New York before United States District Judge Richard Owen ("Court #2");

WHEREAS, Shire and Barr wish to settle the Pending Litigations and have reached an agreement to settle the Pending Litigations, pursuant to the terms and conditions set forth in this Settlement Agreement together with an associated License Agreement (attached hereto as Exhibit A, the "License Agreement"), an agreed dismissal order and consent judgment in Litigation #1 ("Dismissal Order and Consent Judgment #1")(attached hereto as Exhibit B), and a consent judgment with regard to Litigation #2 (the "Consent Judgment #2")(attached hereto as Exhibit C) (the Settlement Agreement, the License Agreement, the Dismissal Order and Consent Judgment #1 and Consent Judgment #2 are collectively referred to as the "Settlement Documents") (Dismissal Order and Consent Judgment #1 and Consent Judgment #2 are collectively referred to as the "Consent Judgments");

WHEREAS, contemporaneously herewith the Parties and their Affiliates are also entering into a Product Acquisition and License Agreement for Shire's Adderall product, currently being sold under Shire's NDA No. 11-522, and a Product Development and License Agreement (collectively, the "Associated Agreements");

WHEREAS, the Settlement Documents constitute both Shire's and Barr's best independent judgment as to the most convenient, effective and expeditious way to mutually settle all prior, present and future disputes that have arisen associated with the filing of Barr's ANDA and the selling, offering for sale, using and/or importing into the United States of a product under Barr's ANDA (the "Barr Product"); and

WHEREAS, except as provided for in Section 15 herein, this Settlement Agreement shall be of no force or effect until such date as the Consent Judgments defined herein are submitted to their respective courts as provided herein and the Consent Judgments are thereafter entered by their respective courts.

NOW, THEREFORE, in consideration of the mutual covenants and agreements described herein, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

1. The Parties consent to the jurisdiction of Court #1 for the purposes of the settlement of Litigation #1 and enforcement of the terms of the Settlement Documents.

2. The Parties agree that Court #1 has jurisdiction over Litigation #1 and over Shire and Barr (solely for the purpose of this settlement), and that venue is proper in the Southern District of New York.

3. Barr admits that the commercial manufacture, use, selling, offering for sale, or importing of the Barr Product would infringe '768 Patent. Barr admits that it has conducted activities to date, including manufacturing large quantities of Barr Product, that infringe the '768 Patent. Barr admits that it has been actively and diligently working to obtain approval of the Barr ANDA to commercially manufacture, use, sell, and offer for sale the Barr Product in the United States. Barr admits that the '768 patent is valid and enforceable.

4. The Parties consent to the jurisdiction of Court #2 for the purposes of the settlement of Litigation #2 and enforcement of the terms of the Settlement Documents.

5. The Parties agree that Court #2 has jurisdiction over Litigation #2 and over Shire and Barr (solely for the purpose of this settlement), and that venue is proper in the Southern District of New York.

6. Barr admits that each of the '819 Patent and the '300 Patent are valid and enforceable.

7. Barr agrees that, except as is otherwise expressly provided for in the License Agreement, it shall not commercially make, use, sell, offer for sale or import, directly or indirectly the Barr Product.

8. Subject to Barr's continued compliance with the terms of the Settlement Documents, Shire agrees that it will not enforce the '819 Patent, the '300 Patent and the '768 Patent against Barr or its affiliates with respect to the Barr Product or seek relief for equitable or legal damages, or other monetary relief, costs, attorneys fees or interest as a result of infringement by Barr and their retailers, distributors or end users, accrued as to the date hereof.

9. Barr represents and warrants that it has not granted or assigned to any Third Party, directly or indirectly, any rights under or to Barr's ANDA and that it will not do so except as may be explicitly provided in the License Agreement.

10. Shire represents and warrants that it has the right and authority to enforce the '819 Patent, the '300 Patent and the '768 Patent.

11. Shire and Barr each represents and warrants that it has the full right, authority and power to enter into this Settlement Agreement on its own behalf and that this Settlement Agreement shall create and constitute a binding obligation on its part.

12. Shire and Barr shall each execute the License Agreement contemporaneously with the execution of this Settlement Agreement and any breach of the License Agreement shall constitute a breach of this Settlement Agreement.

13. Within five (5) business days following the date of this Settlement Agreement, the Parties shall cause the Consent Judgments to be filed with their respective courts.

14. To the extent that Court #1 or Court #2 should refuse to enter either of the Consent Judgments, the Parties shall work together in good faith and use their Best Efforts to modify the applicable Consent Judgment to meet the requirements of the applicable Court. If despite such Best Efforts Court #1 refuses to enter a dismissal of the infringement issues in Litigation #1 without prejudice under Fed. R. Civ. P. 41(a)(1)(ii) and also enter a consent judgment that the '819 Patent and the '300 Patent are valid and enforceable, or if despite such Best Efforts Court #2 refuses to enter a consent judgment of validity, enforceability and infringement of the '768 patent, this Settlement Agreement (including without limitation the License Agreement) and the Associated Agreements shall be null and void (also a "Termination Date"). Furthermore, except as provided in Section 15, the Parties agree that this Settlement

Agreement and the License Agreement shall become effective (the "Effective Date") only when each of the following occur: (1) Court #1 has entered the Consent Judgment #1 (as may be modified pursuant to this paragraph above); and (2) Court #2 has entered Consent Judgment #2 (as may be modified pursuant to this paragraph above).

15. This Settlement Agreement and the License Agreement shall be void and of no effect if the Consent Judgments are not entered by their respective courts within thirty (30) days following the date hereof subject to the Parties' agreement to extend such thirty-day period, such agreement not to be unreasonably withheld.

16. For purposes of clarity, and despite anything to the contrary in this Settlement Agreement, Sections 11, 12, 13, 14, 15, 16, 17 and 18 shall be immediately effective and binding upon the Parties upon full execution of this Settlement Agreement, unless and until this Settlement Agreement shall be null and void as provided in Section 15.

17. Within ten (10) business days following the date hereof, each Party shall file or cause to be filed with the U.S. Federal Trade Commission Bureau of Competition ("FTC") and the Antitrust Division of the U.S. Department of Justice ("DOJ") this Settlement Agreement and any notifications required to be filed pursuant to Title XI of the Medicare Prescription Drug Improvement and Modernization Act (Subtitle B - Federal Trade Commission Review) signed into law on December 8, 2003 and any other applicable law.

18. The Parties shall use all commercially reasonable efforts and coordinate to make such filings promptly and to respond promptly to any requests for additional information made by either of such agencies. Each Party reserves the right to communicate with the FTC or DOJ regarding such filings as it believes appropriate. Each Party shall keep the other reasonably informed of such communications and shall not disclose the Confidential Information of the other without such other Party's consent (not to be unreasonably withheld).

19. Shire and Barr each will bear their own costs and legal fees for the Pending Litigations.

20. Confidentiality.

20.1 Confidential Information. As used in this Settlement Agreement, the term "Confidential Information" means all secret, confidential or proprietary information or data, whether provided in written, oral, graphic, video, computer, electronic or other form, provided pursuant to this Settlement Agreement or generated pursuant to this Settlement Agreement by one Party or its Affiliates (the "Disclosing Party") to the other Party or its Affiliates (the "Receiving Party"), including but not limited to, information relating to the Disclosing Party's existing or proposed research, development efforts, patent applications, business or products, and any other materials that have not been made available by the Disclosing Party to the general public. Confidential Information shall not include any information or materials that:

(a) were already known to the Receiving Party (other than under an obligation of confidentiality), at the time of disclosure by the Disclosing Party, to the extent such Receiving Party has documentary evidence to that effect;

(b) were generally available to the public or otherwise part of the public domain at the time of disclosure thereof to the Receiving Party;

(c) became generally available to the public or otherwise part of the public domain after disclosure or development thereof, as the case may be, other than through any act or omission of a Party in breach of such Party's confidentiality obligations under this Settlement Agreement;

(d) were disclosed to a Party, other than under an obligation of confidentiality, by a third party who had no obligation to the Disclosing Party not to disclose such information to others; or

(e) were independently discovered or developed by or on behalf of the Receiving Party without the use of the Confidential Information belonging to the other Party, to the extent such Receiving Party has documentary evidence to that effect.

20.2. Confidentiality Obligations. Each of Barr and Shire shall keep confidential all Confidential Information of the other Party with the same degree of care it maintains the confidentiality of its own Confidential Information but in no event less than a reasonable degree of care. Neither Party shall use such Confidential Information for any purpose other than in performance of this Settlement Agreement or disclose the same to any other Person other than to such of its and its Affiliates' directors, managers, employees, independent contractors, agents or consultants who are bound to confidentiality restrictions consistent with the terms herein and who have a need to know such Confidential Information to implement the terms of this Settlement Agreement or enforce its rights under this Settlement Agreement. Upon termination of this Settlement Agreement, the Receiving Party shall return or destroy all documents, tapes or other media containing Confidential Information of the Disclosing Party that remain in the possession of the Receiving Party and its Affiliates or their directors, managers, employees, independent contractors, agents or consultants, except that the Receiving Party may keep one copy of the Confidential Information in the legal department files of the Receiving Party, solely for archival purposes. Such archival copy shall continue to be subject to the provisions of this Section 20.

20.3. Permitted Disclosure and Use. Notwithstanding Section 20.2, a Party may disclose Confidential Information belonging to the other Party only to the extent such disclosure is reasonably necessary to: (a) obtain Regulatory Approval to the extent such disclosure is made to a Governmental Authority; (b) comply with or enforce any of the

provisions of this Settlement Agreement; (c) comply with Laws; or (d) comply with applicable stock exchange regulations. If a Party deems it necessary to disclose Confidential Information of the other Party pursuant to this Section 20.3, such Party shall give reasonable advance notice of such disclosure to the other Party to permit such other Party sufficient opportunity to object to such disclosure or to take measures to ensure confidential treatment of such information. In addition, notwithstanding Section 20.2, the Parties shall cooperate to prepare standardized public responses to anticipated inquiries from the public, press, stockholders, investors and/or analysts with respect to the activities hereunder. Despite the foregoing, each Party agrees that the other Party is free to disclose this Settlement Agreement in its entirety to the United States Federal Trade Commission and the United States Department of Justice, or to any court with jurisdiction over the litigations settled under this Settlement Agreement.

20.4. Unauthorized Disclosure. The Receiving Party acknowledges and agrees that the Confidential Information of the Disclosing Party constitutes proprietary information and trade secrets valuable to the Disclosing Party, and that the unauthorized use, loss or outside disclosure of such Confidential Information shall be presumed to cause irreparable injury to the Disclosing Party.

20.5. Notification. The Receiving Party shall notify the Disclosing Party promptly upon discovery of any unauthorized use or disclosure of the Disclosing Party's Confidential Information, and shall cooperate with the Disclosing Party in any reasonably requested fashion to assist the Disclosing Party to regain possession of such Confidential Information and to prevent its further unauthorized use or disclosure. The Receiving Party acknowledges that monetary damages may not be a sufficient remedy for unauthorized disclosure of Confidential Information and that the Disclosing Party may be entitled, without waiving other rights or remedies, to such injunctive or equitable relief as may be deemed proper by a court of competent jurisdiction in the event of such unauthorized disclosure.

20.6. Confidentiality of this Settlement Agreement. The terms of this Settlement Agreement shall be Confidential Information of each Party and, as such, shall be subject to the provisions of this Section 20.

20.7. Terms not defined in this Section 20 shall have the meaning given to such terms in the License Agreement.

21. In the event that any of the provisions of this Settlement Agreement shall be held by a court or other tribunal of competent jurisdiction to be illegal, invalid or unenforceable, such provisions shall be limited or eliminated to the minimum extent necessary so that this Settlement Agreement shall otherwise remain in full force and effect. This Settlement Agreement shall be governed by the laws of the State of New York without regard to the conflicts of law provisions thereof. This Settlement Agreement supersedes all prior discussions and writings and constitutes

the entire agreement between the Parties with respect to the subject matter hereof. No waiver or modification of this Settlement Agreement will be binding upon either Party unless made in writing and signed by a duly authorized representative of such Party and no failure or delay in enforcing any right will be deemed a waiver. Notices hereunder will be effective only if in writing and upon receipt if delivered personally or by overnight mail carrier or fax, or three (3) days after deposit in the U.S. mail, first class postage prepaid. The prevailing Party in any action to enforce this Settlement Agreement shall be entitled to costs and fees (including attorneys' fees and expert witness fees) incurred in connection with such action. The individual executing this Settlement Agreement on behalf of a corporation or other legal entity personally represents that he or she is duly authorized to execute this Settlement Agreement on behalf of such entity and that this Settlement Agreement is binding upon such entity. In making and performing this Settlement Agreement, the Parties are acting and shall act as independent contractors. Nothing in this Settlement Agreement shall be deemed to create an agency, joint venture or partnership relationship between the Parties hereto. This Settlement Agreement shall become binding when any one or more counterparts hereof, individually or taken together, bears the signatures of each of the Parties hereto. This Settlement Agreement may be executed in any number of counterparts (including facsimile counterparts), each of which shall be an original as against a Party whose signature appears thereon, but all of which taken together shall constitute one and the same instrument.

[Signature Page Follows]

[Signature Page to Settlement Agreement]

IN WITNESS WHEREOF, the Parties hereto have each caused this Settlement Agreement to be executed by their authorized representatives as of the date first above written.

SHIRE LABORATORIES INC.

Date: _____ By: _____

Name: _____

Title: _____

BARR LABORATORIES, INC.

Date: _____ By: _____

Name: _____

Title: _____

LICENSE AGREEMENT

THIS LICENSE AGREEMENT (this "Agreement") dated as of this 14th day of August, 2006 (the "Effective Date"), is hereby entered into by and between Shire LLC, a Kentucky company with offices located at 9200 Brookfield Court, Florence, KY 41042 (together with its Affiliates, "Shire"), and Barr Laboratories, Inc., a Delaware corporation with offices located at 400 Chestnut Ridge Road, Woodcliff Lake, NJ 07677 ("Barr"). Each of Shire and Barr is sometimes referred to herein, individually, as a "Party" and, collectively, as the "Parties."

RECITALS:

WHEREAS, Shire is the owner of New Drug Application ("NDA") No. 21-303, which was approved by the Food and Drug Administration ("FDA") for the manufacture and sale of a pharmaceutical composition containing mixed amphetamine salts for the treatment of Attention Deficit Hyperactivity Disorder, all strengths of which Shire sells under the tradename Adderall XR (collectively, "Shire Product");

WHEREAS, Barr submitted the Barr ANDA (defined below) to the FDA under the Act with a paragraph IV certification seeking approval to engage in the commercial manufacture, use, and sale of product asserted to be bioequivalent to Shire Product;

WHEREAS, Shire and Barr are parties to the Pending Litigation (defined below) related to the Barr ANDA;

WHEREAS, Shire and Barr are parties to a certain Settlement Agreement of even date herewith (the "Settlement Agreement"), pursuant to which Shire and Barr are settling the Pending Litigation;

WHEREAS, in consideration of and in conjunction with the Settlement Agreement, Shire has agreed to grant and Barr has agreed to accept a license under Shire's Adderall XR Intellectual Property (as defined below) to sell Barr Product (as defined below) and AG Product (as defined below); and

WHEREAS, this Agreement shall be of no force or effect until such date as the Dismissal Order and the Consent Judgment defined in the Settlement Agreement are submitted to their respective courts as provided for in the Settlement Agreement and the Dismissal Order and the Consent Judgment are thereafter entered by their respective courts.

NOW, THEREFORE, in consideration of the foregoing premises and mutual covenants, agreements and provisions herein contained, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto agree as follows:

1. Definitions

1.1. **"Act"** shall mean § 505(j) of the Federal Food, Drug, and Cosmetic Act.

1.2. **"Adderall XR"** shall mean the pharmaceutical products which are approved for Marketing in the Territory pursuant to the NDA.

1.3. **"Adderall XR Intellectual Property"** shall mean (i) U.S. Patent Nos. 6,322,819, 6,605,300, and 6,913,768 and any patent that issues as a result of a reexamination or reissue thereof; (ii) any patent that issues from, or any continuation, continuation-in-part or divisional application relating to, U.S. Patent Application Serial Nos. 09/176,542, 10/353,073, 10/758,417, 10/774,697, and 11/030,174; and (iii) any other present or future U S. patent owned or controlled by Shire and its Affiliates which may be infringed by the making, using, selling or importing of the Generic Product.

1.4. **"Adverse Drug Experience"** has the meaning set forth in 21 C.F.R. § 314.80(a), as amended, supplemented or superceded from time to time.

1.5. **"Affiliate"** shall mean a Person that controls, is controlled by or is under common control with a Party. For the purposes of this definition, the word "control" (including, with correlative meaning, the terms "controlled by" or "under common control with") means the actual power, either directly or indirectly through one or more intermediaries, to direct the management and policies of such Person, whether by the ownership of at least fifty percent (50%) of the voting stock of such Person (it being understood that the direct or indirect ownership of a lesser percentage of such stock shall not necessarily preclude the existence of control), or by contract or otherwise.

1.6. **"AG Product"** shall mean Shire authorized and supplied generically Labeled Adderall XR.

1.7. **"ANDA"** shall mean an abbreviated new drug application to the FDA for approval to manufacture and/or sell a pharmaceutical product in the Territory.

1.8. **"Applicable Law"** shall mean the applicable Laws, rules, regulations, guidelines and requirements of any Governmental Authority related to the development, registration, Manufacture and Marketing of the Generic Product in the Territory or the performance of either Party's obligations under this Agreement.

1.9. **"Authorization and License"** shall have the meaning assigned to such term in Section 2.3.

1.10. **"Barr ANDA"** shall mean ANDA No. 76-536.

1.11. **"Barr Product"** shall mean the Generic Equivalent that is the subject of the Barr ANDA.

1.12. "Business Day" shall mean any day other than a Saturday, Sunday or a day on which banks in New York, New York are authorized or required by Law to close.

1.13. "cGMP" shall mean all applicable standards relating to manufacturing practices for active pharmaceutical ingredients, intermediates, bulk products or finished pharmaceutical products, including (i) the principles detailed in the U.S. Current Good Manufacturing Practices, 21 C.F.R. Parts 210 and 211.

1.14. "Commercially Reasonable Efforts" shall mean efforts and diligence in accordance with the subject Party's reasonable and sound business, legal, medical and scientific judgment and in accordance with the efforts and resources such Party would use in other aspects of its business that have similar commercial value and market potential, taking into account the competitiveness of the marketplace, the business life-cycle, the proprietary position of the Party and the profitability of the pertinent product.

1.15. "Compound" shall mean mixed amphetamine salts, as further defined in the NDA.

1.16. "Confidential Information" shall mean any scientific, technical, formulation, process, Manufacturing, clinical, non-clinical, regulatory, Marketing, financial or commercial information or data relating to the business, projects, employees or products of either Party and provided by one Party to the other by written, oral, electronic or other means in connection with this Agreement.

1.17. "FDA" shall mean the United States Food and Drug Administration or any successor agency thereof.

1.18. "Force Majeure" shall mean acts of God, civil disorders or commotions, acts of aggression, fire, explosions, floods, drought, war, sabotage, embargo, utility failures, a national health emergency, or appropriations of property.

1.19. "GAAP" shall mean generally accepted accounting principles in effect in the United States from time to time, consistently applied.

1.20. "Generic Equivalent" shall mean pharmaceutical products that are a Therapeutic Equivalent of Adderall XR (whether approval for marketing in the Territory is sought or obtained pursuant to an ANDA, a 505(b)(2) application, or an NDA Supplement) including all dosages and formulations and all indications of Adderall XR. "Generic Equivalent" shall include the AG Product and the Barr Product.

1.21. "Generic Product" shall mean the AG Product and the Barr Product.

1.22. "Governmental Authority" shall mean any court, tribunal, arbitrator, agency, legislative body, commission, official or other instrumentality of (i)

any government of any country, or (ii) a federal, state, province, county, city or other political subdivision thereof.

1.23. **"Label"** shall mean any Package (immediate container) labeling designed for use with a product, including the package insert for such product that is approved by the FDA, and **"Labeled"** or **"Labeling"** shall have the correlated meaning.

1.24. **"Launch"** shall mean the first commercial sale of a product to an unaffiliated Third Party.

1.25. **"Law"** or **"Laws"** shall mean all laws, statutes, rules, codes, regulations, orders, judgments and/or ordinances of any Governmental Authority.

1.26. **"License Effective Date"** shall mean the earlier of: (1) April 1, 2009; and (2) the date of a final court decision that is no longer subject to appeal (other than a petition for writ of certiorari) holding U.S. Patents 6,322,819, 6,605,300, and 6,913,768, and any reissues or reexaminations thereof, invalid or unenforceable.

1.27. **"Losses"** means any liabilities, damages, costs or expenses, including reasonable attorneys' fees and expert fees, incurred by any Party that arise from any claim, lawsuit or other action by a Third Party.

1.28. **"Manufacture"** shall mean all activities related to the manufacturing of a pharmaceutical product, or any ingredient thereof, including but not limited to manufacturing Compound or supplies for development, manufacturing of Barr Product or AG Product for commercial sale, packaging, in-process and finished product testing, release of product or any component or ingredient thereof, quality assurance activities related to manufacturing and release of product, ongoing stability tests and regulatory activities related to any of the foregoing, and **"Manufactured"** or **"Manufacturing"** shall have the correlated meaning.

1.29. **"Manufacturing Costs"** for each dosage strength of AG Product shall mean Shire's direct costs (including out-of-pocket costs and directly allocable internal overheads, but not including allocations of corporate or general overheads or of any idle or excess capacity) of Manufacture, Packaging, Labeling, testing, validation and shipping of such AG Product, including, without limitation, Shire's acquisition and shipping costs of Compound, accrued in accordance with GAAP. "Manufacturing Costs" for each dosage strength of Barr Product shall mean Barr's direct costs (including out-of-pocket costs and directly allocable internal overheads, but not including allocations of corporate or general overheads or of any idle or excess capacity) of Manufacture, Packaging, Labeling, testing, validation and shipping of such Barr Product, including, without limitation, Barr's acquisition and shipping costs of Compound, accrued in accordance with GAAP.

1.30. **"Market"** shall mean to distribute, promote, advertise, import, market, offer to sell and sell, and **"Marketing"** or **"Marketed"** shall have the correlated meaning.

1.31. **"NDA"** shall mean new drug application No. 21-303, and all supplements filed pursuant to the requirements of the FDA, including all documents, data and other information concerning Adderall XR which are necessary for FDA approval to Market Adderall XR in the Territory.

1.32. **"Net Profits"** means the gross receipts derived from the sale of Generic Product in the United States by Barr (or by its Affiliates), to independent third parties in the United States, less the sum of the following items:

(a) Import, export, excise and sales taxes and custom duties paid or allowed by the selling party and any other charges imposed by a Governmental Authority upon the production, importation, use or sale of Generic Product by Barr and/or its Affiliates;

(b) Estimated and actual credits for returns, refunds, rebates and allowances, or trades to customers for returned or recalled Generic Product;

(c) Trade, quantity and cash discounts actually allowed;

(d) Transportation, freight and insurance allowances;

(e) Rebates to wholesalers, administrative fees in lieu of rebates paid to managed care and other similar institutions, chargebacks and retroactive price adjustments, including Shelf Stock Adjustments, and any other similar allowances which effectively reduce the net selling price; and

(f) Manufacturing Costs.

Gross and Net Profits shall be calculated according to GAAP. Sales or transfers between or among Barr and its Affiliates shall be excluded from the computation of Net Profits except where such Affiliates are end users, but Net Profits shall include the subsequent final sales to third parties by such Affiliates.

Where (i) Generic Product is sold by Barr or its Affiliates as one of a number of items without a separate price; (ii) the consideration for the Generic Product shall include any non-cash element; (iii) the Generic Product shall be transferred in any manner other than an invoiced sale; or (iv) Barr prices Generic Product in order to gain or maintain sales of other products, the gross receipts applicable to any such transaction shall be deemed to be the selling party's average gross receipts for the applicable quantity of Generic Product during the calendar quarter in which such transaction occurred. If there are no independent sales of Generic Product in the United States at that time, then Barr and Shire shall mutually agree on a surrogate measure to be used in lieu thereof.

1.33. **"Package"** shall mean all primary containers, including bottles, cartons, shipping cases or any other like matter used in packaging or accompanying a product, and "Packaged" or "Packaging" shall have the correlated meaning.

1.34. "Pending Litigation" shall mean the pending litigation Shire Laboratories, Inc., v. Barr Laboratories, Inc., Civil Action No. 03-CV-1219 and 03-CV-6632 (U.S. District Court for the Southern District of New York) and Shire Laboratories Inc. v. Barr Laboratories, Inc. & Impax Laboratories, Inc., Civil Action No. 05-CV-8903 (U.S. District Court for the Southern District of New York).

1.35. "Permitted Agreement" shall mean an agreement between Barr and any other Person to Market or promote Generic Product after the License Effective Date in accordance with the Authorization and License, or as permitted in Section 4.1.

1.36. "Person" shall mean any individual, partnership, association, corporation, limited liability company, trust, or other legal person or entity.

1.37. "Shelf Stock Adjustment" means the customary practice of providing a purchaser of Generic Product an adjustment to the net purchase price for on-hand inventory in response to an offer from a supplier of a competing Generic Equivalent.

1.38. "Term" shall have the meaning assigned to such term in Section 15.1.

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

1.40. "Therapeutic Equivalent" shall have the meaning given to it by the FDA in the current edition of the "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") as may be amended from time to time during the Term.

1.41. "Third Party" or **"Third Parties"** shall mean any Person or entity other than a Party or its Affiliates.

1.42. "Valid Claim" shall mean an issued and unexpired patent claim which has not been held to be invalid or unenforceable by a court of competent jurisdiction in a final unappealable decision.

2. License

2.1. Subject to the terms, conditions and limitations hereof, including the conditions set forth in Section 3, Shire hereby grants to Barr a license, under the Adderall XR Intellectual Property and under any and all statutory and regulatory exclusivities issued by any Governmental Authority to import, Manufacture, have Manufactured and Market Barr Product in the Territory on and after the License Effective Date. Notwithstanding the foregoing, Barr shall have the limited right to Manufacture and/or import reasonable quantities of Barr Product prior to the License Effective Date for the sole purpose of launching and selling such Product in the Territory under the foregoing license on and after the License Effective Date. The license granted under this

Section 2.1 shall include the right of Barr to (i) grant sublicenses to its Affiliates, and (ii) to Manufacture Barr Product or to have Barr Product manufactured outside the Territory for sale in the Territory.

2.2. Solely to the extent that Shire Manufactures and supplies AG Product to Barr pursuant to Section 4 of this Agreement, and subject to the other terms, conditions and limitations hereof, including the conditions set forth in Section 3, Shire hereby authorizes Barr to Market such AG Product in the Territory, but only from and after the License Effective Date. In connection with and solely for purposes of such authorization, Shire hereby grants to Barr a license under the Adderall XR Intellectual Property and under any and all statutory and regulatory authorizations and exclusivities issued by any Governmental Authority to Market such AG Product in the Territory from and after the License Effective Date. The license granted under this Section 2.2 shall include the right of Barr to grant sublicenses to its Affiliates.

2.3. The authorization and license granted by Section 2.1 and Section 2.2 are referred to herein as the "Authorization and License." Except as provided in Sections 2.1, 2.2 and 16.3, Barr shall not have the right to sublicense or assign any of its rights under the Authorization and License.

3. Conditions

3.1. Except to the extent permitted under the Authorization and License, neither Barr nor any of its Affiliates shall: (a) Market any Generic Equivalent that infringes the Adderall XR Intellectual Property or (b) assist or enable any third party to Market, or otherwise contract with any Third Party regarding the Marketing of, any Generic Equivalent (other than as permitted in Section 8.1) that infringes the Adderall XR Intellectual Property. In the event that during the Term of this Agreement Barr challenges the validity or enforceability of any of U.S. Patents 6,322,819, 6,605,300, and 6,913,768 or any reissue thereof or, except as required by Law, otherwise assists or enables or participates with any Third Party to challenge the validity or enforceability of any of the foregoing, Shire shall be free to terminate this Agreement and all obligations provided herein immediately upon written notice to Barr. Notwithstanding anything above to the contrary, Barr is permitted to respond to directives from Governmental Authorities, pursuant to the procedures set forth in Section 10.2 of this Agreement.

3.2. Nothing set forth herein shall be deemed to prevent or restrict Barr or its Affiliates from Marketing any product which would not infringe the Adderall XR Intellectual Property. The foregoing notwithstanding, Barr hereby agrees to provide Shire with detailed information regarding, and samples of, any Generic Equivalent at least forty-five (45) days before Marketing any such Generic Equivalent in order to give Shire reasonable time to evaluate any possible infringement of the Adderall XR Intellectual Property by such Generic Equivalent.

3.3. Anything to the contrary notwithstanding, in the event that Barr markets any Generic Equivalent other than: (i) Barr Product or AG Product under the terms of this Agreement, or (ii) any product which would not infringe the Adderall XR

Intellectual Property, Shire shall be free to terminate the Authorization and License and this Agreement upon notice to Barr.

3.4. Nothing in this Agreement shall be deemed to give Shire any control over any marketing exclusivity that may be granted to Barr by the FDA in connection with the Barr ANDA or Barr Product. Barr must first give Shire forty-five (45) days notice before consummating any agreement with a Third Party related to any Generic Equivalent (a "Third Party Agreement") other than a Permitted Agreement. Additionally, Barr hereby agrees to provide Shire with detailed information regarding, and samples of, any such Generic Equivalent that may be Marketed by Barr or any Third Party in connection with any such Third Party Agreement at least forty-five (45) days before the Marketing of any such Generic Equivalent, other than Barr Product currently described in the Barr ANDA, in order to give Shire reasonable time to evaluate any possible infringement of the Adderall XR Intellectual Property by such Generic Equivalent.

3.5. Anything to the contrary notwithstanding, in the event Barr enters into any Third Party Agreement other than a Permitted Agreement without the prior written consent of Shire, Shire shall be free to terminate the Authorization and License and this Agreement upon notice to Barr.

3.6. Except as explicitly set forth in this Agreement, nothing contained in this Agreement shall grant (or be construed to grant) to Barr (i) any right, title or interest in, to or under the NDA or any Shire intellectual property; (ii) any right to use or reference the NDA; (iii) any right to use any Shire intellectual property outside of the Territory; or (iv) any right to make, have made, use, offer for sale, sell and import any product other than the Barr Product or AG Product as such are permitted herein. Any and all rights not explicitly granted in this Agreement are hereby reserved.

3.7. Shire has not granted and shall not grant a license to, and has not entered and shall not enter into, any supply agreement or other arrangement that allows any Third Party to market a Generic Equivalent before: (i) the License Effective Date or (ii) the expiration of 180 days following Barr's launch of a Generic Product, except that the forgoing clause (ii) shall not apply with respect to a single Third Party to which Shire is obligated under a previous contractual relationship (the "Third Party Licensee"), if, and only if, after Barr Launches a Generic Product a Third Party (other than the Third Party Licensee) gains final Marketing approval from the FDA under an ANDA filed with a paragraph IV certification. Similarly Shire shall not itself Market a Generic Equivalent during the Term.

4. Authorized Generic

4.1. In the event a Third Party, without any cooperation or assistance from Barr, Markets a Generic Equivalent in the Territory prior to the License Effective Date, and Shire elects, in its sole discretion, to Market or have Marketed a Generic Product to compete with such Third Party prior to the License Effective Date, then Shire shall appoint Barr as the exclusive (even as to Shire, but except as to the Third Party

Licensee, if, and only if, after Barr Launches a Generic Product a Third Party (other than the Third Party referred to above or the Third Party Licensee) gains final Marketing approval from the FDA under an ANDA filed with a paragraph IV certification) distributor of the Generic Product for a period of at least 180 days following the launch of the Generic Product by Barr, and as a non-exclusive authorized distributor of the Generic Product thereafter. In the event of such election and appointment by Shire, Barr shall have the option, in its sole discretion, to Market AG Product or Barr Product. Notwithstanding the provisions of Section 9.1, Barr shall pay Shire a royalty of twenty-five percent (25%) of Net Profits during any period prior to the License Effective Date in which Barr is exclusively authorized to Market Generic Product under this Section 4.1. However, this royalty under Section 4.1 shall be reduced to zero percent (0%) of Net Profits if there are two or more Third Parties in addition to Barr Marketing a Generic Product.

4.2. Future Products. Should Shire: (i) gain approval for the Marketing of a new pharmaceutical product not Marketed as of the Effective Date that is covered by the Adderall XR Intellectual Property (each, a "New Product"), (ii) Market the New Product, and (iii) choose, in Shire's sole discretion, to Market or authorize a Third Party to Market a Shire-authorized and supplied generically labeled version of the New Product (the "AG New Product"), then Shire agrees that it shall inform Barr of such decision and shall afford Barr the opportunity, at Barr's discretion, to exclusively Market AG New Product. Barr shall notify Shire within five (5) Business Days of notice of Shire's decision to Market such AG New Product of Barr's decision as to whether it desires to Market the AG New Product. If Barr so notifies Shire of its desire to Market the AG New Product, Shire and Barr shall negotiate in good faith an agreement with respect to such AG New Product, such agreement to be on terms similar to the terms contained in this Agreement, except that Shire and Barr shall share the net profits from the sale of such AG New Product fifty percent (50%) to each Party. For purposes of clarity, Shire is under no obligation to choose to Market an AG New Product and may do so in its sole discretion.

5. Supply of AG Product; Forecasts; Purchase Orders

5.1. If Barr believes in good faith that it will be unable to obtain a final marketing approval for the Barr ANDA before the License Effective Date, then Barr may elect by providing at least 120 days prior written notice to Shire to have Shire supply AG Product to Barr for sale in the Territory from and after the applicable License Effective Date subject to all of the terms and conditions of this Agreement, including this Section 5. Shire shall use Commercially Reasonable Efforts to obtain any required approvals for sale of AG Product from the FDA pursuant to a labeling supplement to the NDA.

5.2. Subject to the terms, conditions and limitations hereof, Shire agrees to supply AG Product to Barr for Marketing pursuant to Section 4 and in accordance with the terms of this Agreement. In order to be in a position to timely and effectively enter the generic market, at Barr's request, the Parties shall cooperate in good faith to determine and prepare for the License Effective Date, including communicating

to one another, on an ongoing basis, developments which may reasonably affect the Launch of AG Product and information necessary to Label the AG Product for sale as a generic by Barr under the NDA.

5.3. All AG Product supplied will be released for sale under a generic Label in Packaging complying with the NDA. Subject to compliance with the NDA, Barr will provide Shire with appropriate and customary generic Packaging and Labeling which will be utilized by Shire in Manufacturing AG Product. Any costs incurred by Shire in utilizing such Packaging or Labeling, or in meeting other manufacturing specifications (such as tablet imprints) requested by Barr and to which Shire agrees (such agreement not to be unreasonably withheld, delayed or conditioned), including related capital expenditures, shall be included in Manufacturing Costs. Shire shall provide current Manufacturing Costs, for guidance purposes only, within ten (10) days of its receipt of a written request from Barr.

5.4. Together with the notice from Barr to supply AG Product pursuant to Section 4 of this Agreement, Barr shall provide Shire with a binding purchase order for the quantities of AG Product required for the initial Launch of AG Product (including the first three months of sales) (the "Launch Quantities"). If requested by Barr, Shire shall use Commercially Reasonable Efforts to deliver the Launch Quantities to Barr on or before the License Effective Date, so that Barr may Launch on the License Effective Date.

5.5. During the Supply Term, Barr shall deliver a quarterly forecast (a "Forecast") to Shire of the quantities of AG Product, by SKU, which Barr reasonably anticipates it will require for Marketing during the twelve (12) month period ("Forecast Period") beginning three months following the date of such Forecast and shall include quantities required to be delivered during each month of the Forecast Period. The foregoing notwithstanding, Barr shall have no obligation to provide Forecasts or orders beyond the Term of this Agreement. For each such Forecast, the first three months of the Forecast Period shall be known as the "Purchase Order Period" and the amounts specified in the Forecast for the Purchase Order Period shall constitute a binding purchase order for such period. In addition, in each subsequent Forecast, the amount ordered for the Purchase Order Period shall not deviate by more than twenty-five percent (25%) (as to the entire period or any month therein) from the second three (3) months of the immediately preceding Forecast. Other than as specifically provided in this paragraph, the amounts set forth in the Forecasts shall only constitute a non-binding estimate of the AG Product requirements of Barr.

5.6. Subject to and in accordance with the terms of Section 5.3 and 5.4, Shire shall make deliveries of AG Product to a single delivery destination specified by Barr no more than five (5) days after Barr's specified delivery dates. All such shipments of AG Product shall be EXW (Incoterms 2000) Shire's manufacturing facilities to a carrier designated by Barr. In no event shall Shire be required to make more than one (1) delivery of AG Product during any month. In the event of any inconsistency between the terms and conditions of this Agreement on the one hand, and, on the other hand, the terms and conditions of any other agreement between the Parties, or in Barr's purchase

order or Shire's invoice or confirmation, then the terms and conditions of this Agreement shall govern to the extent of any such inconsistency or conflict, provided, however, that any terms agreed to in writing by the Parties as reflected in a purchase order, invoice or confirmation that relate specifically to the quantity, quality, Packaging, Labeling, shipment and Manufacturing Costs of AG Product shall govern in the event of any such inconsistency or conflict.

5.7. Shire shall invoice Barr at the time of each shipment of AG Product at the Manufacturing Cost for such shipment. Barr shall pay each such invoice within thirty (30) days of receipt.

5.8. In addition to the foregoing, the Parties shall work together in good faith and make Commercially Reasonable Efforts to timely satisfy any changes in the quantities and delivery dates of AG Product specified in the Forecasts due to changes in demand.

5.9. AG Products supplied by Shire shall (i) have a shelf life of at least twenty four (24) months from the date of Manufacture, (ii) be delivered to Barr within thirty (30) days of Manufacture, and (iii) conform to the NDA.

5.10. All AG Products will be in finished dosage form, filled, Packaged and Labeled for commercial sale in accordance with the terms and conditions of this Agreement, the Quality Agreement (as defined in Section 7), and Applicable Laws.

5.11. During the Term, and for a period of three (3) years thereafter, Shire shall, and shall ensure that its Affiliates shall, keep at either its normal place of business, or at an off-site storage facility, detailed, accurate and up to date:

(a) records and books of account sufficient to confirm the calculation of the Manufacturing Costs; and

(b) information and data contained in any invoices provided to Barr in connection with this Agreement.

5.12. On no less than five (5) Business Days notice from Barr, to the extent that Shire supplies AG Product to Barr, Shire shall make all such records, books of account, information and data concerning the Manufacturing Cost of AG Product available for inspection during normal business hours by Barr or its nominee for the purpose of general review or audit; provided that Barr may not request such inspection more than once in any calendar year. Upon reasonable belief of discrepancy or dispute, Barr's external auditors shall be entitled to take copies or extracts from such records, books of account, information and data (but only to the extent related to the contractual obligations set out in this Agreement) during any review or audit, provided the external auditor signs a confidentiality agreement with Shire providing that such records, books of account, information and data shall be treated as Confidential Information which may be disclosed only to Barr.

5.13. Barr shall be solely responsible for its costs in making any such review and audit, unless Barr identifies a discrepancy in the calculation of Manufacturing Costs paid by Barr to Shire under this Agreement in any calendar year from those properly payable for that calendar year of five percent (5%) or greater, in which event Shire shall be solely responsible for the cost of such review and audit and refund Barr any overpayment. All information disclosed by Shire or its Affiliates pursuant to this Section 5.12 shall be deemed Confidential Information of Shire.

5.14. Nothing in this Agreement shall restrict the right of Barr to simultaneously Market AG Product and Barr Product.

6. Quality Assurance; Acceptance

6.1. Shire represents, covenants and warrants to Barr that:

(a) all AG Product hereunder shall be produced in accordance with cGMP and other Applicable Laws, rules and regulations and that none of the AG Product supplied hereunder shall be adulterated or misbranded as defined by the Act; and

(b) all shipments of AG Product supplied hereunder shall meet the specifications and quality control standards set forth in the NDA or otherwise requested by Barr and approved by Shire.

(c) Shire or a Shire Affiliate will use Commercially Reasonable Efforts to maintain throughout the Term of this Agreement all permits, licenses, registrations and other forms of governmental authorization and approval required in order for Shire to perform its obligations hereunder in accordance with all Applicable Laws.

(d) Shire or a Shire Affiliate owns and possesses all right, title and interest in the NDA.

(e) Shire has the right to grant all of the rights and licenses granted herein to Barr under the Adderall XR Intellectual Property, and it is not under any obligation to any Third Party that conflicts with the terms of this Agreement.

6.2. Shire shall perform all quality control tests and other inspections required by applicable cGMP standards and the NDA and shall furnish to Barr a certificate of analysis together with each lot of AG Product shipped to Barr. Shire will also provide Barr with Material Safety Data Sheets as required by Applicable Law for the AG Products, and updates of same as necessary.

6.3. Shire will promptly notify Barr of any request from the FDA to change AG Product specifications or Labeling and will notify Barr in writing as promptly as practical of any proposed or actual changes in specifications.

6.4. Barr shall conduct, at its own expense, such tests as it deems necessary to determine the compliance of the AG Product with the requirements of Section 6.1. Barr shall notify Shire as soon as possible after its receipt of each shipment of the AG Product of any non-compliance of the AG Product with the requirements of Section 6.1 revealed by such testing.

6.5. Subject to the provisions of Section 6.6, Shire shall replace, at its own expense, including all freight costs, any AG Product that does not meet the requirements of Section 6.1. Subject only to the indemnification obligations set forth in Section 12.1, Shire shall have no other obligations to Barr in respect of such AG Product or the representations set forth in Section 6.1.

6.6. If, following the timely delivery of a notice by Barr pursuant to the provisions of Section 6.4, Barr and Shire do not agree that any lot or lots of the AG Product referred to in the notice meets the requirements of Section 6.1, that lot or those lots of the AG Product shall be tested for such compliance, within thirty (30) days after notice of the defect is delivered to Shire, by a disinterested Third Party expert selected by the mutual agreement of Barr and Shire. The decision of such Third Party expert with respect to the question of compliance shall be binding upon Barr and Shire for the purposes of Section 6.1 of this Agreement only. The costs of such testing shall be borne by Shire if such lot or lots are found not to meet the requirements of Section 6.1 and by Barr if those lot or lots are found to meet the requirements of Section 6.1.

6.7. Barr represents, covenants and warrants to Shire that from and after tender to Barr all AG Product Marketed by Barr will be stored, shipped and handled in accordance with cGMP and all Applicable Laws, rules and regulations.

7. Regulatory Responsibilities; Adverse Event Reporting; Recalls

7.1. As the holder of the NDA, Shire will have sole authority to deal with regulatory matters relating to the NDA or AG Product. During the Term hereof, Shire shall maintain the NDA in accordance with all applicable requirements of the FDA and other Governmental Authorities, including, without limitation, Applicable Law and the filing of all annual and other reports or filings required by the FDA.

7.2. Barr shall submit to Shire all reports of Adverse Drug Experiences, together with all relevant information possessed by it, and will make all reasonable effort to provide such in time for Shire to meet all periodic and annual safety regulatory obligations to the FDA. Barr shall also promptly submit to Shire all AG Product inquiries or complaints for handling by Shire. Each Party shall cooperate with the other and provide information in its possession to the extent necessary for the other Party to comply with all legal requirements relating to the Manufacture or Marketing of Generic Product and the Parties will use diligent efforts to agree upon a customary pharmacovigilance protocol as promptly as practicable after the date hereof to provide for the necessary exchange of adverse event and related information to permit each Party to comply with Applicable Laws and regulations on a timely basis.

7.3. Each of Shire and Barr will immediately inform the other in writing if it believes one or more lots of any AG Product should be subject to recall from distribution, setting forth the reasons therefore with reasonable specificity. To the extent permitted by legal and public safety requirements, the Parties will confer before initiating any recall. If the Parties do not reach agreement on the need for a recall, either Party may initiate a recall. The Party initiating the recall shall initially bear the cost thereof and shall carry out the recall in accordance with best industry practices. In the event it is determined that a recall resulted from a breach by a Party of any of its representations or warranties hereunder, such Party shall be responsible for the costs of the recall and the cost of any unnecessary or groundless recall or other recall which is not the result of a breach by the other Party or any of its representations and warranties hereunder, shall be borne by the Party initiating or requesting such recall. In no event shall a Party's liability to the other hereunder exceed the actual out-of-pocket costs incurred or the cost of replacement of AG Product at a price equal to the Manufacturing Costs, as the case may be, and neither Party shall be liable for lost profits or other consequential damages.

7.4. As the holder of the Barr ANDA, Barr will have sole authority and responsibility to deal with regulatory matters relating to the Barr ANDA or Barr Product including maintaining the Barr ANDA in accordance with all applicable requirements of the FDA, including, without limitation, the filing of all annual and other reports or filings required by the FDA.

7.5. Shire shall keep, or cause its Affiliates to keep, as required, such samples and such records (or copies thereof) in respect of the AG Products as are required by Applicable Law for such period of time as may be required thereunder.

7.6. Each of Shire and Barr shall promptly inform the other of any correspondence from the FDA regarding the Generic Products that would materially affect its ability to meet its obligations under this Agreement. Each of Shire and Barr shall notify the other promptly, but in no event later than ten (10) Business Days following the occurrence thereof, of any materially adverse inspections by the FDA or other regulatory authorities which pertain to the Generic Products or to the facilities of such Party or its Affiliate where the Generic Products are being manufactured or stored.

7.7. Within sixty (60) days following the Effective Date, Barr and Shire shall enter into a Quality Agreement in form and content reasonably acceptable to Barr and Shire ("Quality Agreement"). The Quality Agreement will include protocols and specific responsibilities for handling AG Products quality complaints, ADE reports, and professional medical service inquiries in accordance with mutually acceptable procedures and in conformity with Applicable Laws.

8. Marketing of Generic Product

8.1. During the Term, Barr shall not enter into any arrangements or agreements with any other Person to Market or promote Generic Product other than a Permitted Agreement.

8.2. Barr will have sole discretion in setting the price for the sale of the Generic Product in the Territory.

9. Royalties And Payments

9.1. Barr Product Royalty. Barr shall pay to Shire a royalty at the rate of five percent (5%) of Net Profit on each sale of Generic Product sold by Barr or its Affiliates during any period in which Barr or its Affiliates are the only entities Marketing a Generic Equivalent in the Territory. Barr shall have no obligation to pay a royalty to Shire for Generic Product sold by Barr or its Affiliates during any period in which at least one entity other than Barr or its Affiliates is Marketing a Generic Equivalent in the Territory.

9.2. Payments due under this Section 9 shall be made within thirty (30) days from the end of each calendar quarter in which Generic Product is sold. All such payments shall include an invoice detailing the calculation of Net Sales, Net Profits and the royalties payable hereunder, as each may be applicable.

9.3. Maintenance of Records. During the Term, and for a period of three (3) years thereafter, Barr shall, and shall ensure that its Affiliates shall, keep at either its normal place of business, or at an off-site storage facility, detailed, accurate and up to date:

(a) records and books of account sufficient to confirm the calculation of the Net Sales and Net Profits; and

(b) information and data contained in any invoices or reports accompanying any payment to Shire provided to the other Party in connection with this Agreement.

9.4. Inspection. On no less than five (5) Business Days notice from Shire, Barr shall make all such records, books of account, information and data concerning this Agreement available for inspection during normal business hours by Shire or its auditors for the purpose of general review or audit; provided that Shire may not request such inspection more than once in any calendar year. Upon reasonable belief of discrepancy or dispute, Shire's external auditors shall be entitled to take copies or extracts from such records, books of account, information and data (but only to the extent related to the contractual obligations set out in this Agreement) during any review or audit provided the external auditor signs a confidentiality agreement with Barr providing that such records, books of account, information and data shall be treated as Confidential Information of Barr which may be disclosed to Shire.

9.5. Inspection Costs. Shire shall be solely responsible for its costs in making any such review and audit, unless Shire identifies a discrepancy in the calculation of royalties paid to Shire under this Agreement in any calendar year from those properly payable for that calendar year of five percent (5%) or greater, in which event Barr shall be solely responsible for the cost of such review and audit and pay Shire any underpayment. All information disclosed by Barr or its Affiliates pursuant to this Section 9 shall be deemed Confidential Information of Barr.

10. Confidentiality

10.1. Confidential Information. As used in this Agreement, the term "Confidential Information" means all secret, confidential or proprietary information or data, whether provided in written, oral, graphic, video, computer, electronic or other form, provided pursuant to this Agreement or generated pursuant to this Agreement by one Party or its Affiliates (the "Disclosing Party") to the other Party or its Affiliates (the "Receiving Party"), including but not limited to, information relating to the Disclosing Party's existing or proposed research, development efforts, patent applications, business or products, and any other materials that have not been made available by the Disclosing Party to the general public. Confidential Information shall not include any information or materials that:

(a) were already known to the Receiving Party (other than under an obligation of confidentiality), at the time of disclosure by the Disclosing Party, to the extent such Receiving Party has documentary evidence to that effect;

(b) were generally available to the public or otherwise part of the public domain at the time of disclosure thereof to the Receiving Party;

(c) became generally available to the public or otherwise part of the public domain after disclosure or development thereof, as the case may be, other than through any act or omission of a Party in breach of such Party's confidentiality obligations under this Agreement;

(d) were disclosed to a Party, other than under an obligation of confidentiality, by a third party who had no obligation to the Disclosing Party not to disclose such information to others; or

(e) were independently discovered or developed by or on behalf of the Receiving Party without the use of the Confidential Information belonging to the other Party, to the extent such Receiving Party has documentary evidence to that effect.

10.2. Confidentiality Obligations. Each of Barr and Shire shall keep confidential all Confidential Information of the other Party with the same degree of care it maintains the confidentiality of its own Confidential Information but in no event less than a reasonable degree of care. Neither Party shall use such Confidential Information

for any purpose other than in performance of this Agreement or disclose the same to any other Person other than to such of its and its Affiliates' directors, managers, employees, independent contractors, agents or consultants who are bound to confidentiality restrictions consistent with the terms herein and who have a need to know such Confidential Information to implement the terms of this Agreement or enforce its rights under this Agreement. Upon termination of this Agreement, the Receiving Party shall return or destroy all documents, tapes or other media containing Confidential Information of the Disclosing Party that remain in the possession of the Receiving Party and its Affiliates or their directors, managers, employees, independent contractors, agents or consultants, except that the Receiving Party may keep one copy of the Confidential Information in the legal department files of the Receiving Party, solely for archival purposes. Such archival copy shall continue to be subject to the provisions of this Article 10.

10.3. Permitted Disclosure and Use. Notwithstanding Section 10.2, a Party may disclose Confidential Information belonging to the other Party only to the extent such disclosure is reasonably necessary to: (a) obtain Regulatory Approval to the extent such disclosure is made to a Governmental Authority; (b) comply with or enforce any of the provisions of this Agreement; (c) comply with Laws; or (d) comply with applicable stock exchange regulations. If a Party deems it necessary to disclose Confidential Information of the other Party pursuant to this Section 10.3, such Party shall give reasonable advance notice of such disclosure to the other Party to permit such other Party sufficient opportunity to object to such disclosure or to take measures to ensure confidential treatment of such information. In addition, notwithstanding Section 10.2, the Parties shall cooperate to prepare standardized public responses to anticipated inquiries from the public, press, stockholders, investors and/or analysts with respect to the activities hereunder. Despite the foregoing, each Party agrees that the other Party is free to disclose this Agreement in its entirety to the United States Federal Trade Commission and the United States Department of Justice, or to any court with jurisdiction over the litigations settled under the Settlement Agreement between Shire Laboratories Inc. and Barr Laboratories, Inc. dated August 14, 2006.

10.4. Unauthorized Disclosure. The Receiving Party acknowledges and agrees that the Confidential Information of the Disclosing Party constitutes proprietary information and trade secrets valuable to the Disclosing Party, and that the unauthorized use, loss or outside disclosure of such Confidential Information shall be presumed to cause irreparable injury to the Disclosing Party.

10.5. Notification. The Receiving Party shall notify the Disclosing Party promptly upon discovery of any unauthorized use or disclosure of the Disclosing Party's Confidential Information, and shall cooperate with the Disclosing Party in any reasonably requested fashion to assist the Disclosing Party to regain possession of such Confidential Information and to prevent its further unauthorized use or disclosure. The Receiving Party acknowledges that monetary damages may not be a sufficient remedy for unauthorized disclosure of Confidential Information and that the Disclosing Party may be entitled, without waiving other rights or remedies, to such injunctive or equitable relief as

may be deemed proper by a court of competent jurisdiction in the event of such unauthorized disclosure.

10.6. Confidentiality of this Agreement. The terms of this Agreement shall be Confidential Information of each Party and, as such, shall be subject to the provisions of this Article 10.

11. Representations and Warranties of Both Parties

With respect to Sections 11.1 and 11.2 below, each of Shire and Barr represents, warrants, and covenants, to the other Party that:

11.1. Organization and Authority. Such Party is a corporation duly organized, validly existing and in good standing under the Laws of its jurisdiction of incorporation. Such Party has the requisite corporate power and authority to enter into this Agreement and to perform all of its obligations hereunder. The execution and delivery of this Agreement and the performance by such Party of its obligations hereunder have been authorized by all requisite corporate action on its part. This Agreement has been validly executed and delivered by such Party, and, assuming that this Agreement has been duly authorized, executed and delivered by the other Party, constitutes a valid and binding obligation of such Party, enforceable against such Party in accordance with its terms.

11.2. Consents and Approvals; No Violations.

(a) Except as otherwise set forth in this Agreement or the Settlement Agreement, no material filing with, and no material permit, authorization, consent such Party of the transactions contemplated by this Agreement, except for those filings, permits, authorizations, consents or approvals, the failure of which to be made or obtained would not materially impair such Party's ability to consummate the transactions contemplated hereby or materially delay the consummation of the transactions contemplated hereby.

(b) Neither the execution nor the delivery of this Agreement by such Party, nor the performance by such Party of its obligations hereunder, will (i) violate the certificate of incorporation, by-laws or other organizational document of such Party; (ii) conflict in any material respect with or result in a material violation or breach of, or constitute a material default under, any material contract, agreement or instrument to which such Party is a party; or (iii) violate or conflict in any material respect with any material Law, rule, regulation, judgment, order or decree of any court or Governmental Authority applicable to such Party, except in the case of clause (ii) or (iii) for violations, breaches or defaults which would not have a material adverse effect on such Party's ability to consummate the transactions contemplated hereby.

12. Indemnities; Product Liability; Insurance

12.1. Indemnity by Shire. Shire shall defend, indemnify and hold harmless each of Barr and its Affiliates and its and their directors, officers, employees and contractors ("Barr Party") from and against any and all Losses ("Shire Liability") arising from or in connection with:

(a) any Third Party claim, lawsuit, investigation, proceeding, regulatory action, or other cause of action ("Claim") resulting from any negligent acts or negligent omissions to act, or willful misconduct of any Shire Party in connection with the performance of its obligations under this Agreement;

(b) except to the extent subject to indemnification by Barr pursuant to Section 12.2(c), any Claim for personal injury or property damage based on or arising out of the use, Manufacturing or Marketing of Shire Product or AG Product;

(c) Shire's failure to Manufacture, store or release the AG Product for shipment in accordance with Applicable Laws, regulations, the NDA or this Agreement;

(d) the breach by Shire of any of its representations or warranties contained in this Agreement; or

(e) any misuse by a Shire Party of Barr's company name or logo or other trademark;

except, in each case, to the extent that the Losses are caused by the negligence, breach of the terms of this Agreement, or willful misconduct of a Barr Party.

12.2. Indemnity by Barr. Barr shall defend, indemnify and hold harmless each of Shire and its Affiliates and its and their directors, officers, employees and contractors ("Shire Party") from and against any Losses ("Barr Liability") arising from or in connection with:

(a) any Claim resulting from any negligent acts or negligent omissions to act, or willful misconduct of any Barr Party in connection with the performance of its obligations under this Agreement;

(b) any Claim for personal injury or property damage based on or arising out of the use, Manufacturing or Marketing of Barr Product;

(c) any Claim for personal injury or property damage based on or arising out of the Marketing of AG Product by Barr, to the extent that such liability is a result of the acts or failure to act of Barr, its Affiliates, or its employees, agents, partners or contractors;

(d) the breach by Barr of any of its representations or warranties contained in this Agreement; or

(e) any misuse by the Barr Parties of Shire's company name or logo or other trademark;

except, in each case, to the extent that the Barr Liability is caused by the negligence, breach of the terms of this Agreement, or willful misconduct of a Shire Party.

12.3. Control of Proceedings. A Party seeking indemnification hereunder shall provide prompt written notice to the other Party (and, in any event, within fifteen (15) Business Days) of the assertion of any claim against such Party as to which indemnity is to be requested hereunder. The indemnifying Party shall have the sole control over the defense of any Claim, provided that, the indemnifying Party shall obtain the written consent of the indemnified Party prior to settling or otherwise disposing of such Claim if as a result of the settlement or Claim disposal the indemnified Party's interests are in any way adversely affected.

12.4. No Admissions. The indemnified Party shall not make any payment or incur any expenses in connection with any Barr Liability or Shire Liability (as the case may be), or make any admissions or do anything that may compromise or prejudice the defense of any Claim without the prior written consent of the indemnifying Party.

12.5. Claim Information. Each Party shall promptly:

(a) inform the other by written notice of any actual or threatened Claim to which Sections 12.1 or 12.2 apply;

(b) provide to the other Party copies of all papers and official documents received in respect of any such Claim; and

(c) cooperate as reasonably requested by the other Party in the defense of any such Claim.

12.6. Contributory Negligence. If any Shire Liability or Barr Liability is caused by the negligence of both Shire and Barr, the apportionment of liability shall be shared between Shire and Barr based upon the comparative degree of each Party's negligence and each Party shall be responsible for its own defense and its own costs including, but not limited to, the cost of defense attorneys' fees and witnesses' fees and expenses incident thereto.

12.7. Limitation of Liability. Except as may be included in a Claim under Section 12.1 or 12.2, or in the event of a breach of Article 10, in no event shall either Party or their respective Affiliates be liable for special, punitive, indirect, incidental or consequential loss or damage based on contract, tort or any other legal theory arising out of this Agreement.

12.8. Product Liability Insurance. Each Party shall maintain, at its own cost, general commercial liability insurance (including comprehensive product

liability) in such amount as Shire and Barr respectively, customarily maintain with respect to its other products and which is reasonable and customary in the U.S. pharmaceutical industry for companies of comparable size and activities but in any event not less than $10,000,000 per occurrence and $10,000,000 in the aggregate. In the event the insurance policy obtained by a Party is a "claims made" policy (as opposed to an "occurrence" policy), such Party shall obtain comparable insurance for not less than six (6) years following the expiry or termination of this Agreement. Barr will cause Shire to be named as an additional insured under Barr's product liability insurance.

12.9. Irreparable Harm. Barr acknowledges that in the event of: (i) a Launch by Barr of Generic Product in the Territory prior to the License Effective Date or as authorized by Shire under Section 4.1, or (ii) any breach of Section 3 by Barr, the damages to Shire and its business (including, but not limited to, lost sales of Adderall XR) would be difficult to calculate and the adequacy of monetary damages calculated at Law would be uncertain. Accordingly, Barr agrees that in any action by Shire seeking injunctive or other equitable relief in connection with any such Launch prior to the License Effective Date or as authorized by Shire under Section 4.1, or any breach of Section 3, Barr shall not assert or plead the availability of an adequate remedy at Law as a defense to the obtaining of any such remedy. The foregoing shall not be in lieu of any other remedy to which Shire may be entitled hereunder in equity or at Law as a result of such a breach.

12.10. Limitation on Representations, Warranties and Indemnification. NEITHER PARTY SHALL BE DEEMED TO MAKE ANY REPRESENTATIONS OR WARRANTIES, WHETHER EXPRESS OR IMPLIED, EXCEPT AS SPECIFICALLY SET FORTH HEREIN. ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, WITH REGARD TO THE AG PRODUCT TO BE SUPPLIED BY SHIRE HEREUNDER, THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, ARE HEREBY DISCLAIMED BY EACH PARTY.

13. Force Majeure

13.1. Force Majeure. Neither Party shall be entitled to terminate this Agreement or shall be liable to the other under this Agreement for loss or damages attributable to any Force Majeure, provided the Party affected shall give prompt notice thereof to the other Party. Subject to Section 13.2, the Party giving such notice shall be excused from such of its obligations hereunder for so long as it continues to be affected by Force Majeure.

13.2. Continued Force Majeure. If any Force Majeure continues unabated for a period of at least ninety (90) days, the Parties shall meet to discuss in good faith what actions to take or what modifications should be made to this Agreement as a consequence of such Force Majeure in order to alleviate its consequences on the affected Party.

14. Trademarks and Trade Names

14.1. Except for the identification of Shire as manufacturer of AG Product on Packaging or Labeling to the extent required by Law, Barr shall have no right to use any trademark or trade dress of Shire and shall have no rights to any other intellectual property of Shire or its Affiliates (including patents or other intellectual property relating to the shape, consistency, formulation or manufacturing process for the AG Product) other than to the extent of the Authorization and License. This Agreement shall not provide to Shire any right to use (except for the purposes of labeling AG Product for Barr hereunder) any trademark or trade dress of Barr or any rights to any intellectual property of Barr or its Affiliates.

15. Term and Termination

15.1. Term. Unless sooner terminated in accordance with the terms hereof, the Term of this Agreement shall extend from the date hereof until the expiration of the last Valid Claim within the Adderall XR Intellectual Property (the "Term"). The foregoing notwithstanding, the obligations of Shire regarding supply of AG Product under this Agreement shall extend from the date hereof only until the fifth (5^{th}) anniversary of the License Effective Date (the "Initial Supply Term"). Thereafter, the Initial Supply Term shall automatically be extended for successive twelve (12) month periods (each, an "Additional Supply Term"), unless either Party gives to the other Party not less than one hundred eighty (180) days written notice of termination prior to the expiration of the Initial Supply Term, or any Additional Supply Term, of this Agreement.

15.2. Termination. -Either Party may terminate this Agreement at any time in the event that the other Party materially breaches this Agreement and, if the material breach is capable of cure, such material breach continues uncured for a period of forty-five (45) days after written notice thereof; provided, however, in the event that the breaching Party has in good faith commenced such cure within such forty-five (45) day period, but cannot practically complete such cure within such forty-five (45) day period, the breaching Party shall have an additional forty-five (45) day cure period. The foregoing notwithstanding, in the event a material breach is incapable of cure, without limiting any other rights of the non-breaching Party, including the right to seek injunctive relief, the non-breaching Party shall have the right to terminate this Agreement only if (i) the breach is the result of ongoing willful misconduct by the breaching Party, and (ii) the breaching Party is not providing cooperation to mitigate the breach; or

15.3. Effect of Termination. In the event of expiry or termination of this Agreement for any reason:

(a) Barr shall no longer have the right to Market product under the Authorization and License; provided that Barr may continue to Market inventory then on hand for an additional period not to exceed six (6) months, subject to the continued payment to Shire in accordance with Section 9; and

(b) Each Party shall promptly return to the other Party all Confidential Information of the other Party or its Affiliates received during the Term, provided that each Party may keep one copy of such Confidential Information for recordkeeping and compliance purposes.

15.4. Liability on Termination. The termination or expiry of this Agreement shall not release either of the Parties from any liability which at the time of termination or expiry has already accrued to the other Party, nor affect in any way the survival of any other right, duty or obligation of the Parties which is expressly stated elsewhere in this Agreement to survive such termination or expiry.

15.5. Surviving Sections. The provisions of Sections 5.11, 5.12, 5.13, 7.5, 9.3, 9.4 and 9.5 and Articles 10, 12, 14, 15 and 16, and any other provisions necessary and proper to give effect to the intention of the Parties as to the effect of the Agreement after termination, shall continue in force in accordance with their respective terms notwithstanding expiry or termination of this Agreement for any reason.

16. Miscellaneous Provisions

16.1. Notice.

(a) Any notice or other document given under this Agreement shall be in writing in the English language and shall be given by hand or sent by prepaid mail or fax transmission to the address of the receiving Party as set out in Section 16.2 below unless a different address or fax number has been notified to the other in writing for this purpose.

(b) Each such notice or document shall:

(i) if sent by hand, be deemed to have been given when delivered at the relevant address;

(ii) if sent by prepaid mail, be deemed to have been given five (5) days after posting; or

(iii) if sent by fax be deemed to have been given when transmitted, provided that, a confirmatory copy of such fax transmission shall have been sent by prepaid mail within twenty-four (24) hours of such transmission.

16.2. Address for Notice. The address for services of notices and other documents on the Parties shall be:

To Shire	**To Barr**
Address:	**Address**:
Shire LLC 725 Chesterbrook Boulevard	Barr Laboratories, Inc. 400 Chestnut Ridge Road,

Wayne, PA 19087
United States of America

Attention: James J. Harrington, Esq.

Fax: 484-595-8674

Woodcliff Lake, NJ 07677
United States of America

Attention: Frederick J. Killion, Esq.

Fax: 888-843-0563

16.3. Assignment.

(a) Subject to Section 16.3(b), Barr shall not assign or transfer any of its rights or obligations under this Agreement without the prior written consent of Shire, such consent not to be unreasonably withheld or delayed.

(b) Each Party shall be entitled to assign all or any of its rights or obligations under this Agreement to an Affiliate or to a successor entity by way of merger or acquisition of substantially all of the assets of such Party; provided the Affiliate or other successor entity expressly assumes in writing those rights, duties and obligations under this Agreement and this Agreement itself, and provided further that the assigning Party shall remain responsible for the assignee's performance of those rights, duties and obligations.

(c) Subject to the foregoing this Agreement shall be binding upon and inure to the benefit of the Parties and their respective successors and permitted assigns. Any assignment or transfer in contravention of the terms of this Agreement shall be null and void.

16.4. Amendment. This Agreement may not be varied, changed, waived, discharged or terminated orally, except by an instrument in writing signed by the Party against which enforcement of such variation, change, waiver, discharge or termination is sought.

16.5. Public Announcements. Except as expressly provided for in the Settlement Agreement, neither Party shall make any publicity releases, interviews or other dissemination of information concerning this Agreement or its terms, or either Party's performance hereunder, to communication media, financial analysts or others without the prior written approval of the other Party, which approval shall not be unreasonably withheld, delayed or conditioned. Notwithstanding anything to the contrary in this Agreement, the Parties understand and agree that either Party, may, if so required, disclose some or all of the information included in this Agreement or other Confidential Information of the other Party (i) in order to comply with its obligations under the Law, including the United States Securities Act of 1933, the United States Securities Exchange Act of 1934, (ii) the listing standards or agreements of any national or international securities exchange or The NASDAQ Stock Market or other similar Laws of a Governmental Authority, (iii) to respond to an inquiry of a Governmental Authority or regulatory authority as required by Law, or (iv) in a judicial, administrative or arbitration proceeding. In any such event the Party making such disclosure shall (A) provide the

other Party with as much advance notice as reasonably practicable of the required disclosure, (B) cooperate with the other Party in any attempt to prevent or limit the disclosure, and (C) limit any disclosure to the specific purpose at issue.

16.6. Superiority of Agreement. The Parties agree that the provisions of this Agreement, together with any amendments hereto, shall prevail over any inconsistent statements or provisions contained in any prior discussions, arrangements or comments between the Parties. It is agreed that:

(a) neither Party has entered into this Agreement in reliance upon any representation, warranty or undertaking of the other Party which is not expressly set out in this Agreement;

(b) neither Party shall have any remedy in respect of misrepresentation or untrue statement made by the other Party or for any breach of warranty which is not contained in this Agreement;

(c) this Section 16.6 shall not exclude any liability for, or remedy in respect of, fraudulent misrepresentation; and

(d) notwithstanding the foregoing, the Settlement Agreement shall be deemed of equal dignity to this Agreement and this Agreement shall be construed together with the Settlement Agreement in a consistent manner as reflecting a single intent and purpose.

16.7. Governing Law. This Agreement shall be governed by and construed in accordance with the internal Laws of the State of New York, without giving effect to principles of conflicts of law. The Parties irrevocably agree that the federal district courts in the State of New York shall have exclusive jurisdiction to deal with any disputes arising out of or in connection with this Agreement and that, accordingly, any proceedings arising out of or in connection with this Agreement shall be brought in the U.S. District Court for the Southern District of New York. Notwithstanding the foregoing, if there is any dispute for which the federal district courts in the State of New York do not have subject matter jurisdiction, the state courts in New York shall have jurisdiction. In connection with any dispute arising out of or in connection with this Agreement, each Party hereby expressly consents and submits to the personal jurisdiction of the federal and state courts in the County, City and State of New York.

16.8. Agreement Costs. Each Party shall pay its own costs, charges and expenses incurred in connection with the negotiation, preparation and completion of this Agreement.

16.9. Counterparts. This Agreement may be executed in any number of counterparts and may be executed by the Parties on separate counterparts, each of which is an original but all of which together constitute the same instrument.

16.10. Severability. If and to the extent that any provision of this Agreement is held to be illegal, void or unenforceable, such provision shall be given no effect and shall be deemed not to be included in this Agreement but without invalidating any of the remaining provisions of this Agreement.

16.11. Relationship of the Parties. In making and performing this Agreement, the Parties are acting, and intend to be treated, as independent entities; and nothing contained in this Agreement shall be construed or implied to create an agency, partnership, joint venture, or employer and employee relationship between Shire and Barr. Except as otherwise provided herein, neither Party may make any representation, warranty or commitment, whether express or implied, on behalf of, or incur any charges or expenses for or in the name of, the other Party.

16.12. Construction. The language in all parts of this Agreement shall be construed, in all cases, according to its fair meaning. Shire and Barr acknowledge that each Party and its counsel have reviewed and revised this Agreement and that any rule of construction to the effect that any ambiguities are to be resolved against the drafting Party shall not be employed in the interpretation of this Agreement. The words "hereof," "herein," "hereto" and "hereunder" and words of similar import, when used in this Agreement, shall refer to this Agreement as a whole and not to any particular provision of this Agreement. The terms defined in the singular shall have a comparable meaning when used in the plural, and vice versa. Whenever used herein, the words "include," "includes" and "including" shall mean "include, without limitation," "includes, without limitation" and "including, without limitation," respectively. The masculine, feminine or neuter gender and the singular or plural number shall each be deemed to include the others whenever the context so indicates. With respect to any particular action or agreement, the use of the words "Shire shall" or "Shire will" herein shall also mean "Shire shall cause" the particular action to be performed. Similarly, with respect to any particular action or agreement, the use of the words "Barr shall" or "Barr will" herein shall also mean "Barr shall cause" the particular action to be performed. Nothing in this Agreement shall operate to exclude any provision implied into this Agreement by Law and which may not be excluded by Law or limit or exclude any liability, right or remedy to a greater extent than is permissible under Law.

16.13. Dispute Resolution.

(a) Preliminary Process. If there is a disagreement between the Parties as to the interpretation of this Agreement or in relation to any aspect of the performance by either Party of its obligations under this Agreement, the Parties shall, within ten (10) Business Days of receipt of a written request from either Party, meet in good faith and try to resolve the disagreement without recourse to legal proceedings.

(b) Escalation of Dispute. If resolution of the disagreement does not occur within five (5) Business Days after such meeting, the matter shall be escalated for determination by the President of Barr and Shire's President, Specialty

Pharmaceuticals for resolution, who may resolve the matter themselves or jointly appoint a mediator or independent expert to do so.

(c) Equitable Relief. Nothing in this Section 16.13 restricts either Party's freedom to seek urgent relief to preserve a legal right or remedy, or to protect a proprietary or trade secret right, or to otherwise seek legal remedies through any available channel if resolution is not otherwise achieved under this Section 16.13.

16.14. Cumulative Rights. The rights and remedies of each of the Parties under or pursuant to this Agreement are cumulative, may be exercised as often as such Party considers appropriate and are in addition to its rights and remedies under general aw.

16.15. No Third Party Benefit. This Agreement shall be binding upon and inure solely to the benefit of the Parties hereto, their successors and permitted assigns, and nothing in this Agreement, express or implied, is intended to or shall confer upon any other Person or Persons any right, benefits or remedies of any nature whatsoever under or by reason of this Agreement.

16.16. Further Assurance. Each of the Parties shall do, execute and perform and shall procure to be done and perform all such further acts deeds documents and things as the other Party may reasonably require from time to time to give full effect to the terms of this Agreement.

16.17. Waiver. No failure or delay by either Party in exercising any right or remedy provided by law under or pursuant to this Agreement shall impair such right or remedy or operate or be construed as a waiver or variation of it or preclude its exercise at any subsequent time and no single or partial exercise of any such right or remedy shall preclude any other or further exercise of it or the exercise of any other right or remedy.

[Signature Page Follows]

[Signature Page to the License Agreement]

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

SHIRE LLC

Date: _____ By: _____

Name: _____

Title: _____

BARR LABORATORIES, INC.

Date: _____ **By:** _____

Name: _____

Title: _____