

foiapa

18-04149-E

**From:** Request@ip-10-170-25-201.ec2.internal  
**Sent:** Friday, April 27, 2018 4:20 AM  
**To:** foiapa  
**Subject:** Request for Document from Norkeviciute, Auguste



Auguste Norkeviciute  
Darius ir Gireno st. 42  
Vilnius, Foreign Country LT02189  
Lithuania

0037062443528  
[auguste.norkeviciute@royaltyrange.com](mailto:auguste.norkeviciute@royaltyrange.com)  
RoyaltyRange Europe UAB

Request:  
COMP\_NAME: DYAX CORP  
DOC\_DATE: 2010-11-02  
TYPE: 10-Q (Quarterly Report)  
COMMENTS: Exhibit 10.1, Form 10-Q, filed on 2010-11-02 by DYAX CORP  
FEE\_AUTHORIZED: Willing to Pay \$61  
FEE\_WAIVER\_REQUESTED: No  
EXPEDITED\_SERVICE\_REQUESTED: NO



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

Office of FOIA Services

June 6, 2018

Ms. Auguste Norkeviciute  
RoyaltyRange Europe UAB  
Dariaus ir Gireno st. 42  
Vilnius, Lithuania LT02189

RE: Freedom of Information Act (FOIA), 5 U.S.C. § 552  
Request No. 18-04149-E

Dear Ms. Norkeviciute:

This letter is in response to your request, dated and received in this office on April 27, 2018, for Exhibit 10.1, Form 10-Q, filed on November 2, 2010 by Dyax Corp.

The search for responsive records has resulted in the retrieval of 54 pages of records that may be responsive to your request. They are being provided with this letter.

No fees were assessed in the processing of your request. If you have any questions, please contact me at [morrowa@sec.gov](mailto:morrowa@sec.gov) or (202) 551-8376. You may also contact me at [foiapa@sec.gov](mailto:foiapa@sec.gov) or (202) 551-7900. You also have the right to seek assistance from Jeffery Ovalle 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](http://Archives.gov) or via e-mail at [ogis@nara.gov](mailto:ogis@nara.gov).

Sincerely,

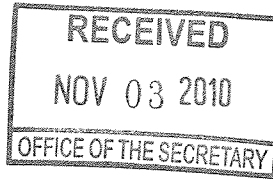
A handwritten signature in cursive script that reads "Alysia Morrow".

Alysia Morrow  
FOIA Research Specialist

Enclosure

Dyax Corp. has requested that the highlighted portions of this document be accorded confidential treatment pursuant to Rule 24b-2 promulgated under the Securities Exchange Act of 1934, as amended.

**CONFIDENTIAL DOCUMENT  
EXECUTION COPY**



**PRODUCT DEVELOPMENT AND LICENSE AGREEMENT**

**BY AND BETWEEN**

**DYAX CORP.**

**AND**

**CMIC CO. LTD.**

**DATED AS OF SEPTEMBER 28, 2010**

**PRODUCT DEVELOPMENT AND LICENSE AGREEMENT**

This Product Development and License Agreement (this "Agreement") is made effective as of September 28, 2010 (the "Effective Date") by and between Dyax Corp., with offices at 300 Technology Square, Cambridge, Massachusetts 02139, U.S.A. ("Dyax"), and CMIC Co. Ltd., with offices at Kongo Bldg, 7-10-4 Nishigotanda, Shinagawa-ku, Tokyo 141-0031 ("CMIC").

**INTRODUCTION**

WHEREAS, Dyax owns or controls certain patents, know-how and other rights related to its proprietary novel plasma kallikrein inhibitor known as DX-88 (ecallantide);

WHEREAS, CMIC is engaged in the development and commercialization of pharmaceutical products in Japan;

WHEREAS, CMIC desires to obtain a license from Dyax to develop products incorporating DX-88 for the treatment of angioedemas in the CMIC Territory (as such term is defined herein); and

WHEREAS, Dyax is willing to grant CMIC such a license on the terms and conditions set forth herein;

NOW, THEREFORE, for and in consideration of the mutual covenants contained herein, Dyax and CMIC hereby agree as follows:

**ARTICLE I  
DEFINITIONS**

As used in this Agreement, the following terms shall have the meanings set forth below:

1.1 "Affiliate". Affiliate shall mean with respect to any Person, any Person controlling, controlled by or under common control with the former Person. For the purposes of this Section 1.1, "control" shall mean (a) in the case of a Person that is a corporate entity, the direct or indirect ownership of more than fifty percent (50%) of the stock, shares or ownership interest having the right to vote for the election of directors of such Person and (b) in the case of a Person that is an entity, but is not a corporate entity, the direct or indirect possession of the power to direct, or cause the direction of, the management or policies of such Person, whether through the ownership of voting securities, by contract or otherwise.

1.2 "Alliance Manager". Alliance Manager shall have the meaning given to that term under Section 2.6.

1.3 "Bankruptcy Code". The Bankruptcy Code shall mean Title 11 of the United States Code.

1.4 "Batch". Batch shall mean a quantity of Drug Substance manufactured by Dyax (or its CMO) that (a) is expected to have a uniform character and quality within specified limits, and (b) is produced according to a single manufacturing run during the same cycle.

1.5 "Blocking Third Party Patent Rights". Blocking Third Party Patent Rights shall mean, with respect to any country in the CMIC Territory, on a country-by-country basis, the Patent Rights in such country owned or controlled by a Third Party that would Cover Product or its Manufacture or Commercialization in the Field. Notwithstanding the foregoing, the Patent Rights licensed from RCT to Dyax under the RCT License Agreement shall not constitute Blocking Third Party Patent Rights.

1.6 "Breaching Party". Breaching Party shall have the meaning given to that term under Section 12.2(b).

1.7 "Business Day". Business Day shall mean a day that is not a Saturday, Sunday or a day on which banking institutions in Cambridge, Massachusetts, USA or Tokyo, Japan remain closed.

1.8 "Calendar Quarter". Calendar Quarter shall mean each of the periods ending on March 31, June 30, September 30 and December 31 of any year.

1.9 "Challenging Party". Challenging Party shall have the meaning given to that term under Section 12.2(d).

1.10 "CMIC Development Data". CMIC Development Data shall mean, as it pertains to Product or its use, all pharmacology and toxicology data and information, pre-clinical study data, clinical trial data, protocols, safety data, quality data and other regulatory information and reports, whether in written or electronic form, generated or developed by CMIC or any of its Affiliates in the course of performing the activities under this Agreement during the Term.

1.11 "CMIC Intellectual Property". CMIC Intellectual Property shall mean CMIC Know-How and CMIC Patent Rights, collectively.

1.12 "CMIC Know-How". CMIC Know-How shall mean any Know-How that (a) comes within CMIC's Control during the Term, including CMIC's rights in Joint Know-How and CMIC Sole Inventions, and (b) is useful for the Development, Manufacture and/or Commercialization of Compound or Product as contemplated by this Agreement.

1.13 "CMIC Patent Rights". CMIC Patent Rights shall mean any Patent Rights that (a) claim CMIC Know-How, and (b) come within CMIC's Control during the Term. CMIC Patent Rights shall include CMIC's rights in Joint Patent Rights as well as any Patent Rights covering CMIC Sole Inventions.

1.14 "CMIC Product Trademarks". CMIC Product Trademarks shall have the meaning given to that term under Section 8.8(d)

1.15 "CMIC Promotional Materials". CMIC Promotional Materials shall have the meaning given to that term in Section 5.2.

1.16 "CMIC Sole Inventions". CMIC Sole Inventions shall have the meaning given to that term under Section 8.1(b).

1.17 "CMIC Territory". CMIC Territory shall mean Japan. Furthermore, if, pursuant to the Right of Second Offer described in Section 3.6, Dyax and CMIC reach a full agreement on the terms and conditions of a license to develop, manufacture and/or commercialize Product in the People's Republic of China, then, subject to such terms and conditions, CMIC Territory shall thereafter include the People's Republic of China.

1.18 "CMO". CMO shall mean a contract manufacturing organization contracting with Dyax to supply Dyax or CMIC with Drug Substance or Drug Product pursuant to Article VI.

1.19 "Commercialization" or "Commercialize". Commercialization or Commercialize shall mean the activities to market, promote, store, import, export, offer to sell and sell Product, including conducting any Post-Approval Studies to support Commercialization. Commercialization shall not include any activities that are covered by the definitions of "Development", "Manufacturing" or "Post-Filing Activities".

1.20 "Commercially Reasonable Efforts". Commercially Reasonable Efforts shall mean the conduct and completion of an activity by a Party in a diligent and commercially reasonable manner, using efforts not less than the efforts the Party uses to other similar activities, based on conditions then prevailing and any other technical, legal, scientific, medical or commercial factors that the Party deems in good faith to be relevant.

1.21 "Competitive Infringement". Competitive Infringement shall have the meaning given to that term under Section 8.3(a).

1.22 "Competitive Product". Competitive Product shall mean the following therapeutic or prophylactic products; (1) Cinryze of ViroPharma Inc., (2) Berinert P of CSL Behring, (3) Firazyl of Jerini AG / Shire plc., (4) Ruconest of Pharming Group NV and (5) MDCO-2010 of The Medicines Company.

1.23 "Complaint". Complaint shall mean any information concerning any side effect, injury, toxicity or sensitivity reaction, or any unexpected incident, adverse drug experience (as that term is defined in Section 505-1 of the FDCA) or adverse event (as that term is defined under the ICH Guidelines) in or involving a subject or, in the case of pre-clinical studies, an animal in a toxicology study, and the seriousness thereof, whether or not determined to be attributable

to Compound or Product, including any such information received by either Party from its Related Parties or other Third Parties.

1.24 "Compound". Compound shall mean the compound known as DX-88 (ecallantide) with the amino acid sequence described in Exhibit A.

1.25 "Confidential Information". Confidential Information shall have the meaning given to that term under Section 9.1.

1.26 "Confidentiality Agreement". Confidentiality Agreement shall mean the Confidentiality Agreement executed by and between the parties hereto as of June 2, 2009.

1.27 "Control" or "Controlled". Control or Controlled shall mean, with respect to any intellectual property right or other intangible property, or Know-How, the possession (whether by license granted to or ownership vested in a Party or its Affiliate, other than pursuant to this Agreement) by the Party of the ability to grant to the other Party access, ownership and/or a license or sublicense as provided for herein without violating the terms and conditions of any agreement with any Third Party; provided that the Party shall be deemed not to Control any intellectual property right or other intangible property or Know-How it acquires after the Effective Date (whether by license or otherwise), unless and until the other Party agrees in writing to:

- (a) accept the terms and conditions of the license (to such intellectual property right or other intangible property or Know-How) to such other Party, which shall be consistent with all the terms and conditions of the relevant Third Party agreement; and
- (b) pay the licensing Party its proportionate share of fees, milestones, royalties and other payments due under such license, taking into account any other licensees which are granted rights under the license by the licensing Party, if and to the extent paid by the licensing Party to acquire such intellectual property right or other intangible property or Know-How.

For clarity, this proviso shall not apply to any In-License of Blocking Third Party Patent Rights.

1.28 "Cover", "Covering" or "Covered". Cover, Covering or Covered shall mean, with respect to Compound, Product and/or technology, that (a) in the absence of a license granted under a Valid Claim of an issued patent, the making, use, offering for sale, sale, or importation of Compound or Product, or the practice of such technology would infringe such Valid Claim, and (b) in the absence of a license granted under a Valid Claim of a patent application, the making, use, offering for sale, sale, or importation of Compound or Product, or the practice of such technology would infringe such Valid Claim if it were to issue in a patent.

1.29 "Development" or "Develop". Development or Develop shall mean, in respect of Compound or Product, pre-clinical and clinical research and drug development activities, including toxicology, test method development and stability testing and studies, process development, formulation development, delivery system development, quality assurance and quality control development, statistical analysis, clinical studies (other than post-approval studies), regulatory affairs, and product approval and regulatory activities (excluding regulatory activities directed to obtaining pricing and reimbursement approvals).

1.30 "Development Costs". Development Costs shall mean, with respect to Compound or Product, all of the out-of-pocket and internal costs and expenses incurred by or on behalf of the Parties after the Effective Date in connection with the Development of Compound or Product for use in the Field. Development Costs shall consist of:

- (a) Manufacturing Costs for obtaining the Drug Substance and/or Drug Product to be used for the Development of Product;
- (b) costs of the studies on the preclinical, toxicological, pharmacokinetic, metabolic, clinical and/or stability aspects of Compound or Product;
- (c) costs of conducting the clinical studies for Product (other than Post-Approval Studies), including the costs of clinical supplies, and all of the internal and external costs incurred in purchasing and/or packaging comparator drugs, disposal of clinical samples, related regulatory

compliance, quality control, medical affairs, clinical operations, study subject recruitment and the preparation, collation and/or validation of data from such clinical studies;

- (d) costs of preparing, submitting, reviewing or developing data or information, and preparing medical writing, for the purpose of submission to a Regulatory Authority to obtain approval to commence clinical studies (other than Post-Approval Studies) or to obtain Regulatory Approval for Product and the costs associated with submitting for, amending or maintaining such approval(s); and
- (e) the fully allocated costs of internal clinical, regulatory, scientific, or technical personnel engaged in such Development.

Development Costs shall not include any costs associated with Post-Filing Activities or Post-Approval Studies, which shall be included in Regulatory Activities Costs.

1.31 "Development Plan". Development Plan shall mean (i) the HAE Development Plan approved by the JSC under Section 4.1 and (ii) any Other Angioedema Development Plan approved by the JSC under Section 4.2.

1.32 "Drug Product". Drug Product shall mean the finished Product formulation containing Drug Substance filled into unlabelled vials.

1.33 "Drug Product Order Limit". Drug Product Order Limit shall mean, with respect to any order for Drug Product placed during a Calendar Quarter, a quantity equal to the maximum amount of Drug Product that can be Manufactured from Drug Substance Inventory that is, or is anticipated to be, available for use in the Manufacture of Drug Product as of the start of the relevant batch run.

1.34 "Drug Substance". Drug Substance shall mean Compound in bulk form manufactured for use as an active pharmaceutical ingredient in Drug Product.

1.35 "Drug Substance Inventory". Drug Substance Inventory shall mean Drug Substance that (i) has been Manufactured by Dyax (and for which quality release has been completed) pursuant to an order placed by CMIC in accordance with Section 6.1(c), and (ii) is being held by Dyax (or its contractor) on behalf of CMIC for use in the Manufacture of Drug Product ordered by CMIC in accordance with Section 6.1(d).

1.36 "Drug Substance Order Limit". Drug Substance Order Limit shall mean, with respect to any order for Drug Substance placed during a Calendar Quarter, a quantity equal to the lower of:

- (a) the quantity of Drug Substance forecasted for the order during the Calendar Quarter in the most recent forecast provided by CMIC to Dyax plus one additional Batch; and
- (b) one hundred twenty percent (120%) of the average of the quantity of Drug Substance forecasted for the order during the Calendar Quarter in the four (4) most recent forecasts provided by CMIC to Dyax.

1.37 "Dyax Development Data". Dyax Development Data shall mean, as it pertains to Product or its use in Field, all pharmacology and toxicology data and information, pre-clinical study data, clinical trial data, protocols, safety data, quality data and other regulatory information and reports, whether in written or electronic form, generated or developed by Dyax or its Affiliates in the course of developing Product in Field.

1.38 "Dyax Intellectual Property". Dyax Intellectual Property shall mean Dyax Know-How and Dyax Patent Rights.

1.39 "Dyax Know-How". Dyax Know-How shall mean any Know-How that (a) either is owned or Controlled by Dyax on the Effective Date or comes within Dyax's Control during the Term, including Dyax's rights in Joint Know-How and Dyax Sole Inventions and (b) is necessary for the Development, Manufacture and/or Commercialization of Product as contemplated by this Agreement, including all Know-How generated or developed by or for Dyax or its Affiliates in the course of Development of Product. Notwithstanding the foregoing, Dyax Know-How shall specifically exclude:

- (i) technologies applied to peptides or proteins with the primary purpose to extend the in vivo half-life of peptides or proteins;
- (ii) Dyax's proprietary display discovery technologies for generating and screening peptide libraries, Kunitz domains or antibody libraries or any peptide libraries, Kunitz domains or antibody libraries generated through the use of such technologies, or any molecules (other than Compound) generated from such libraries; and
- (iii) RCT Intellectual Property.

1.40 "Dyax Patent Rights". Dyax Patent Rights shall mean any Patent Rights that (a) Cover Dyax Know-How and (b) are owned or Controlled by Dyax on the Effective Date or come within Dyax's Control during the Term, including Existing Dyax Patent Rights, Dyax's rights in Joint Patent Rights, and any Patent Rights applicable to Dyax Sole Inventions. Notwithstanding the foregoing, Dyax Patent Rights shall specifically exclude RCT Intellectual Property.

1.41 "Dyax Product Trademarks". Dyax Product Trademarks shall have the meaning given to that term under Section 8.8(b).

1.42 "Dyax Sole Inventions". Dyax Sole Inventions shall have the meaning given to that term under Section 8.1(b).

1.43 "Dyax Territory". Dyax Territory shall mean all the countries of the world outside CMIC Territory.

1.44 "Executive Officers". Executive Officers shall mean the Chief Executive Officer of Dyax (or a senior executive officer of Dyax designated by Dyax's Chief Executive Officer) and the Chief Executive Officer of CMIC (or a senior executive officer of CMIC designated by CMIC's Chief Executive Officer).

1.45 "Existing Dyax Patent Rights". Existing Dyax Patent Rights shall mean those Dyax Patent Rights specifically listed on Exhibit B.

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

1.47 "FDCA". FDCA shall mean the United States Federal Food, Drug and Cosmetic Act, as amended.

1.48 "Field". Field shall mean use in the HAE and Other Angioedema Indications. Notwithstanding anything to the contrary contained herein, in no event shall Field include any use in any other Indications (including any Indications in Ophthalmic Field or Surgical Field, which are specifically excluded from the rights granted to CMIC under this Agreement).

1.49 "First Commercial Sale". First Commercial Sale shall mean, with respect to Product in a country, the first commercial sale of Product in the country.

1.50 "GAAP". GAAP shall mean (a) with respect to Dyax, generally accepted accounting principles in the United States as consistently applied by Dyax in the preparation of its financial statements and (b) with respect to CMIC, generally accepted accounting principles in Japan as consistently applied by CMIC in the preparation of its financial statements.

1.51 "HAE". HAE shall mean hereditary angioedema.

1.52 "HAE Development Plan". HAE Development Plan shall have the meaning given to that term under Section 4.1.

1.53 "ICH Guidelines". ICH Guidelines shall mean the International Conference on Harmonisation guidelines, including E2A, E2B, E2C and E2D thereof as amended and any replacement thereof.

1.54 "IND". IND shall mean an Investigational New Drug Application filed with FDA or a similar application to conduct clinical studies filed with an applicable Regulatory Authority outside of the United States.

11.3. 1.55 "Indemnified Parties". Indemnified Parties shall have the meaning given to that term under Section 11.3.

11.3. 1.56 "Indemnifying Parties". Indemnifying Parties shall have the meaning given to that term under Section 11.3.

1.57 "Indication". Indication shall mean a specified therapeutic use of a Product, which use has been approved by a Regulatory Authority (whether through a label expansion or a separate Regulatory Approval).

1.58 "In-License". In-License shall mean an agreement between a Party or its Affiliate and a Third Party pursuant to which the Party or its Affiliate has been granted a license to Blocking Third Party Patent Rights for use by either Party or both Parties in accordance with Section 3.4.

1.59 "Invention". Invention shall mean any Know-How or Patent Right that is generated, conceived, reduced to practice and/or developed during the Term in relation to Compound or Product (or the use thereof).

1.60 "Joint Intellectual Property". Joint Intellectual Property shall mean Joint Know-How and Joint Patent Rights, collectively.

1.61 "Joint Inventions". Joint Inventions shall have the meaning given to that term under Section 8.1(c).

1.62 "Joint Know-How". Joint Know-How shall mean any Know-How that is generated, conceived, reduced to practice, developed or acquired jointly by the Parties in the course of performing the activities under this Agreement, including Joint Inventions.

1.63 "Joint Patent Rights". Joint Patent Rights shall mean the Patent Rights that Cover Joint Know-How.

1.64 "Joint Steering Committee" or "JSC". Joint Steering Committee or JSC shall have the meaning given to that term under Section 2.1(a).

1.65 "Know-How". Know-How shall mean any information, whether proprietary or not and whether patentable or not, including ideas, concepts, inventions, formulas, methods, protocols, procedures, knowledge, know-how, trade secrets, processes, assays, skills, experience, techniques, designs, compositions, plans, documents, results of experimentation and testing, including pharmacological, toxicological, and pre-clinical and clinical test data and analytical and quality control data, improvements, discoveries and works of authorship.

1.66 "Knowledge." Knowledge shall mean, with respect to a Party or its Affiliates, the actual awareness of a certain fact or information by an officer or senior manager or other employee with a similar responsibility, regardless of title, of the Party or its Affiliate.

1.67 "Manufacturing" or "Manufacture". Manufacturing or Manufacture shall mean the activities directed to producing, manufacturing, processing, filling and finishing (including packaging and labeling) any Product or component thereof.

1.68 "Manufacturing Costs". Manufacturing Costs shall mean with respect to Drug Substance or Drug Product, the manufacturing Party's fully-loaded internal and external costs, determined in accordance with GAAP by the manufacturing Party in the ordinary course of its business and incurred in the course of Manufacturing the Drug Substance or Drug Product, which costs shall include:

- (a) the costs for (i) stability and other product testing and activities relating to quality assurance and quality control, and/or (ii) any incremental validation activities required by any Regulatory Authority in the CMIC Territory (e.g. the validation of additional shipping lanes associated with delivery of Drug Substance or Drug Product to CMIC); and
- (b) the direct labor, material, overhead and Third Party expenses allocable to the Manufacture of Drug Substance or Drug Product.

1.69 "Marketing Authorization Application". Marketing Authorization Application shall mean the application submitted to the competent government agency to manufacture, market and sell Product in Field in one or more countries within Territory.

1.70 "Net Sales". Net Sales shall mean, with respect to Product, the gross invoiced sales price of the Product in CMIC Territory by CMIC and its Related Parties, less the following deductions to the extent included in the gross invoiced sales price for the Product or otherwise directly paid or incurred by CMIC or its Related Parties with respect to the sale of the Product:

- (a) discounts, credits, retroactive price reductions, rebates, allowances and adjustments granted to Third Parties that are not the Related Parties of CMIC, and rejections, recalls and returns, to the extent reasonably consistent with the industry practice for similar products;
- (b) trade, quantity, and cash discounts, and fee-for-service wholesaler fees and inventory management fees paid to wholesalers and reasonably allocated to Product, to the extent reasonably consistent with the industry practice for similar products;
- (c) amounts payable resulting from governmental (or any agency thereof) mandated rebate programs;
- (d) chargebacks and other amounts paid on the sale or dispensing of Product;
- (e) sales, excise, turnover, inventory, value-added, and similar taxes assessed on the sale of Product (other than taxes on CMIC's or its Related Parties' net income), tariffs and import, export and customs duties;
- (f) transportation, freight, postage, importation, shipping insurance and other handling expenses;
- (g) delayed ship order credits;
- (h) discounts pursuant to indigent patient programs and patient discount programs and coupon discounts; and
- (i) amounts that are written off as uncollectible in accordance with CMIC's accounting procedures consistently applied.

In the case of any sale or other disposal of Product between or among CMIC, its Affiliates or Sublicensees for resale to Third Party, the Net Sales of the Product shall be calculated as above only on the value charged or invoiced on the first arm's-length sale or other disposition of the Product to Third Party.

Notwithstanding the foregoing, in any case where Product is sold or otherwise disposed of in a transaction that is not the arm's length sale of Product only in cash that is separate from any sale or disposition of other products or of services, the Net Sales of the Product shall mean the greatest of:

- (x) the net sales amount, determined as provided for above, for the Product sold or disposed of in such transaction, with any non-cash consideration attributable to such transaction and valued at fair market value;
- (y) if, in CMIC Territory, there has been any arm's length sale of Product separate from any sale or disposition of other products or of services to Third Party that is not Related Party of CMIC, the net sales amount, determined as provided for above, for the most contemporaneous such sale in CMIC Territory; or
- (z) if, in CMIC Territory, there has been no such arm's length sale as referred to in above (y), the fraction of the overall value of such transaction (with any non-cash consideration attributable to such transaction and valued at fair market value) reasonably attributed to the Product sold in such transaction.

1.71 "Non-Breaching Party". Non-Breaching Party shall have the meaning given to that term under Section 12.2(b).

1.72 "Ophthalmic Field". Ophthalmic Field shall mean all uses in the therapeutic treatment or prevention of any ophthalmic disease, infection or other ophthalmic condition.

1.73 "Other Angioedema". Other Angioedema shall mean acquired angioedema, drug-induced angioedema and idiopathic angioedema.

1.74 "Parties". Parties shall mean Dyax and CMIC.

1.75 "Party". Party shall mean either Dyax or CMIC.

1.76 "Patent Rights". Patent Rights shall mean any and all patents and patent applications anywhere in the world, including provisional, utility, substitution, divisional, continuation and continuation-in-part applications, and reissues, reexaminations and extensions thereof, patents of addition and any Supplementary Protection Certificates, restoration of patent term and other similar rights.

1.77 "PMDA". PMDA shall mean the Pharmaceuticals and Medical Devices Agency or any successor agency thereto responsible for reviewing the application for Regulatory Approval in Japan.

1.78 "Person". Person shall mean any natural person, corporation, firm, business trust, limited liability company, joint venture, association, organization, company, partnership or other business entity, or any government, or any agency or political subdivisions thereof.

1.79 "Post-Approval Studies". Post-Approval Studies shall mean those studies and activities subsequent to the granting of Regulatory Approval that are required or necessary for the maintenance of the Regulatory Approval.

1.80 "Post-Filing Activities". Post-Filing Activities shall mean all the studies and activities subsequent to filing an application for Regulatory Approval in the CMIC Territory but prior to obtaining the Regulatory Approval that are required, or are necessary to comply with the requirements by the Regulatory Authority for obtaining the Regulatory Approval in the CMIC Territory.

1.81 "Product". Product shall mean any pharmaceutical product containing Compound for subcutaneous administration.

1.82 "Product Competitor". Product Competitor shall mean any Third Party that is engaged in the clinical development, manufacture and/or commercialization of a therapeutic or prophylactic product that has its intended inhibitory activity against plasma kallikrein, bradykinin or antagonists of their respective receptors. As of the Effective Date, Product Competitors consist of: ViroPharma Inc., CSL Behring, Jerini AG/Shire plc, The Medicines Company, and Pharming Group NV.

1.83 "Product Manufacturing Process". Product Manufacturing Process shall mean the processes used to complete the Manufacture of unlabeled vials of Product for CMIC under this Agreement, which processes shall include the Manufacture of Drug Substance and Drug Product.

1.84 "Product Trademark(s)". Product Trademark(s) shall mean the trademark(s) and service mark(s) distinguishing Product, and used in connection with the Commercialization and/or any other distribution, marketing, promotion and sale activities of or for Product according to Section 8.8, and/or accompanying logos, trade dresses and/or indicia of origin.

1.85 "Prosecuting Party". Prosecuting Party shall have the meaning given to that term under Section 8.2(a).

1.86 "Quality Agreement". Quality Agreement shall have the meaning given to that term under Section 6.5.

1.87 "RCT". RCT shall mean Research Corporation Technologies, Inc.

1.88 "RCT License Agreement". RCT License Agreement shall mean the License Agreement effective April 3, 1997 between RCT and Dyax.

1.89 "RCT Intellectual Property". RCT Intellectual Property shall mean the "RCT Expression System", the "RCT Expression Technology" and the "RCT Patent Rights" as such terms are defined in Paragraphs 1.3, 1.5 and 1.8 of RCT License Agreement.

1.90 "Regulatory Activities". Regulatory Activities shall mean all of the activities associated with the submission of Regulatory Filings, including (i) preparing and drafting of the reports for and the correspondence with

Regulatory Authorities, (ii), holding meetings and conversations with Regulatory Authorities, (iii) Post-Filing Activities, (iv) the activities relating to the maintenance of Regulatory Approval and (v) the performance of Post-Approval Studies.

1.91 "Regulatory Activities Costs". Regulatory Activities Costs shall mean all the costs and expenses (excluding Development Costs) for Regulatory Activities, including (i) the fully allocated costs of both Parties' internal clinical, regulatory and technical personnel engaged in the Regulatory Activities, (ii) the fees and other amounts to be paid to Regulatory Authority in connection therewith, and (iii) the costs associated with any Post-Filing Activities or Post-Approval Studies.

1.92 "Regulatory Approval". Regulatory Approval shall mean all the governmental and regulatory approvals required to Commercialize Product for a particular indication in a particular country, including any permit, authorization, license or approval (or waiver) from any Regulatory Authority required for the Commercialization of Product and separate pricing and/or reimbursement approvals from Regulatory Authorities even if not legally required for the Commercialization of Product.

1.93 "Regulatory Authority". Regulatory Authority shall mean any federal, national, multinational, state, provincial or local regulatory agency, department, bureau or other governmental entity with authority over the clinical trial, marketing and/or sale of a pharmaceutical product in a country, including FDA in the United States and PMDA in Japan.

1.94 "Regulatory Exclusivity". Regulatory Exclusivity shall have the meaning given to that term under Section 8.6.

1.95 "Regulatory Filings". Regulatory Filings shall mean all the applications and registrations, including any INDs, submitted to any Regulatory Authority with respect to Product to obtain the Regulatory Approval of the Product in a country.

1.96 "Related Party". Related Party shall mean any of a Party's Affiliates and Sublicensees.

1.97 "Royalty Term". Royalty Term shall be the time-period during which CMIC shall pay royalties to Dyax under Section 7.5(b).

1.98 "Safety Data". Safety Data shall mean adverse event or adverse experience information, as defined under 21 C.F.R. §600.80 or ICH Guidelines, as applicable, or their equivalent under any other applicable law, and other information regarding health risks posed by Product, including Complaints.

1.99 "Sole Inventions". Sole Inventions shall have the meaning given to that term under Section 8.1(b).

1.100 "Specifications". Specifications shall mean the specifications, including the necessary documentation, certificates of analysis and test results, for Drug Substance and Drug Product, as mutually agreed upon by the Parties. For the sake of clarity, the Specifications for Drug Substance and Drug Product may vary by country, depending on the countries in which Product is Developed or in which Product is Commercialized.

1.101 "Sublicensee". Sublicensee shall mean any Third Party to whom a license or sublicense under any Dyax Intellectual Property or CMIC Intellectual Property, as the case may be, has been granted pursuant to this Agreement to Develop, Manufacture or Commercialize products containing Compound.

1.102 "Sublicensee Development Data". Sublicensee Development Data shall, as it pertains to Product or its use, mean all the pharmacology and toxicology data and information, pre-clinical study data, clinical trial data, protocols, safety data, quality data and other regulatory information and reports, whether in written or electronic form, generated or developed by Sublicensee of either Party, in the course of performing activities under this Agreement during the Term.

1.103 "Subsidiary". Subsidiary shall mean any Person (a) of which CMIC or Dyax (as applicable) is the direct or indirect owner of over fifty percent (50%) of the voting share capital or ownership interest, and/or (b) of which CMIC or Dyax (as applicable) has the ability to control the policies (or to control the recruitment and dismissal of the management who determine the policies) through a voting agreement or other contract or through the articles of association, bylaws or other internal regulations.

1.104 "Supply Agreement". Supply Agreement shall have the meaning given to that term under Section 6.5.

1.105 "Surgical Field". Surgical Field shall mean use of a product to prevent or treat bleeding during the conduct of any procedure involving the use of instruments (including lasers) to cut, abrade, suture or otherwise physically change body tissues and/or organs. Notwithstanding anything to the contrary, Surgical Field shall specifically exclude all uses in the treatment of HAE and/or other angioedemas (even during surgery).

1.106 "Term". Term shall have the meaning given to that term under Section 12.1.

1.107 "Territory". Territory shall mean CMIC Territory or Dyax Territory, as the context requires.

1.108 "Third Party". Third Party shall mean any Person other than Party or any of its Affiliates.

1.109 "Transfer Price". Transfer Price shall mean, with respect to any amount of the Drug Substance or Drug Product delivered to CMIC by Dyax for use in the Development, Manufacture or Commercialization of Product, the Manufacturing Costs of such Drug Substance or Drug Product plus a mark-up of 15%.

1.110 "United States". The United States shall mean the United States of America and its territories and possessions.

1.111 "Valid Claim". Valid Claim shall mean a claim (a) of any issued, unexpired patent that has not been revoked or held unenforceable or invalid by a decision of a court or governmental agency of competent jurisdiction from which no appeal can be taken, or with respect to which an appeal is not taken within the time allowed for the appeal, and that has not been disclaimed or admitted to be invalid or unenforceable through reissue, disclaimer or otherwise or (b) of any patent application that has not been cancelled, withdrawn or abandoned or been pending for more than ten (10) years.

## **ARTICLE II** **MANAGEMENT OF AGREEMENT ACTIVITIES**

### 2.1 Joint Steering Committee.

- (a) Formation; Purposes and Principles. As soon as practicable after the Effective Date, Dyax and CMIC shall establish a joint steering committee (the "JSC"), which shall have the overall responsibility for the oversight of the Parties' activities in Field in accordance with the terms of this Agreement.
- (b) Specific Responsibilities. In addition to its overall responsibility for such oversight, the JSC shall in particular:
  - (i) review, discuss and agree on the Development activities of CMIC under any Development Plan, including without limitation, the clinical study endpoints, clinical methodology, monitoring and analysis requirements for the clinical studies described in any Development Plan;
  - (ii) review and approve the updates by CMIC to each Development Plan not less than annually;
  - (iii) review, discuss and agree on the strategy to seek and obtain Regulatory Approval of Product, as well as the related pricing and reimbursement approvals, in Field in CMIC Territory;
  - (iv) review and monitor the progress in seeking and obtaining Regulatory Approval of Product, as well as the related pricing and reimbursement approvals, in Field in CMIC Territory;
  - (v) review, discuss and agree on the Trademarks that shall be used in connection with the Commercialization of Products in Field in CMIC Territory;
  - (vi) review, discuss and comment on the Commercialization plans and strategies for Product in Field in CMIC Territory;

- (vii) review, discuss and comment on CMIC's order forecasts and commercial supply requirements for Product;
- (viii) facilitate the exchange of data, information, materials and results that may be required for the purposes of obtaining Regulatory Approvals for Product in Field in CMIC Territory; and
- (ix) perform such other functions as are expressly provided for elsewhere in this Agreement or as are appropriate to further the purposes of this Agreement as determined by the Parties, including the periodic evaluations of performance against goals under this Agreement.

2.2 Working Groups. From time to time, the JSC may establish working groups (each, a "Working Group") to oversee the particular projects or activities hereunder, and each Working Group shall be constituted and shall operate as the JSC determines.

2.3 Membership. Each of the JSC and any Working Group shall be composed of an equal number of representatives appointed by each of Dyax and CMIC. The JSC shall initially have three (3) representatives of each Party, but the JSC may change its size of the JSC from time to time by the mutual consent of the members of the JSC. Each Party may replace its JSC and Working Group representatives at any time upon written notice to the other Party. The JSC shall be chaired by a representative of Dyax. The JSC chairperson shall be responsible for calling its meetings, preparing and circulating an agenda for the JSC meeting in advance of the meeting, and preparing and issuing the minutes of the meeting within thirty (30) days thereafter. The JSC meetings shall be called by its chairperson upon the request of either Party.

2.4 Decision-Making. The JSC and any Working Group shall operate by consensus. With respect to the decisions of the JSC and any Working Group, the representatives of each Party shall have collectively one vote on behalf of such Party. Should the members of a Working Group maintain their disagreement on any matter for which consensus has been sought and Dyax or CMIC requests a resolution for the matter, the matter shall be referred to the JSC for resolution. Should the members of the JSC maintain their disagreement, either with respect to a matter referred from a Working Group or with respect to a matter initially arising within the JSC, for sixty (60) days, and Dyax or CMIC requests a resolution for the matter, either Party may commence the dispute resolution process pursuant to Article XIII.

2.5 Meetings of the JSC and Working Groups. The JSC and each Working Group shall hold meetings at such times as the JSC and such Working Group may determine, but in no event shall the meetings of the JSC be held less frequently than once every quarter during the Term. The JSC and any Working Groups shall meet alternately at Dyax's facilities in Cambridge, Massachusetts, USA and CMIC's facilities in Tokyo, Japan or at such locations as the Parties may otherwise agree. Other representatives of each Party or, with approval of the JSC and subject to the confidentiality and limited-usage obligations which are no less stringent than those set forth in Article IX of this Agreement, representatives of Third Parties involved in the Development, Manufacture or Commercialization of Product (or the conduct of Regulatory Activities relating thereto), may attend the meetings of the JSC or such Working Group as nonvoting observers. Meetings of the JSC and any Working Groups may be held by audio or video teleconference with the consent of each Party. Each Party shall be responsible for all of its own costs and expenses of participating in the JSC and any Working Groups. No action taken at a meeting of the JSC or a Working Group shall be effective unless a representative of each Party is present or participating in the meeting.

2.6 Alliance Managers. Each Party shall designate a single alliance manager, who may be a member of the JSC and/or any Working Group (the "Alliance Manager"), for all of the activities contemplated under this Agreement. The Alliance Managers shall be responsible for the day-to-day worldwide coordination of the activities contemplated by this Agreement and shall serve to facilitate communication between the Parties. The Alliance Managers shall have the experience and knowledge appropriate to manage such project management responsibilities. Each Party may change its designated Alliance Manager from time to time upon written notice to the other Party.

2.7 Third Party Performance of Agreement Activities. CMIC shall be entitled to utilize the services of Third Parties to Develop, Manufacture (to the extent permitted under Article VI) and Commercialize Product (and conduct Regulatory Activities in connection therewith) under the following conditions:

- (a) any use of such Third Party that is Product Competitor shall be subject to Dyax's prior written approval;

- (b) CMIC shall remain at all times fully liable for its responsibilities under this Agreement;
- (c) CMIC shall not use any Third Party to conduct part or all of its obligations under this Agreement unless CMIC's rights under its agreement with such Third Party guarantee Dyax the same rights under this Agreement, as guaranteed as if CMIC had conducted such obligations; and
- (d) any of CMIC's agreements with such Third Parties shall provide for confidentiality and limited-usage obligations imposed on such Third Parties, which are no less stringent than those set forth in Article IX of this Agreement.

**ARTICLE III**  
**LICENSE GRANTS; TRANSFERS AND ASSIGNMENTS**

3.1 Dyax Grants.

- (a) Grant of Rights for Development. Subject to the terms and conditions of this Agreement, Dyax hereby grants to CMIC an exclusive license under Dyax Intellectual Property, with the right to grant sublicenses solely as set forth in Section 3.1(d), to Develop, have Developed and conduct Regulatory Activities for Compound and Product for use in Field in CMIC Territory. Notwithstanding the foregoing, the exclusive license granted by Dyax to CMIC under this Section 3.1(a) does not exclude or limit the right of Dyax to use and exploit itself Dyax Intellectual Property according to this Agreement, or to license Dyax Intellectual Property to Third Parties to Develop Compound or Product for use in Field in CMIC Territory, in either case to the extent necessary for Dyax to perform its obligations under this Agreement.
- (b) Grant of Rights for Manufacture. Subject to the terms and conditions of this Agreement, Dyax hereby grants to CMIC an exclusive license under Dyax Intellectual Property, with the right to grant sublicenses solely as set forth in Section 3.1(d), to Manufacture and have Manufactured Drug Substance and Drug Product for use by or on behalf of CMIC, its Affiliates, Sublicensees and Third Party contractors for the Development and Commercialization of Product in Field in CMIC Territory; provided that, except for Manufacturing activities to package and label Product for use in Field in CMIC Territory (which activities shall be conducted by CMIC at its cost and expense), CMIC shall not exercise any of the rights granted to it under this Section 3.1(b) unless and until CMIC exercises its step-in rights in accordance with Article VI hereof .
- (c) Grant of Rights for Commercialization. Subject to the terms and conditions of this Agreement, Dyax hereby grants to CMIC an exclusive license under Dyax Intellectual Property, with the right to grant sublicenses solely as set forth in Section 3.1(d), to Commercialize Product for use in Field in CMIC Territory.
- (d) Sublicense Rights. CMIC shall be entitled to grant sublicenses under the licenses granted to it under Sections 3.1(a), (b) and (c) to its Affiliates and to Third Parties under the following conditions:
  - (i) Any such sublicense to Product Competitor shall be subject to Dyax's prior written approval;
  - (ii) CMIC may only grant a sublicense to its Affiliate or any Third Party who has:
    - (A) assigned to CMIC all Sublicensee Development Data and all Know-How and Patent Rights Controlled by such Affiliate or Third Party that is necessary to Develop, Manufacture and Commercialize Product in Field in Dyax Territory or outside Field in all countries of the world; or
    - (B) granted to CMIC a fully paid, royalty-free, exclusive or non-exclusive license with the right to grant further sublicenses through multiple tiers, to

all Sublicensee Development Data and all Know-How and Patent Rights Controlled by such Affiliate or Third Party that is necessary to Develop, Manufacture and Commercialize Product in Field in Dyax Territory or outside Field in all countries of the world.

For clarity, any Know-How and Patent Rights so assigned or licensed to CMIC by any such Affiliate or Third Party shall be deemed to be CMIC Intellectual Property hereunder;

- (iii) Each permitted sublicense under this Section 3.1(d) shall be in writing, shall not contravene or be inconsistent or in conflict with the terms of this Agreement and shall include the provisions requiring the applicable Sublicensee to acknowledge and agree that such sublicense is subject to the applicable license(s) granted hereunder and to the relevant terms of this Agreement;
- (iv) CMIC shall at all times remain responsible for the performance of its Sublicensees in relation to the sublicenses granted to the Sublicensees under Section 3.1 (d) and
- (v) CMIC shall provide, or cause to be provided, to Dyax a copy of each such sublicense agreement promptly following its execution; provided that CMIC shall have the right to redact any terms contained in such sublicense agreement that are not material to Dyax's assessment of whether the sublicense agreement complies with the requirements of this Section 3.1(d).

3.2 Grant Back License.

- (a) Subject to the terms and conditions of this Agreement, CMIC hereby grants to Dyax a non-exclusive, fully paid, royalty-free license, with the right to grant sublicenses solely as set forth in Section 3.2(b), under CMIC Intellectual Property, to Develop, conduct Regulatory Activities for, Manufacture and Commercialize Compound or Product (i) in Field in Dyax Territory, and (ii) outside Field in all countries of the world.
- (b) Dyax shall be entitled to grant sublicenses under the non-exclusive licenses granted to it under to Section 3.2(a) to its Affiliates and to Third Parties under the following conditions:
  - (i) Each permitted sublicense under this Section 3.2(b) shall be in writing, shall not contravene or be inconsistent or in conflict with the terms of this Agreement, and shall include the provisions requiring the applicable Sublicensee to acknowledge and agree that such sublicense is subject to the applicable license(s) granted hereunder and to the relevant terms of this Agreement;
  - (ii) Dyax may only grant a sublicense to its Affiliate or any Third Party who has:
    - (A) assigned to Dyax all Sublicensee Development Data Controlled by such Affiliate or Third Party that is necessary to Develop, Manufacture and Commercialize Product in Field in CMIC Territory; or
    - (B) granted to Dyax a fully paid, royalty-free, exclusive or non-exclusive license with the right to grant further sublicenses through multiple tiers, to all Sublicensee Development Data Controlled by such Affiliate or Third Party that is necessary to Develop, Manufacture and Commercialize Product in Field in CMIC Territory.

For clarity, any Patent Rights or Know-How so licensed or assigned to Dyax by any such Affiliate or Third Party shall be deemed to be Dyax Intellectual Property hereunder;

- (iii) Dyax shall at all times remain responsible for the performance of its Sublicensees; in relation to the sublicenses granted to the Sublicensees under Section 3.2 (b) (ii) and

- (iv) Dyax shall provide, or cause to be provided, to CMIC a copy of each such sublicense agreement promptly following its execution; provided that Dyax shall have the right to redact any terms contained in such sublicense agreement that are not material to CMIC's assessment of whether the sublicense agreement complies with the requirements of this Section 3.2(b).

3.3 Retained Rights. Any rights of a Party that are not expressly granted by such Party to the other Party under this Agreement shall be retained by such Party. Furthermore, if any right which is granted by a Party to the other Party is expressly restricted or limited under this Agreement, then any right outside of the scope of such restriction or limitation shall also be retained by such Party. Without limiting the generality of the immediately preceding sentence, Dyax shall retain the right to (i) exploit and license Dyax Intellectual Property to Develop, Manufacture and Commercialize Compound and Product for use in Field in Dyax Territory, without any duty to account to CMIC or to obtain CMIC's consent for such exploitation or license; (ii) exploit and license Dyax Intellectual Property to Develop, Manufacture and Commercialize Compound and Product outside Field in CMIC Territory, without any duty to account to CMIC or obtain CMIC's consent for such exploitation or license, (iii) exploit Dyax Intellectual Property for the purposes unrelated to Compound or Product without any duty to account to CMIC or obtain CMIC's consent for such exploitation or license, and (iv) otherwise exercise Dyax's rights and perform Dyax's obligations under this Agreement.

3.4 In-Licenses of Blocking Third Party Patent Right; Compliance with In-Licenses. If, at any time or from time to time after the Effective Date and during the Term, Party becomes aware of any Blocking Third Party Patent Rights that at the time of such identification are not Controlled by the Party, the Party shall promptly notify the JSC of the identification and include in such notification a summary of such Blocking Third Party Patent Rights, the anticipated terms applicable to a license to such Blocking Third Party Patent Rights and any other relevant information. The JSC shall discuss whether a license to such Blocking Third Party Patent Rights should then be obtained by either of the Parties, taking into consideration any commercial advantages associated with the timing of such license, the necessity of such license to the success of the Development, Manufacture or Commercialization of Product and any other factors the JSC deems relevant.

- (a) If the JSC determines that such license should be obtained by either of the Parties, the JSC shall determine which Party shall be responsible for negotiating such license agreement; provided that:
  - (i) Dyax shall be responsible for negotiating and entering into such license agreement in the event that such Blocking Third Party Patent Rights:
    - (A) Cover the composition of matter or chemical structure of Compound or Product; or
    - (B) are otherwise required for Development, Manufacture or Commercialization of Product in any Indication within Dyax Territory; and
  - (ii) CMIC shall be responsible for negotiating and entering into such license agreement for such Blocking Third Party Patent Rights as are solely required for Development, Manufacture (to the extent that such Manufacture will be conducted by CMIC in accordance with this Agreement) or Commercialization of Product in any Indication in Field in CMIC Territory (provided that such Indication will be Developed or Commercialized by CMIC in accordance with this Agreement).

The Party responsible for negotiating and entering into such license agreement shall use Commercially Reasonable Efforts to negotiate such license agreement and ensure that such license agreement shall provide, among other things, that the Party that executes such license agreement shall acquire the Control of such Blocking Third Party Patent Rights. Prior to execution of any such license agreement, the negotiating Party shall present such license agreement in substantially final form to the JSC for review and approval. Upon such review and approval by the JSC, the negotiating Party shall execute and deliver such license agreement and such license agreement shall be an In-License of the executing Party. The executing Party shall provide the other Party with a copy of such executed license agreement.

- (b) If the JSC determines that the JSC should not request either of the Parties to obtain such license or if the JSC does not give approval to the substantially final form of such license agreement, then either Party may nevertheless negotiate and enter into such license agreement but such license shall not be an In-License and, notwithstanding anything express or implied in this Agreement to the contrary, the executing Party shall not be deemed to have granted, and shall not be under any obligation to grant to the other Party a sublicense under such license even if the executing Party Controls such Blocking Third Party Patent Rights as a result of such license agreement.
- (c) In addition, if despite the use of Commercially Reasonable Efforts, the executing Party is not able to acquire Control of such Blocking Third Party Patent Rights in such license agreement, then the executing Party may exclude the other Party's Indication and Territory from the scope of such license agreement and shall assist the other Party in obtaining a license from such Third Party for the other Party's Indication and Territory.
- (d) Each Party shall comply with all the applicable terms and conditions of the In-Licenses executed by the other Party and shall take such actions as may be required to allow such Party to comply with its obligations thereunder, including, without limitation, the obligations relating to patent matters, confidentiality, indemnification and diligence.

For clarity, the Parties agree that RCT License Agreement shall not be considered an In-License subject to this Section 3.4.

3.5 Scope of Agreement: Activities in the Dyax Territory. The Parties acknowledge and agree that, unless otherwise expressly stated herein:

- (a) this Agreement sets forth the terms and conditions pursuant to which (i) CMIC shall Develop and seek Regulatory Approval for Product in Field in CMIC Territory, and (ii) CMIC shall Manufacture and Commercialize Product in Field in CMIC Territory; and
- (b) the activities of Dyax to Develop, seek Regulatory Approval for, Manufacture and/or Commercialize Compound and/or Product in Field in Dyax Territory and outside Field in all countries of the world shall be outside the scope of this Agreement and under the sole responsibility of Dyax at its cost and expense.

3.6 Right of Second Offer: China. In the event that Dyax has first offered to Defiante Farmaceutica S.A. ("Defiante") certain terms and conditions (the "Original Terms") of a license to Develop, Manufacture and/or Commercialize Product in the People's Republic of China, and if the Original Terms have not been accepted by Defiante within ninety (90) days of such offer or if the Original Terms have been accepted by Defiante within such ninety (90) day period, however, a final and definite agreement on the full terms and conditions of such license have not been executed by Dyax and Defiante within one hundred fifty (150) days of such offer, Dyax shall secondly offer the Original Terms to CMIC (the "Second Offer"). The Original Terms shall set forth the material terms and conditions applicable to such license. Within forty-five (45) days following its receipt of the Second Offer, CMIC shall notify Dyax in writing of whether it wishes to obtain such license on the Original Terms. If CMIC does wish to obtain such license on the Original Terms, the Parties shall negotiate in good faith for a period of ninety (90) days regarding any additional terms and conditions (other than those set forth herein) applicable to such license. If CMIC does not wish to obtain such license on the Original Terms or if the Parties fail to execute a final and definite agreement on the full terms and conditions of such license within such ninety (90) day period, Dyax shall be free to offer such license to any other Person, provided, however, that the terms and conditions so offered to such other Person should not be more favorable to such other Person than the Original Terms. If CMIC does wish to obtain such license on the Original Terms and the Parties has executed a final and definite agreement on the full terms and conditions of such license within such ninety (90) day period, then all the terms and conditions of such license shall be deemed to be part of this Agreement. Furthermore, CMIC Territory shall thereafter include the People's Republic of China.

**ARTICLE IV**  
**DEVELOPMENT AND REGULATORY MATTERS**

4.1 HAE Development Plan. As soon as practicable after the Effective Date, the JSC shall convene to review and discuss the activities that are necessary to obtain Regulatory Approval of Product for the treatment of HAE in CMIC Territory. Following this process, but in any event no later than one hundred twenty (120) days after the first day of the first JSC meeting for the HAE Indication, CMIC and Dyax shall jointly complete, and the JSC shall approve, a formal plan to obtain Regulatory Approval for Product in CMIC Territory for the HAE Indication (the "HAE Development Plan"). The HAE Development Plan shall set forth all the activities that are necessary to obtain Regulatory Approval of Product for the treatment of HAE in CMIC Territory as well as the strategies and timelines for completing such activities.

4.2 Development Plan for Other Angioedema Indications. As soon as practicable after Dyax's proof of concept for Product in any Other Angioedema Indication, the JSC shall convene to review and discuss the activities that are necessary to Develop and obtain Regulatory Approval of Product for the treatment of such Other Angioedema in CMIC Territory. Following this process, as soon as it is practicable after the first JSC meeting for such Other Angioedema Indication, CMIC and Dyax shall jointly complete, and the JSC shall approve, a formal plan to Develop and obtain Regulatory Approval for Product in CMIC Territory for such Other Angioedema Indication (each, an "Other Angioedema Development Plan"). Each Other Angioedema Development Plan shall set forth all the activities that are necessary to obtain Regulatory Approval of Product for the treatment of such Other Angioedema in CMIC Territory as well as the strategies and timelines for completing such activities.

4.3 Roles and Responsibilities.

- (a) Development Activities. CMIC shall assume all the authority and responsibility for all the activities conducted relating to the Development of Product for any Indication in Field in CMIC Territory; provided that the JSC shall review and monitor such activities in accordance with Section 2.1(b) and the following process:
  - (i) CMIC shall review and update each Development Plan from time to time (but not less frequently than annually) to include therein any additional activities required by any Regulatory Authority in CMIC Territory, up until filing of the application for Regulatory Approval of Product for the applicable Indication in CMIC Territory or the completion of the activities covered thereunder;
  - (ii) CMIC shall submit all such proposed updates to the JSC for review and approval at the first JSC meeting after such proposal; and
  - (iii) the JSC shall review such proposed updates and may approve such proposed updates and, upon such approval by the JSC, the HAE Development Plan shall be amended accordingly.
- (b) Regulatory Activities. CMIC shall assume all the authority and responsibility for all Regulatory Activities relating to Product for any Indication in Field in CMIC Territory; provided that the JSC shall review and monitor such activities in accordance with Section 2.1(b). In connection with any such Regulatory Activities, Dyax shall, upon CMIC's request, promptly provide CMIC with any Dyax Development Data that is reasonably deemed to be necessary or useful for Regulatory Approval of Product in Field in CMIC Territory. For the avoidance of doubt, CMIC shall be the holder of all the Marketing Authorization Applications filed in CMIC Territory. CMIC may have its Affiliate hold the Marketing Authorization Application and Regulatory Approval of Product in Field in CMIC Territory.
- (c) Reformulation. Notwithstanding anything to the contrary contained herein, any Development or other activities relating to the reformulation of Product (including the activities conducted under any Development Plan) shall be conducted by Dyax.

4.4 Diligent Development Efforts

- (a) CMIC shall use Commercially Reasonable Efforts to Develop and obtain Regulatory Approval for Product in the HAE Indication according to the HAE Development Plan and in any Other Angioedema Indication according to the Other Angioedema Development Plan approved by the JSC for such Indication in CMIC Territory. For the purpose of this Section 4.4(a), CMIC's Commercially Reasonable Efforts shall be deemed satisfied by the performance of at least one of the following events in each Calendar Year during the Term with respect to each such Indication: (i) CMIC, together with its Related Parties, has expended at least two million dollars (\$2,000,000), or any lesser amount authorized by the JSC, in pursuit of Regulatory Approval for Product; (ii) CMIC and/or any of its Related Parties is actively conducting a Phase II or III clinical study with respect to Product; or (iii) CMIC and/or any of its Related Parties has filed the application for Regulatory Approval for Product with the Japanese Government.
- (b) Without limiting the generality of Section 4.4(a), CMIC (directly or through its Related Parties) shall, subject to the provisions of Section 4.4(c) and Section 4.4(d), achieve the following specific development milestones for Product in the HAE Indication in CMIC Territory.

<u>Milestone Event</u>	<u>Deadline</u>
Dosing of the first patient in a Phase I clinical study of Product in the HAE Indication	Within 90 days of the date (of such dosing) expected in the first version of the HAE Development Plan approved by the JSC
Dosing of the first patient in a Phase III clinical study of Product in the HAE Indication	Within 240 days of the date (of such dosing) expected in the first version of the HAE Development Plan approved by the JSC

Each date indicated in this Section 4.4(b) (and any subsequent dates reflecting an extension permitted hereunder) shall be extended automatically to reflect any delay in the achievement of the applicable milestone attributable to External Factors. For the purposes of this Section 4.4(b), an "External Factor" shall mean that one or more of the following events or circumstances, which has delayed the Development of Product in the HAE Indication in CMIC Territory, has occurred in the Development, Manufacturing or regulatory conditions relating to Product; provided that such events or circumstances were not caused by the negligent act or omission of CMIC or any of its Related Parties: (i) the rejection of any IND or protocol by PMDA; (ii) any clinical study of Product is suspended, put on hold, not initiated, or terminated as a result of any action by PMDA or an independent data monitoring committee; (iii) failure to achieve the primary end points in a clinical study for Product; (iv) the decisions, communications or directives by PMDA regarding Product that delay achievement of the applicable milestone; (v) manufacturing or supply difficulties, including failure of Dyax to fulfill its supply obligations to CMIC under this Agreement or the Supply Agreement; (vi) any breach by Dyax of its obligations under this Agreement or the Supply Agreement; (vii) changes in the applicable laws or regulations relating to the Development, Manufacture or regulatory conditions of Product; or (viii) the request or recommendation for the material change to the HAE Development Plan by the Japanese Government including PMDA. The relevant date(s) in this Section 4.4(b) (and any subsequent dates reflecting an extension permitted hereunder) shall be extended by the number of days to be agreed upon by the Parties reasonably based upon the JSC's reasonable assessment of the period of time required to reach the applicable milestone event in light of the relevant External Factors.

- (c) In addition to the foregoing, CMIC may extend the period for completion of any milestone event described in Section 4.4(b) above by up to twelve (12) months, in one (1) month increments, upon prior written notice to Dyax and the payment to Dyax of a monthly extension fee of Fifty Thousand Dollars (\$50,000) for each such one (1) month extension.
- (d) If CMIC fails to meet its obligations under Section 4.4(b) in any material respect, then Dyax shall have, as its sole and exclusive remedy for such failure by CMIC, the right to terminate this Agreement pursuant to Section 12.2(a).

4.5 Manner of Performance: Reports.

- (a) CMIC shall perform, or cause to be performed, all of the Development activities for which it is responsible under this Agreement, in good scientific manner and in compliance with all the applicable laws and regulations and good clinical and laboratory practices.
- (b) CMIC agrees to keep Dyax fully informed of its progress in, results (including the development of any technology or inventions) of, status on and plans for developing Product in Field in CMIC Territory.
- (c) Within thirty (30) days after the end of each Calendar Quarter in which the Development activities are performed by CMIC and at least ten (10) days prior to the quarterly meeting of the JSC, CMIC shall provide to the JSC a written progress report, which shall describe the Development activities that CMIC has performed or caused to be performed during such Calendar Quarter, shall evaluate the works performed in relation to the goals and timelines established under the applicable Development Plan, and shall provide such other information as may be reasonably requested by the JSC with respect to such Development activities.

4.6 Exchange of Development Information. In accordance with and subject to the terms of Article IX, on an ongoing basis during the Term:

- (a) Dyax shall, within fifteen (15) days of the Effective Date, disclose and transfer to CMIC an electronic copy of the Common Technical Document for Product in the HAE Indication. Furthermore, within ninety (90) days of the Effective Date, Dyax shall disclose and transfer to CMIC all other Dyax Development Data necessary or useful to the Development of Compound or Product for use in Field in CMIC Territory and shall update such Dyax Development Data and disclose and transfer such updated Dyax Development Data to CMIC at least once semi-annually. Dyax acknowledges and agrees that all the data generated in connection with the Development activities conducted by Dyax and/or its Related Parties with respect to Compound or Product in Field may be used by CMIC to obtain the Regulatory Approval for Product in Field in CMIC Territory.
- (b) CMIC shall semi-annually disclose and transfer to Dyax all the CMIC Development Data necessary or useful to the Development of Compound or Product for use in Field in Dyax Territory or outside Field in any country in the world and shall update such CMIC Development Data and disclose and transfer such updated CMIC Development Data to Dyax at least once semi-annually. CMIC acknowledges and agrees that all such data may be used by Dyax to obtain the Regulatory Approval for Product in Field in Dyax Territory or outside Field in any country of the world.
- (c) Upon reasonable notice during normal business hours as coordinated through the Alliance Managers and the JSC, each Party shall provide the other Party with such assistance and access to its employees, consultants and subcontractors as may be reasonably necessary for such other Party to exercise its rights and perform its obligations with respect to the Development, Regulatory Activities, Manufacture and/or Commercialization of Product under this Agreement.

4.7 Regulatory Submissions and Regulatory Approvals.

- (a) CMIC shall own, and may have its Affiliate own, all the Regulatory Filings and Regulatory Approvals for Product in Field in CMIC Territory, and shall be responsible for the Regulatory Activities for Product in Field in CMIC Territory; provided that, unless Dyax otherwise agrees in good faith, any Regulatory Filings for Product in the HAE Indication in CMIC Territory shall be consistent (to the extent permitted by the applicable law) with the Regulatory Filings for Product in the HAE Indication in the United States. If permitted under the Japanese laws, Dyax and its Related Parties shall have the right to access all the data contained or referenced in such Regulatory Filings, including all reports, correspondence and conversation logs ("Access and Reference Rights"), and CMIC shall provide appropriate notification of Dyax's and its Related Parties' Access and Reference Rights to the related Regulatory Authorities. Again, if permitted under the Japanese laws, CMIC hereby grants, and shall ensure that its Related Parties grant, to Dyax a "Right of Reference or Use," as that term is defined in 21 C.F.R. §314.3(b) as amended from time to time, and any foreign equivalents thereto, to any and all the data contained or referenced in any such Regulatory Filing, including all reports, correspondence and conversation logs, and CMIC shall provide appropriate notification of Dyax's and its Related Parties' Access and Reference Rights to the related Regulatory Authorities. Notwithstanding the foregoing, CMIC agrees that Dyax shall have the right to access all the data contained or referenced in such Regulatory Filings, through CMIC, to the same extent that CMIC or its Related Parties is granted such access.
- (b) Dyax shall own all the Regulatory Filings and Regulatory Approvals for Compound and for Product (i) in Field in Dyax Territory and (ii) outside Field in any country of the world, and shall be responsible for all the Regulatory Activities (i) in Field in Dyax Territory and (ii) outside Field in any country of the world. CMIC and its Related Parties shall have the right to access all the data contained or referenced in such Regulatory Filings, including all reports, correspondence and conversation logs, to the extent applicable to use of Product in Field in CMIC Territory, and Dyax shall provide appropriate notification of CMIC's and its Related Parties' Access and Reference Rights to the related Regulatory Authorities. Dyax hereby grants, and shall ensure that its Related Parties grant, to CMIC a "Right of Reference or Use," as that term is defined in 21 C.F.R. §314.3(b) as amended from time to time, and any foreign equivalents thereto, to any and all data contained or referenced in any such Regulatory Filings, including all reports, correspondence and conversation logs, and Dyax shall provide appropriate notification of CMIC's and its Related Parties' Access and Reference Rights to the related Regulatory Authorities.

4.8 Complaints; Adverse Event Reporting Procedures; Notice of Adverse Events Affecting Compound.

- (a) Each Party may and shall have access to all the Complaints and Safety Data generated by the other Party and/or its Related Parties and contractors in connection with the Development, Regulatory Activities, Manufacture and Commercialization of Product, subject to and to the extent provided for in this Agreement.
- (b) Each Party shall maintain a record of any and all the Complaints and Safety Data it receives with respect to Product. Each Party shall notify the other Party in reasonable detail of any Complaint or Safety Data received by such Party with respect to Product within sufficient time to allow such other Party and/or its Related Parties to comply with any and all regulatory and other requirements imposed upon them in any jurisdiction in which or for which such Product is being Developed in clinical studies or Commercialized.
- (c) Each Party shall require its Related Parties to provide it with all the Complaints and Safety Data relating to Product which they receive. Each Party shall provide the other Party with all the Complaints and Safety Data which it receives relating to Product and which is necessary or desirable for the other Party to comply with all the applicable laws, rules and regulations with respect to Product. Each Party shall provide such information to the other Party within five (5) calendar days after its first receipt; provided that any information relating to a serious adverse experience (SAE), as that term is defined at 21 C.F.R. §600.80, in the ICH Guidelines and/or in the Directive 2001/83/EC, shall be provided to the other Party by such Party within two (2)

Business Days after such party initially receives it. The Party providing Complaints or Safety Data shall make all reasonable efforts to assist the receiving Party with any follow-up investigation necessary to comply with applicable laws, rules and regulations with respect to Product.

- (d) Dyax shall maintain, or Dyax shall enter into an Agreement with a Third Party to maintain, a global adverse event database for Product (the "AE Database") and shall record any and all Complaints and Safety Data, which Dyax receives in relation to Product, in the AE Database for CMIC's use in CMIC Territory. CMIC shall have access to all data in the AE Database.
- (e) With respect to Product in Field in CMIC Territory, CMIC shall be responsible for submitting adverse event reports to the applicable Regulatory Authorities. With respect to Product in Field in Dyax Territory and outside Field in all countries of the world, Dyax shall be responsible for submitting adverse event reports to the applicable Regulatory Authorities.
- (f) Within one hundred twenty (120) days after the Effective Date, the Parties shall develop and agree in writing upon the safety data exchange procedures governing the coordination of collection, investigation, reporting, and exchange of the information concerning any adverse experiences, and any product quality and product complaints involving adverse experiences, and any other Complaints and Safety Data, related to Product, sufficient to enable each Party to comply with its legal and regulatory obligations (the "Pharmacovigilance Agreement"). Dyax shall execute pharmacovigilance agreements with any of CMIC's future Related Parties involved in the Development, Manufacture or Commercialization of Product. Such pharmacovigilance agreements shall conform in all material respects with the Pharmacovigilance Agreement to be executed by and between Dyax and CMIC.
- (g) The Parties acknowledge and agree that all the safety data maintained in the AE Database for Product may be used by both Parties and their respective Related Parties (i) to obtain all the applicable Regulatory Approvals in accordance with the terms of this Agreement and (ii) in connection with any litigation relating to Product.

4.9 Audits. CMIC shall, and shall require its Related Parties to, keep the true and accurate records containing all CMIC Development Data. Such records shall be kept by CMIC and its Related Parties during the periods required by the applicable laws and regulations, provided that such periods should not be shorter than three (3) years following the end of the calendar year to which they relate. Upon thirty (30) day prior written notice to CMIC, Dyax and its Related Parties (or any Person contracted by Dyax) shall be permitted by CMIC, during normal business hours, to inspect such records and any facilities used by CMIC or its Related Parties in connection with the Development, Manufacture and Commercialization of Product for the purpose of ensuring that such activities are conducted in accordance with the applicable laws and regulations and in conformity with this Agreement. The notice provided by Dyax to CMIC with respect to any such inspection shall indicate the nature and scope of any such inspection. Dyax shall be responsible for all the external costs associated with any such inspection, including the cost of translating any internal documents of CMIC or its Related Parties (if such translation is deemed to be necessary by Dyax).

## **ARTICLE V COMMERCIALIZATION**

### 5.1 Commercialization Efforts: Manner of Performance.

- (a) Following the Regulatory Approval of Product in any Indication in Field in CMIC Territory, CMIC shall use Commercially Reasonable Efforts to Commercialize Product in CMIC Territory in such Indication.
- (b) In connection with its obligation to use Commercially Reasonable Efforts to Develop, obtain the Regulatory Approval of and Commercialize Product in CMIC Territory in Field, CMIC acknowledges and agrees that it shall not engage in the clinical development, manufacture and/or commercialization of a therapeutic or prophylactic product that would compete, with Product in Field in CMIC Territory. Notwithstanding the foregoing, the Parties understand

that CMIC's dominant business is a contracting business and that such contracting business could not affect the extent of such Commercially Reasonable Efforts regardless of any products or services which CMIC would provide as contractor on behalf of a third party. With such understanding, the Parties agree that this Agreement should not prevent CMIC from developing or manufacturing any products on behalf of a third party as CRO or CMO; although CMIC agrees that it shall not serve as a CRO with respect to Competitive Products until it completes enrollment of all subjects necessary to complete the clinical development of Product in the HAE Indication.

- (c) CMIC shall perform, or cause to be performed, all the Commercialization activities for which it is responsible under this Agreement in compliance with all the applicable laws and regulations.

5.2 Advertising and Promotional Materials. CMIC shall be responsible, at its own cost and expense, for the creation, preparation, production, reproduction and filing with the applicable Regulatory Authorities, of the relevant written sales, promotion and advertising materials relating to Product ("CMIC Promotional Materials") for Commercialization in Field in CMIC Territory. All CMIC Promotional Materials shall be compliant in all material respects with all the applicable laws, rules and regulations and any guidelines established by the pharmaceutical industry in the applicable country in CMIC Territory. When distributing the information related to Product or its use (including the information contained in scientific articles, reference publications and publicly available healthcare economic information), CMIC shall comply in all material respects with all the applicable laws, rules and regulations and any guidelines established by the pharmaceutical industry in the applicable country in CMIC Territory. CMIC shall submit all the material CMIC Promotional Materials developed by it for use in CMIC Territory to the JSC for review and comment prior to use. Upon Dyax's request, copies of all the CMIC Promotional Materials submitted by CMIC to the JSC shall be translated into English.

5.3 Sales and Distribution. CMIC and its Related Parties shall be responsible for booking sales of Product in Field in CMIC Territory and for all the aspects of the Product order processing, invoicing and collection, distribution, inventory and receivables, and for handling (at its own cost and expense) all returns, recalls, and other withdrawals of the Product sold for use in Field in CMIC Territory. Dyax and its Related Parties shall be responsible for booking sales of Product in Field in Dyax Territory and outside Field in any country in the world and for all the aspects of the Product order processing, invoicing and collection, distribution, inventory and receivables, and for handling (at its own cost and expense) all returns, recalls, and other withdrawals of the Product sold for use in Field in Dyax Territory and outside Field in any country in the world.

5.4 Cross-Territory and Cross-Field Sales. CMIC shall not, and shall ensure that its Related Parties agree not to, sell Product in Field in Dyax Territory or outside Field in any country in the world. If CMIC or any of its Related Parties receives any orders relating to use of Product in Field in Dyax Territory or outside Field in any country of the world, it shall refer such orders to Dyax. Dyax shall be a third party beneficiary of the agreements between or among CMIC, its Affiliates, licensees, distributors and wholesalers with respect to such restriction, with the right to enforce such agreements. Furthermore, CMIC shall make Commercially Reasonable Efforts to restrict the ability of any Third Parties to export Product outside of CMIC Territory for sale and/or use in Field in Dyax Territory or outside Field in any country of the world.

5.5 Recalls and Market Withdrawals. If any Regulatory Authority in CMIC Territory requests a recall or takes a similar action in connection with the Product being Developed, Manufactured or Commercialized by CMIC under this Agreement, or if either Party determines that an event, incident or circumstance has occurred that may result in the need for a recall or market withdrawal of such Product, the Party notified of such recall or similar action, or the Party that determines the need for such recall or market withdrawal, shall, within twenty-four (24) hours of such notification or determination, advise the other Party thereof by e-mail, overnight courier or facsimile. CMIC shall, in consultation with Dyax, determine whether to conduct a recall of Product in CMIC Territory and the manner in which any such recall shall be conducted (except in the case of a government mandated recall, when CMIC may act for such recall without such advance notice but shall notify Dyax thereof as soon as possible). In the event that CMIC is responsible for such recall, CMIC shall bear the expense of such recall conducted in CMIC Territory. In the event that Dyax is responsible for such recall, Dyax shall reimburse CMIC for the expense of such recall conducted by CMIC in CMIC Territory and shall repay CMIC for the amount in which CMIC has paid to Dyax for such recalled Product. Each Party shall make available to the other Party all of its pertinent records that may be reasonably requested in order to effect any such recall.

ARTICLE VI  
MANUFACTURE AND SUPPLY OF DRUG PRODUCT

6.1 Manufacture of Drug Substance and Drug Product. Dyax shall Manufacture Drug Substance and Drug Product for CMIC (or its designee) in sufficient quantities to satisfy the requirements of CMIC and its Related Parties for use in Developing, obtaining Regulatory Approval of, and Commercializing Product in Field in CMIC Territory pursuant to this Agreement; provided that such Manufacture by Dyax shall not include packaging and labeling (which shall be conducted by CMIC at its cost and expense) and that the foregoing obligation of Dyax to Manufacture Drug Substance and Drug Product shall be subject to the following terms and conditions:

- (a) Exclusivity. Dyax shall be CMIC's sole and exclusive manufacturer of all Drug Substance and Drug Product requirements of CMIC and its Related Parties, unless otherwise agreed by Dyax in writing.
- (b) Forecasts. Within thirty (30) days following the filing of the Marketing Authorization Application for Product in the HAE Indication in CMIC Territory, and within five (5) Business Days following the commencement of each Calendar Quarter occurring thereafter, CMIC shall give to Dyax a forecast of Product supply requirements for the next twelve (12) Calendar Quarters, determined in good faith and based upon commercially reasonable estimates of Product sales. Each such forecast shall summarize the projected Product demand, inventory targets, and inventory levels (including the projected Drug Substance Inventory levels) and the estimated quantities of Drug Substance and Drug Product that CMIC expects to order, in accordance with Sections 6.1(c) and (e).
- (c) Orders for Drug Substance; Delivery.
  - (i) For quantities of Drug Substance required by CMIC, CMIC shall provide Dyax with binding purchase orders for Drug Substance. CMIC may place no more than one (1) binding order for Drug Substance during any Calendar Quarter and no more than two (2) binding orders for Drug Substance during any twelve (12) month period.
  - (ii) Upon CMIC's issuance of a binding order for Drug Substance:
    - (A) Each such order shall be considered accepted by and binding upon Dyax, unless such order exceeds the Drug Substance Order Limit for the relevant Calendar Quarter, in which case such order shall be considered accepted by Dyax unless Dyax provides written notice objecting to such order within fifteen (15) Business Days after Dyax's receipt of such order. In case of objection, Dyax shall provide the quantity requested up to the Drug Substance Order Limit for the relevant Calendar Quarter and shall use Commercially Reasonable Efforts to provide the additional requested quantity.
    - (B) Dyax shall have fifteen (15) Business Days after Dyax's receipt of such order to provide CMIC the latest start and completion date for that order. In turn, CMIC will have fifteen (15) Business Days thereafter to acknowledge and accept this schedule, negotiate a change, or cancel the order. In order to keep cost of goods as low as possible, the preference will be to combine all binding orders for Drug Substance into single campaigns. Any binding order placed per the above conditions will be scheduled to begin production not less than six (6) months and not more than eighteen (18) months from the date of the order unless otherwise agreed to by CMIC and Dyax.
  - (iii) All Drug Substance manufactured by Dyax shall, at the option of CMIC, be (A) held as Drug Substance Inventory by Dyax (or its Third Party contractor) on behalf of CMIC pursuant to Section 6.1(d) or (B) delivered Ex Works (Incoterms 2008) from the Drug Substance manufacturer's facility. All Drug Substance shall be delivered within thirty (30) days following the quality release of such Drug Substance.

- (d) Drug Substance Inventory. If and to the extent that CMIC requests that Drug Substance manufactured by Dyax for CMIC be held as Drug Substance Inventory, then Dyax shall be responsible for the handling and custody of such Drug Substance Inventory (including insurance to cover risk of loss of such Drug Substance Inventory); provided that all costs directly related to the handling, custody and insurance of the Drug Substance Inventory shall be reimbursed by CMIC.
- (e) Orders for Drug Product: Delivery.
- (i) For the quantities of Drug Product required by CMIC, CMIC shall provide Dyax with the binding purchase orders for Drug Product. The Parties shall agree on the frequency of such purchase orders and on the maximum and minimum numbers of vials per such a purchase order in the Supply Agreement. Notwithstanding the foregoing, CMIC may at any time provide Dyax with the binding purchase orders for any number of vials of Drug Product to be used as investigational new drug for Development of Product in Field in CMIC Territory.
- (ii) Upon CMIC's issuance of a binding order for Drug Product:
- (A) Each such order shall be considered accepted by and binding upon Dyax, unless such order exceeds the Drug Product Order Limit for the relevant Calendar Quarter, in which case such order shall be considered accepted by Dyax unless Dyax provides CMIC with written notice objecting to such order within fifteen (15) Business Days after Dyax's receipt of such order. In case of such objection, Dyax shall provide CMIC with Drug Product in the quantity up to the Drug Product Order Limit for the relevant Calendar Quarter and shall use Commercially Reasonable Efforts to provide CMIC with the additional quantity of Drug Product based upon Dyax's determination of the Drug Product supply requirements for it and its other licensees.
- (B) Dyax shall have fifteen (15) Business Days after Dyax's receipt of such order to provide CMIC the latest start and completion date for the order. In turn, CMIC shall have fifteen (15) Business Days thereafter to acknowledge and accept this schedule, negotiate a change thereto, or cancel the order. The Parties agree that the delivery dates of Drug Product from Dyax to CMIC shall be provided for in the Supply Agreement.
- (iii) All the Drug Products manufactured by Dyax shall be delivered Ex Works (Incoterms 2008) from Drug Product manufacturer's facilities. Any Drug Product shall be delivered within thirty (30) days following the quality release of such Drug Product (but not later than four (4) months after such Drug Product is filled). At the time of such delivery, such Drug Product shall have a shelf life equal to the lesser of (A) two (2) years, or (B) the shelf life approved by the Japanese government less the time required for the quality release of such Drug Product.
- (f) Supply Shortage: Allocation of Drug Substance and Drug Product. Upon the occurrence of any event that causes the amount of Drug Substance and/or Drug Product Manufactured by Dyax to be insufficient to fully meet the quantities ordered by CMIC under Sections 6.1(c) and (e), then Dyax shall promptly notify CMIC thereof. Thereafter:
- (i) if such a supply shortage in fulfilling the orders properly placed by CMIC on Dyax for Drug Substance or Drug Product is caused by manufacturing failures or delays, the then current Drug Substance or Drug Product available for supply by Dyax shall be allocated between the Parties and Dyax's Sublicensees on a pro-rata basis based on the then current good faith forecasted requirements for Drug Substance or Drug Product by such entities; and

- (ii) if such a supply shortage is caused by CMIC's inaccurate forecasts or otherwise arisen as a result of the orders placed on Dyax by CMIC for Drug Substance in excess of the applicable Drug Substance Order Limit or the orders placed on Dyax by CMIC for Drug Product in excess of the applicable Drug Product Order Limit, then the allocation provided for in Section 6.1(f)(i) above shall not apply.
- (g) Pricing. With respect to any amount of Drug Substance or Drug Product Manufactured by Dyax for CMIC for use in the Development or Commercialization of Product, CMIC shall pay to Dyax the applicable Transfer Price for such Drug Substance or Drug Product. Such Transfer Price shall be paid as follows:
  - (i) if and to the extent that the external Manufacturing Costs of Drug Substance and/or Drug Product are incurred by Dyax in advance of the actual delivery of Drug Product to CMIC, such Manufacturing Costs shall be invoiced to CMIC and CMIC shall pay such invoice within thirty (30) days after receipt thereof; and
  - (ii) the balance of the Transfer Price and such external Manufacturing Costs of Drug Substance and/or Drug Product paid under item (i) above shall be paid by CMIC within thirty (30) days after receipt of the relevant invoice to be issued by Dyax after the quality release (duly documented) of the Drug Product.

6.2 Quality.

- (a) Certificates of Analysis. Dyax shall provide CMIC with the certificates of analysis related to each batch of Drug Substance or Drug Product delivered to CMIC hereunder. These certificates shall document that each such batch delivered to CMIC conforms to Specifications. Further, Dyax shall provide CMIC with the batch disposition paperwork documenting the requirements of cGMPs at the time of such delivery. These materials shall include the date of Manufacture and the applicable expiry date of each such batch.
- (b) Quality Control Testing. Dyax shall perform, or have performed such quality control tests as are indicated in Specifications. Dyax shall make the results of such quality control tests available to CMIC on or before the date that the related Drug Substance or Drug Product is delivered to CMIC hereunder. No production batch of the Drug Substance or Drug Product shall be released for such delivery unless such quality control tests show that the Drug Substance or Drug Product meets Specifications. CMIC shall not perform or re-perform the control quality tests that support any such certificate of analysis. Notwithstanding the foregoing, CMIC may perform such quality tests if required by any Regulatory Authority in CMIC Territory.

6.3 Responsibility for Product Manufacturing Process. At all times during which Dyax is manufacturing Drug Substance and Drug Product for CMIC (or its designee) under Section 6.1, Dyax shall have the sole authority over Product Manufacturing Process under this Agreement, and shall be fully responsible for all the costs and expenses incurred in connection therewith, except to the extent that Dyax is to be reimbursed by CMIC for such costs and expenses as provided for herein. Without in any way limiting the foregoing, Dyax shall have the sole authority to (i) select the contract manufacturers involved in Product Manufacturing Process, (ii) terminate any contracts with the contract manufacturers involved in Product Manufacturing Process, and/or (iii) internalize Product Manufacturing Process by Manufacturing Drug Substance and/or Drug Product within the facilities owned or controlled by Dyax.

6.4 Step-in Rights.

- (a) For Cause. Notwithstanding the restrictions set forth in Section 3.1(b) that preclude CMIC from Manufacturing or having Manufactured Drug Substance and Drug Product, CMIC shall have the option, exercisable at any time within 120 days after occurrence of any of the following events, to enter into a direct contractual relationship with Dyax's CMO(s) to have them Manufacture Drug Substance and/or Drug Product as necessary to meet the requirements of CMIC and its Related Parties for Development and Commercialization of Product in Field in CMIC Territory:

- (i) the quantity of such Drug Substance and/or Drug Product as supplied by Dyax pursuant to the binding orders placed by CMIC under Section 6.1(c) or (e) is less than seventy-five percent (75%) of the quantity so ordered by CMIC, as measured over a period of any four consecutive Calendar Quarters; provided that, for the purposes of this Section 6.4(a)(i), the amount of any order placed by CMIC under Section 6.1(c) that is in excess of the related Drug Substance Order Limit or the amount of any order placed by CMIC under Section 6.1(e) that is in excess of the related Drug Product Order Limit may not be applied toward the calculation of any supply shortage contemplated under this Section 6.4(a)(i);
- (ii) Regulatory Authority notifies Dyax or CMIC in writing that Product Manufacturing Process does not comply with the applicable laws and regulations in CMIC Territory and Dyax does not cure such noncompliance within a six (6) month period of such notification to the satisfaction of the Regulatory Authority; or
- (iii) Dyax elects to discontinue the Manufacture of Drug Substance and Drug Product to CMIC as provided for in the Supply Agreement.

If CMIC elects to exercise its option under this Section 6.4(a), then all of Dyax's obligations under Section 6.1 shall terminate; provided that:

- (iv) Dyax shall provide reasonable assistance to CMIC, at its expense, to enable CMIC to assume the responsibility for Product Manufacturing Process as it applies to Drug Substance and/or Drug Product. The assistance shall include introducing CMIC to Dyax's CMOs and working with CMIC and the CMOs to coordinate technology transfers and any other actions reasonably required in order to enable CMIC to enter into a direct contractual relationship with, and be supplied Drug Substance and Drug Product directly from, any such CMO. Any Drug Substance or Drug Product so Manufactured by CMIC may be used solely for the Development and Commercialization of Product in Field and in CMIC Territory in accordance with the terms of this Agreement.
  - (v) At CMIC's option and request, Dyax shall continue to Manufacture and supply Drug Product to CMIC on the terms no less favorable than those on which Dyax supplies Drug Product to CMIC prior to such termination for a period of twenty four (24) months, or until such time as all of the assistance under Section 6.4(a)(iv) has been completed.
  - (vi) Each Party shall appoint at least one manufacturing logistics and quality assurance manager to support the Parties' respective Manufacturing activities, and to function as a liaison with the other Party's manufacturing logistics and quality assurance manager on the matters relating to the Manufacture and supply of Drug Substance and Drug Product under this Agreement.
- (b) For Convenience. Notwithstanding the restrictions set forth in Section 3.1(b) that preclude CMIC from Manufacturing or having Manufactured Drug Product, CMIC shall have the right, exercisable at its convenience, to obtain from Dyax the right to Manufacture and have Manufactured Drug Product (but not Drug Substance) as necessary to meet the requirements of CMIC and its Related Parties for Development and Commercialization of Product in Field in CMIC Territory. If CMIC has elected to exercise its option under this Section 6.4(b), then all of Dyax's obligations with respect to the Manufacture of Drug Product (but not Drug Substance) under Section 6.1 shall terminate; provided that:
- (i) Dyax shall provide reasonable assistance to CMIC at CMIC's expense to enable CMIC to assume the responsibility for the Manufacture of Drug Product. The assistance shall include introducing CMIC to Dyax's CMOs and working with CMIC and the CMOs to coordinate any necessary technology transfers and taking such other actions as may be reasonably required in order to enable CMIC to assume the responsibility for the Manufacture of Drug Product. Any Drug Product so

Manufactured by CMIC may be used solely for the Development and Commercialization of Product in Field and in CMIC Territory in accordance with the terms of this Agreement.

- (ii) Each Party shall appoint at least one manufacturing logistics and quality assurance manager to support the Parties' respective Manufacturing activities, and to function as a liaison with the other Party's manufacturing logistics and quality assurance manager on the matters relating to the Manufacture of Drug Substance and Drug Product under this Agreement.

Notwithstanding the election by CMIC to assume the Manufacture of Drug Product under this Section 6.4(b), Dyax shall remain responsible for the Manufacture of Drug Substance and, in lieu of holding all the Drug Substance ordered by CMIC under Section 6.1(d) as Drug Substance Inventory, Dyax shall deliver all such Drug Substance directly to CMIC (or its designee). In consideration for the Drug Substance so delivered by Dyax to CMIC, CMIC shall pay to Dyax the applicable Transfer Price for the Drug Substance. Such Transfer Price shall be paid as follows:

- (iii) if and to the extent that the external Manufacturing Costs of Drug Substance are incurred by Dyax in advance of the actual delivery thereof to CMIC, such Manufacturing Costs shall be invoiced to CMIC and CMIC shall pay such invoice within thirty (30) days after receipt thereof; and
- (iv) the balance of the Transfer Price and such external Manufacturing Costs of Drug Substance paid under item (iii) above shall be paid by CMIC within thirty (30) days after receipt of the relevant invoice to be issued by Dyax after the quality release (duly documented) of the Drug Substance.

6.5 Supply and Quality Agreements. After the Effective Date, the Parties shall negotiate in good faith and enter into a comprehensive supply agreement pursuant to which Dyax shall supply Drug Substance and Drug Product to CMIC (the "Supply Agreement") together with a quality agreement. The quality agreement shall conform with the industry standards governing the Drug Substance and Drug Product supplied pursuant to the Supply Agreement (the "Quality Agreement"). The Supply Agreement and the Quality Agreement shall include the terms and conditions similar to those set forth in Sections 6.1 through 6.4 of this Agreement and shall contain such other terms and conditions that the Parties mutually agree that are customary for supply agreements and quality agreements of this type.

6.6 RCT License. Dyax shall ensure that any of Dyax's CMOs engaged to Manufacture Drug Substance in accordance with this Article VI shall have obtained a license under RCT Intellectual Property, as and to the extent that such license may remain necessary for such Manufacture.

## ARTICLE VII FINANCIAL PROVISIONS

7.1 License Fee. As soon as possible following the Effective Date (but in no event no later than thirty (30) days thereafter), CMIC shall pay to Dyax an upfront license fee in the amount of Four Million Dollars (\$4,000,000) as partial consideration for the rights granted by Dyax to CMIC under this Agreement.

### 7.2 Milestone Payments.

- (a) Approval in HAE Indication. Within twenty (20) Business Days following the Regulatory Approval of Product for the HAE Indication by the Japanese Government, CMIC shall pay to Dyax a one-time milestone payment in the amount of Three Million Dollars (\$3,000,000).
- (b) Approval in Acquired Angioedema Indication. Within twenty (20) Business Days following the Regulatory Approval of Product for the acquired angioedema Indication by the Japanese Government, CMIC shall pay to Dyax a one-time milestone payment in the amount of Two Million Dollars (\$2,000,000).

- (c) Approval in Drug-Induced Angioedema Indication. Within twenty (20) Business Days following the Regulatory Approval of Product for the drug-induced angioedema Indication by the Japanese Government, CMIC shall pay to Dyax a one-time milestone payment in the amount of Two Million Dollars (\$2,000,000).

7.3 Ongoing Costs. CMIC shall be solely responsible for (i) all the Development Costs incurred in connection with the Development of Product for any Indication in Field in CMIC Territory, (ii) all the Regulatory Activities Costs associated with obtaining the Regulatory Approval for Product for any Indication in Field in CMIC Territory, and (iii) all the costs associated with the Commercialization of Product in Field in CMIC Territory.

7.4 Sales Milestones. Within thirty (30) days of the end of the calendar year in which each of the following events has occurred for the first time with respect to annual Net Sales of Product (cumulative for all Indications) in CMIC Territory, CMIC shall make the following payments to Dyax:

<u>Milestone Event</u>	<u>Payment</u>
First calendar year in which Net Sales of Product in CMIC Territory are greater than \$25,000,000	\$5,000,000
First calendar year in which Net Sales of all Product in CMIC Territory are greater than \$50,000,000	\$5,000,000
First calendar year in which Net Sales of all Product in CMIC Territory are greater than \$75,000,000	\$5,000,000
First calendar year in which Net Sales of all Product in CMIC Territory are greater than \$100,000,000	\$10,000,000
First calendar year in which Net Sales of all Product in CMIC Territory are greater than \$150,000,000	\$15,000,000
First calendar year in which Net Sales of all Product in CMIC Territory are greater than \$200,000,000	\$15,000,000
First calendar year in which Net Sales of all Product in CMIC Territory are greater than \$300,000,000	\$20,000,000
First calendar year in which Net Sales of all Product in CMIC Territory are greater than \$400,000,000	\$20,000,000

For the avoidance of doubt, each of the foregoing milestone payments is a separate payment and shall be paid only once by CMIC. Consequently, the maximum amount that CMIC is obligated to pay to Dyax under this Section 7.4 is Ninety-Five Million Dollars (\$95,000,000).

7.5 Royalties.

- (a) Royalty Rates. For each calendar year during Royalty Term, CMIC shall pay Dyax royalties on the annual Net Sales of Product in CMIC Territory at the following rates:

<u>Net Sales of Product during a Calendar Year</u>	<u>Rate</u>
Portion of Net Sales ≤ \$75,000,000	20.00%
Portion of Net Sales > \$75,000,000 ≤ \$150,000,000	22.00%
Portion of Net Sales > \$150,000,000	24.00%

- (b) Royalty Term. The royalty payment obligations of CMIC for the Net Sales of Product in CMIC Territory at the rates set forth in Section 7.5(a) shall be determined on a country-by-country basis and shall continue until the later of (i) the expiration of the last Valid Claim of the Dyax Patent Rights Covering the composition of matter, use or sale of Product in Field in such country or (ii) the tenth anniversary of the First Commercial Sale of such Product in Field in such country.
- (c) Blocking Third Party Patent Rights: In-Licenses.
- (i) Dyax shall be responsible for paying any milestones, royalties or other payments due for any In-License of the Blocking Third Party Patent Rights that are allocable to the Development, Manufacture or Commercialization of Product (in its existing form as of the Effective Date) in the HAE Indication in CMIC Territory.
- (ii) CMIC shall be responsible for paying any milestones, royalties or other payments due for any In-License of the Blocking Third Party Patent Rights that are allocable to the Development, Manufacture or Commercialization of Product for any Indications other than the HAE Indication in Field in CMIC Territory.
- (d) Royalties to RCT. Dyax shall be responsible for all the royalties, milestones or other payments payable to RCT under RCT License Agreement with respect to the Net Sales of Product by CMIC and its Related Parties in Field in CMIC Territory.
- (e) General.
- (i) Royalties shall be calculated (and paid) only once for each Product sold.
- (ii) No royalties shall be due upon the sale or other transfer of Product among CMIC or its Related Parties, but in such cases royalties shall be due and calculated upon CMIC's or its Related Party's Net Sales of such Product to the first Third Party.
- (iii) No royalties shall accrue on the disposition of Product in reasonable quantities by CMIC or its Related Parties as samples (for promotion or otherwise).

7.6 Net Sales Reports and Royalty Payments. Within sixty (60) days after the end of each Calendar Quarter during which royalties are due from CMIC to Dyax pursuant to Section 7.5, CMIC shall submit to Dyax a report, on a country-by-country basis, providing an accounting of the Net Sales of Product during such Calendar Quarter, and the calculation of the royalties due for such Net Sales under Section 7.5. Within sixty (60) days after the end of such Calendar Quarter, CMIC shall pay to Dyax all such royalties payable by it under Section 7.5, as indicated in the report.

7.7 Audits. Each Party shall, and shall require its Related Parties to, keep the true and accurate records and books of account containing all the data necessary for the calculation of the amounts payable by it and its Related Parties under this Agreement, including the royalties due under Section 7.5. Such records and books of account shall be kept by such Party and its Related Parties during the periods required by the applicable laws and regulations, provided that such periods should not be shorter than three (3) years following the end of the calendar year to which they relate. Upon one

Party's written request (the "Requesting Party"), the other Party (the "Audited Party") shall permit and have its Related Parties permit an international firm of independent certified public accountants which is appointed by agreement between the Parties or, failing such agreement within twenty (20) Business Days after the initiation of discussions between them, appointed by the Requesting Party from such firms that have not performed auditing or other services for either Party or their Related Parties in the previous three (3) years, to inspect such records and books of account of the Audited Party and its Related Parties and to carry out the following activities:

- (a) such accounting firm shall be given access to and shall be permitted to examine and copy such books and records of the Audited Party and its Related Parties and any other documentation that may be relevant for the purposes hereof upon twenty (20) Business Day notice having been given to the Audited Party by the Requesting Party and during any reasonable time periods on Business Days for the purpose of certifying (i) if the Audited Party is CMIC, that the Net Sales or other relevant sums calculated by CMIC and its Related Parties during any calendar year have been reasonably calculated, true and accurate in conformity with this Agreement or, if this is not their opinion, certifying the Net Sales or other relevant sums for such period which in their judgment and evaluation is true and correct; or (ii) if the Audited Party is Dyax, that the Manufacturing Costs charged by Dyax to CMIC during any calendar year have been reasonably calculated, true and accurate in conformity with this Agreement or, if this is not their opinion, certifying the Manufacturing Costs for such period which in their judgment and evaluation is true and correct;
- (b) prior to any such examination taking place, such accounting firm shall undertake to the Audited Party in writing that it shall keep all the information and data contained in such books and records strictly confidential and shall not disclose such information and data or copies of such books and records to any Person, including the Requesting Party, but shall only use the same for the purpose of performing the calculations referred to in Section 7.7(a);
- (c) any such access, examination and certification shall occur no more than once per calendar year;
- (d) the Audited Party shall make and shall have its Related Parties make available to such accounting firm the personnel to answer such accounting firm's reasonable queries on all such books and records which are required for the purpose of calculating the amounts referred to in Section 7.7(a);
- (e) any amount that is found by such accounting firm to be due by one Party to the other Party shall be paid by the owing Party to such other Party within sixty (60) days of the final determination of such amount by such accounting firm, provided that, in the event that either Party disagrees on such determination, such Party may refer the matter to the arbitration pursuant to Section 13.3 within thirty (30) days of the date of being notified in writing of such determination; and
- (f) the reasonable cost of such certification by such accounting firm shall be the responsibility of the Audited Party if the certification shows either (i) that the Audited Party has underpaid monies due to the Requesting Party by more than five percent (5%) over a calendar year, or (ii) that the Audited Party has overcharged the Requesting Party for Manufacturing Costs, Development Costs or other relevant sums subject to reimbursement under this Agreement by more than five percent (5%) over a calendar year. In all other instances, the reasonable cost of such certification by such accounting firm shall be the responsibility of the Requesting Party.

7.8 Taxes; Deductions and Set-Offs. All the payments required under this Agreement shall be made without deduction or withholding of any taxes or similar governmental charges imposed by any governmental agencies in any jurisdictions. Any withholding taxes imposed on such payments shall be the sole responsibility of the paying Party. Such payments shall be made without deduction, deferment, set-off, lien or counterclaim of any nature. The Parties recognize that the Parties are required to follow the procedures under the "Convention between the Government of Japan and the Government of the United States of America for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with respect to Taxes on Income" that may apply to any payments under this Section 7.

7.9 United States Dollars. All the dollar (\$) amounts specified in this Agreement are the United States dollar amounts.

7.10 Currency Exchange. With respect to the Net Sales invoiced and the expenses incurred in U.S. dollars hereunder, such Net Sales and expenses and the amounts due to the receiving Party hereunder shall be expressed in U.S. dollars. With respect to the Net Sales invoiced and the expenses incurred in a currency other than U.S. dollars hereunder, such Net Sales and expenses shall be expressed in the currency, in which such Net Sales have been invoiced or such expenses have been incurred, together with their U.S. dollar equivalents, calculated at the average of the spot rate on the first and last Business Days of the Calendar Quarter in which such Net Sales have been invoiced or such expenses have been incurred. The "closing mid-point rates" found in the "dollar spot forward against the dollar" table published by The Financial Times or any other publication as agreed to by the Parties shall be used as the source of such spot rates. All the payments hereunder shall be made in U.S. dollars.

7.11 Blocked Payments. If, by reason of the applicable laws, rules or regulations in any country, it becomes impossible or illegal for CMIC or its Related Parties to transfer, or have transferred on their behalf, the royalties or other payments hereunder to Dyax, CMIC shall promptly notify Dyax of the conditions preventing such transfer and such royalties or other payments shall be deposited by CMIC or its Related Parties in the local currency in the relevant country to the credit of Dyax in a recognized banking institution designated by Dyax or, if none is designated by Dyax within a period of thirty (30) days after such notification, in a recognized banking institution selected by CMIC or its Related Party, as the case may be, and identified in a notice given to Dyax.

7.12 Late Payments. The owing Party shall pay interest to the owed Party on the aggregate amount of any payments that are not paid on or before thirty (30) days after the date such payments are due under this Agreement at a rate per annum equal to LIBOR plus four percent (4%), calculated on the number of days which elapse on and until such payments are paid after the date such payments are due hereunder. The interest shall be compounded monthly.

## ARTICLE VIII INTELLECTUAL PROPERTY OWNERSHIP, PROTECTION AND RELATED MATTERS

### 8.1 Ownership of Inventions.

- (a) Ownership of Product Intellectual Property. Notwithstanding anything to the contrary contained in this Agreement, the Parties acknowledge and agree that Dyax is, and throughout the Term of this Agreement shall remain, the owner of:
  - (i) Existing Dyax Patent Rights; and
  - (ii) all other Know-How, Patent Rights and other intellectual property that Covers the Compound or its sale, use or manufacture in Field, including without limitation, any such intellectual property generated, developed, conceived or reduced to practice by or on behalf of CMIC or any of its Related Parties.
- (b) Sole Inventions. Except as set forth in Section 8.1(a), each Party shall exclusively own all the Inventions generated, developed, conceived or reduced to practice in the course of performing the activities under this Agreement solely by such Party, its Related Parties and its and their employees, agents, consultants and contractors ("Sole Inventions"). The Sole Inventions generated, developed, conceived or reduced to practice solely by CMIC, its Related Parties, and its and their employees, agents, consultants and contractors are referred to herein as "CMIC Sole Inventions". The Sole Inventions generated, developed, conceived or reduced to practice solely by Dyax, its Related Parties, and its and their employees, agents, consultants and contractors, as well as any Invention that would otherwise be a Joint Invention but would be patentable under the United States patent law claiming in a patent application the priority to Existing Dyax Patent Rights, are referred to herein as "Dyax Sole Inventions".
- (c) Joint Inventions and Joint Know-How. Except as set forth in Section 8.1(a), the Parties shall jointly own all the Inventions generated, developed, conceived or reduced to practice in the course of performing the activities under this Agreement jointly by the employees, agents,

consultants, and contractors of CMIC and its Related Parties on the one hand, and by the employees, agents, consultants and contractors of Dyax and its Related Parties on the other hand, on the basis of each Party having an undivided interest therein in whole ("Joint Inventions"). The Parties shall jointly own all Joint Know-How and Joint Patent Rights on a worldwide basis deeming such joint ownership to be the same rights as the joint ownership interests of co-inventors named on the United States patents under the United States patent laws, including the right to practice Joint Know-How and Joint Patents and to grant to others a license to the same, without obtaining the consent of or accounting to the other Party.

- (d) Inventorship; Implementation of Joint Ownership.
- (i) For the purposes of determining whether a certain Invention is a CMIC Sole Invention, a Dyax Sole Invention or a Joint Invention, the questions of inventorship shall be resolved in accordance with the United States patent laws. If a dispute arises between the Parties as to such inventorship determination, and such dispute cannot be resolved by the patent counsels to the Parties, the Parties shall refer such determination to a third patent counsel reasonably acceptable to the Parties, who shall make the final determination of such inventorship which shall be binding upon the Parties and their respective inventors.
  - (ii) In order to implement the rights of joint ownership throughout the world as provided for in Section 8.1(c), each Party hereby assigns to the other Party, and hereby grants to the other Party all the consents, licenses and waivers, in each case that are necessary to achieve such joint ownership and the rights associated with such joint ownership worldwide, and agrees to provide to the other Party the documents that evidence or may be required to record such assignments, consents, licenses and waivers promptly upon the other Party's request. Promptly after being requested in writing by the other Party, each Party shall provide to the other Party all the documents and instruments required to evidence or record any such assignments, consents, licenses or waivers, or (to the extent consistent with this Agreement) to enforce the rights in Joint Patent Rights. Each Party hereby appoints the other Party as the appointing Party's attorney-in-fact to execute and deliver each of the foregoing documents and instruments if the other Party is unable to obtain the appointing Party's signature on any such documents and instruments though making reasonable efforts to obtain it.

8.2 Prosecution and Maintenance of Patent Rights.

- (a) As used in this Section 8.2(a), the term "Prosecuting Party" shall mean (i) Dyax with respect to the filing, prosecution and maintenance of Dyax Patent Rights, and any Joint Patent Rights that Cover Compound or Product or their Manufacture, use or sale outside of Field, and (ii) CMIC with respect to the filing, prosecution and maintenance of all other Joint Patent Rights. The Prosecuting Party shall use Commercially Reasonable Efforts to prepare, file, prosecute and maintain the Patent Rights for which it is responsible under this Section 8.2(a) and shall confer with and keep the other Party reasonably informed regarding the status of such activities. In addition, the Prosecuting Party shall have the following obligations with respect to the filing, prosecution and maintenance of any Patent Rights for which it is responsible under this Section 8.2(a):
- (i) the Prosecuting Party shall use Commercially Reasonable Efforts to provide to the other Party for review and comment a substantially completed draft of any patent applications included within the Patent Rights for which it is responsible under this Section 8.2(a) at least thirty (30) days prior to the filing of any such patent applications and consider in good faith any comments from such other Party if it has received such comments timely;
  - (ii) the Prosecuting Party shall provide the other Party promptly after any such filing with copies of all the material communications received by it from or filed by it in patent offices with respect to such filing; and

- (iii) the Prosecuting Party shall consult with the other Party on any action that would materially affect the scope, validity, enforceability, or maintenance of any Valid Claim included within the Patent Rights for which it is responsible under Section 8.2(a) a reasonable time prior to taking or failing to take such action, including providing access by such other Party to the complete files of any patent nullification, opposition, interference, re-examination, reissue or patent term extension proceedings instituted anywhere in the world without regard to Territory or Field.

Furthermore, if the Prosecuting Party elects not to undertake the preparation, filing, prosecution, defense and/or maintenance of any Patent Rights for which it is made the Prosecuting Party hereunder (or, after commencement of such filing, prosecution, defense and/or maintenance, desires to cease the prosecution, defense or maintenance of any Patent Rights for which it is responsible hereunder), then the Prosecuting Party shall promptly notify the other Party of such election and the other Party shall be entitled (but not obligated), at its expense, to assume the preparation, filing, prosecution, defense and/or maintenance of such Patent Rights. Notwithstanding the foregoing, CMIC shall not be entitled to assume the preparation, filing, prosecution, defense and/or maintenance of any Dyax Patent Rights that Cover Compound or its use in Field.

- (b) Costs and Expenses. Any costs and expenses incurred by a Party in preparing, filing, prosecuting, maintaining or defending the Joint Patent Rights shall be shared equally by the Parties. Any costs and expenses incurred by Dyax in preparing, filing, prosecuting, maintaining or defending Dyax Patent Rights in any Territory shall be paid solely by Dyax.

### 8.3 Third Party Infringement.

- (a) Notice. Each Party shall promptly report in writing to the other Party during the Term any known or suspected (i) infringement of any of Dyax Patent Rights, CMIC Patent Rights or Joint Patent Rights or (ii) unauthorized use of any of Dyax Know-How, CMIC Know-How or Joint Know-How that, in each case, would involve the activities of Third Parties that may adversely affect the Commercialization of Product in Field (a "Competitive Infringement") of which such Party becomes aware and shall provide the other Party with all the available evidence supporting such known or suspected Competitive Infringement. Dyax shall keep CMIC informed of any disputes or proceedings involving any of Dyax Patent Rights anywhere in the world where a Competitive Infringement would involve a product containing Compound.
- (b) Cooperation with Respect to Competitive Infringements. With respect to any Competitive Infringement described in Section 8.3(a) above, the Parties shall at all times cooperate with, share all material notices and filings in a timely manner with, provide all reasonable assistance to each other and use Commercially Reasonable Efforts to mutually agree upon an appropriate course of action, including, as appropriate, the preparation of material court filings and any discussions concerning prosecution and/or settlement of any claims against any such Competitive Infringements.
- (c) Final Authority. The final decisions on whether to initiate a proceeding, against a Competitive Infringement and the course of action in such proceeding, including settlement negotiations and settlement terms, shall be made (i) with respect to Dyax Patent Rights and any Patent Rights owned solely by Dyax under this Agreement, by Dyax in consultation with CMIC, (ii) with respect to any CMIC Patent Rights, by CMIC in consultation with Dyax, and (iii) with respect to any Joint Patent Rights, jointly by the Parties. Any disagreement between the Parties concerning the enforcement of Joint Patent Rights shall be referred to Executive Officers for resolution pursuant to Section 13.1 and, if not resolved as provided for in Section 13.1, shall be resolved as provided for in Sections 13.2 and 13.3.
- (d) Conduct of Litigation; Costs. The Party initiating suit with respect to any Competitive Infringement shall have the sole and exclusive right to select counsel for the suit, provided that such selected counsel shall be reasonably acceptable to the other Party and neither previously nor presently adverse to such other Party. If and to the extent that the initiating Party is unable

to initiate or prosecute the suit solely in its own name or it is otherwise advisable in order to obtain an effective remedy through the suit, the other Party shall join the suit at the initiating Party's cost and shall execute and cause its Related Parties to execute all the documents necessary for the initiating Party to initiate, prosecute and maintain the suit; provided that CMIC shall be required to join any suit initiated by Dyax with respect to a Competitive Infringement only to the extent that such suit relates to the Competitive Infringement in CMIC Territory. Such other Party shall offer reasonable assistance to the initiating Party in connection with the suit at no charge except for reimbursement of the reasonable out-of-pocket expenses incurred by it in rendering the assistance; provided that CMIC shall be required to offer reasonable assistance to Dyax only to the extent relating to a suit initiated by Dyax in connection with the Competitive Infringement in CMIC Territory. The initiating Party shall assume and pay all of its own out-of-pocket costs incurred by it in connection with any suit, litigation or proceedings initiated by it with respect to a Competitive Infringement, including the fees and expenses of the counsel selected by it. CMIC shall have the right to participate and be represented in any such suit as is based on a Competitive Infringement in CMIC Territory, by its own counsel at its own expense.

- (e) Recoveries. With respect to any suit or action that is based on a Competitive Infringement in CMIC Territory, any recovery obtained as a result of any such proceedings by settlement or otherwise shall be allocated in the following order of priority:
- (i) first, the Parties shall be reimbursed for all the costs incurred by them in connection with such proceedings and not otherwise recovered and, if such obtained recovery is less than such costs, the amount of such reimbursement shall be shared pro rata in accordance with the cost incurred by each Party in connection therewith; and
  - (ii) second, any remainder, if any, shall be allocated and distributed between the Parties as follows:
    - (A) if the entire recovery is based upon the effect of the Competitive Infringement on the Development, Manufacture and/or Commercialization of Product in Field in CMIC Territory; then such amount shall be treated as if it were Net Sales during the relevant Calendar Quarter subject to the applicable terms of this Agreement (i.e., CMIC shall be entitled to all of such recovery less any royalties due to Dyax under Section 7.5);
    - (B) if the entire recovery is based upon the effect of the Competitive Infringement on the Development, Manufacture and/or Commercialization of Product in Field in Dyax Territory or outside Field in any country of the world; then Dyax shall be entitled to all of such remainder;
    - (C) if the entire recovery is based upon the effect of the Competitive Infringement on the Development, Manufacture and/or Commercialization of Product in both Dyax Territory and CMIC Territory or in and outside of Field in CMIC Territory, then such remainder shall be allocated between the Parties based upon the relative effects of the Competitive Infringement on the Development Manufacture and/or Commercialization of Product in Field in CMIC Territory and of Product in Field in Dyax Territory or outside Field in any country of the world, as determined by the Parties in good faith. Any amounts so allocated to CMIC shall be treated as if it were Net Sales during the relevant Calendar Quarter subject to the applicable terms of this Agreement (i.e., CMIC shall be entitled to all of such recovery less any royalties due to Dyax under Section 7.5). Any disagreement between the Parties concerning the allocation of recoveries under this Section 8.3(e)(ii)(C) shall be referred to Executive Officers for resolution pursuant to Section 13.1 and, if not resolved as provided for in Section 13.1, shall be resolved as provided in Sections 13.2 and 13.3.

8.4 Claimed Infringement; Patent Invalidity Claims. If a Party becomes aware of any claim that the Development, Manufacture or Commercialization of Product would infringe the intellectual property rights of any Third Party, the Party shall promptly notify the other Party of such claim. For any such case, the Parties shall cooperate and shall mutually agree upon an appropriate course of action. The costs and expenses of any action instituted for any such case (including the reasonable fees of attorneys and other professionals) shall be borne by the Party defending against the claim. The other Party may, at its own expense and with its own counsel, participate in such action, defending against the claim. Each Party shall provide to the other Party copies of any notices it receives from Third Parties regarding any patent nullity actions, any declaratory judgment actions and any alleged infringement or misappropriation of Third Party's intellectual property rights relating to the Development, Manufacture or Commercialization of Product. Such notices shall be so provided promptly, but in no event after more than five (5) Business Days following receipt thereof. Neither Party shall enter into any settlement of such action without the prior written consent of the other Party (which consent shall not unreasonably be withheld, delayed or conditioned) if such settlement includes a finding, stipulation or agreement that any Dyax Intellectual Property or CMIC Intellectual Property is invalid or unenforceable, or results in or requires a reduction in the scope or abandonment of a claim or enforceable right in any Dyax Intellectual Property or CMIC Intellectual Property. Any disputes between the Parties under this Section 8.4 shall be determined in accordance with the provisions of Section 13.3.

8.5 Patent Term Extensions. The Parties shall cooperate with each other in gaining patent term extensions and supplemental protection certificates wherever applicable to Patent Rights in CMIC Territory Controlled by either Party that Cover Compound, Product or their method of manufacture or use. The Parties shall use reasonable efforts to agree upon a joint strategy relating to such patent term extensions and supplemental protection certificates, but, in the absence of such mutual agreement with respect to any extension issue in CMIC Territory, a patent eligible for such extension shall be extended if either Party elects to extend it; provided that Dyax shall finally determine which patents to be so extended if more than one patent is eligible for such extension. All filings for such extension shall be made by the Party Controlling such patent or, in the case of Joint Patent Rights, by the Party responsible for filing, prosecuting and maintaining such Joint Patent Rights in accordance with Section 8.2. Any costs and expenses of such extension of Dyax Patent Rights shall be incurred solely by Dyax. Any costs and expenses of such extension of CMIC Patent Rights shall be incurred solely by CMIC. Any costs and expenses of such extension of Joint Patent Rights shall be equally incurred by the Parties.

8.6 Non-Patent Regulatory Exclusivity. CMIC shall have the exclusive right to apply for Regulatory Exclusivity for Product in Field in CMIC Territory. As used in this Section 8.6, "Regulatory Exclusivity" shall mean a government-granted right to exclude others from manufacturing, using or selling a pharmaceutical product, other than a right conferred solely by a Patent Right.

8.7 Patent Marking. To the extent customary in the pharmaceutical industry in each Party's respective Territory and where notice is required to accrue damages or other rights for patent infringement, each Party agrees to comply with the patent marking statutes in each country in its Territory in which Product is sold by such Party and/or its Related Parties.

8.8 Trademarks.

- (a) Each Party and its Affiliates shall retain all right, title and interest in and to its and their respective corporate names and logos.
- (b) Dyax shall own all Product Trademarks applicable to Product in Field in Dyax Territory or outside of Field in all the countries of the world during the Term ("Dyax Product Trademarks").
- (c) Dyax hereby grants CMIC a royalty-free and paid-up license, with the right to grant sublicenses to the Sublicensees under Section 3.1(d), to use Dyax Product Trademarks in connection with the Commercialization of Products in Field in CMIC Territory. CMIC shall use and shall have such Sublicensees use Dyax Product Trademarks in accordance with the sound trademark and trade name usage principles and any reasonable guidelines provided to CMIC by Dyax in connection therewith.
- (d) If and to the extent that Dyax Product Trademarks are not capable of being used in connection with the Commercialization of Product in Field in any country of CMIC Territory, then CMIC and its Sublicensees under Section 3.1(d) shall be free to select and utilize the trademarks of its

own ("CMIC Product Trademarks") in connection with the Commercialization of Product in Field in such country of CMIC Territory; provided that any such trademark or its use in the Commercialization of Product shall not adversely affect Dyax's own trademarks or other rights.

- (e) If Dyax or CMIC has Knowledge of any suspected infringement of Dyax Product Trademarks or CMIC Product Trademarks by Third Parties, the Party having such Knowledge shall promptly inform the other Party of such suspected infringement. Dyax and CMIC shall thereafter consult and cooperate with each other to determine the course of action against such suspected infringement. In any event, Dyax shall have the sole right to take such steps as may be required to enforce Dyax Product Trademarks in any countries of the world, and CMIC shall have the sole right to take such steps as may be required to enforce CMIC Product Trademarks in CMIC Territory. Each Party shall keep the other Party informed of developments in any court action or proceedings for such suspected infringement, including the status of any settlement negotiations and the terms of any offer related thereto.
- (f) CMIC shall have the sole responsibility and authority for, and control of, all the package labeling and all the package inserts (and any changes or supplements thereto) for Product for Commercialization in CMIC Territory, including determining the packaging and trade dress for Product.

**ARTICLE IX  
CONFIDENTIALITY AND PUBLICITY**

9.1 Confidential Information. Each Party shall keep in confidence and not disclose to any Third Party, or use for any purpose, except pursuant to, and in order to carry out, the terms and objectives of this Agreement, any Confidential Information of the other Party. As used herein, "Confidential Information" shall mean all the trade secrets or confidential or proprietary information designated as such in writing by the disclosing Party, including any CMIC Know-How and Dyax Know-How, whether by appropriate letters or by the use of an appropriate stamp or legend, prior to or at the time when any such trade secret or confidential or proprietary information is disclosed by the disclosing Party to the receiving Party. Notwithstanding the foregoing, the information which is orally or visually disclosed to the receiving Party by the disclosing Party, or is disclosed in writing without appropriate letters, stamps or legends to the receiving Party by the disclosing Party, shall constitute Confidential Information if (x) it would be apparent to a reasonable person, familiar with the disclosing Party's business and the industry in which it operates, that such information is of a confidential or proprietary nature, the maintenance of which is important to the disclosing Party, or (y) the disclosing Party, within thirty (30) days after such disclosure, delivers to the receiving Party the written documents describing such information as confidential or proprietary and referencing the place and date of such oral, visual or written disclosure and the names of the employees or officers of the receiving Party to whom such disclosure has been made. Confidential Information shall further include all the Confidential Information (as such term is defined in the June 4, 2009 Confidentiality Agreement between the Parties) disclosed to the receiving Party by the disclosing Party pursuant to such Confidentiality Agreement prior to the Effective Date. The restrictions on the disclosure and use of Confidential Information set forth in this Section 9.1 shall not apply to any Confidential Information that:

- (a) is known to the receiving Party or its Affiliates, without any confidentiality and limited-usage obligations for such Confidential Information, prior to disclosure of such Confidential information to them by the disclosing Party or its Affiliates hereunder or under the Confidentiality Agreement (as evidenced by the receiving Party's or its Affiliates' written records);
- (b) is part of the public domain or publicly known prior to disclosure of such Confidential Information to the receiving Party or its Affiliates by the disclosing Party or its Affiliates, or becomes part of the public domain or publicly known through no fault of the receiving Party or its Affiliates;
- (c) is disclosed to the receiving Party or its Affiliates, without any confidentiality and limited-usage obligations for such Confidential Information, by Third Party having the legal right to

make such disclosure without violating any confidentiality and limited usage obligations that such Third Party assumes towards the disclosing Party or its Affiliates; or

- (d) is independently discovered or developed by the receiving Party or its Affiliates (as evidenced by the receiving Party's or its Affiliates' written records).

Notwithstanding the obligations of confidentiality and limited-usage set forth above, the receiving Party may provide the Confidential Information disclosed to it to (i) Regulatory Authorities or other governmental authorities in order to seek or seek or obtain patents or to gain or maintain the authorization to Develop, Manufacture or Commercialize Product hereunder; provided that such Confidential Information shall be disclosed only to the extent reasonably necessary to seek or obtain patents or to gain or maintain such authorization, (ii) the extent required by the applicable laws, including the rules or regulations of the United States Securities and Exchange Commission or similar governmental authorities in countries other than the United States, as well as the rules or regulations of any stock exchange or listing entities, (iii) any bona fide actual or prospective underwriters, investors, lenders, other financing sources, collaborators, licensees, sublicensees, strategic partners or acquirors, in each case who are subject to the confidentiality and limited-usage obligations with respect to such Confidential Information no less strict than those set forth in this Section 9.1, to the extent reasonably necessary to enable such actual or prospective underwriters, investors, lenders, other financing sources, collaborators, licensees, sublicensees, strategic partners or acquirors to determine their interest in underwriting an issue of, making an investment in, lending money to, otherwise providing financing to, collaborating with, licensing intellectual properties from, partnering with or acquiring, the receiving Party. In addition, if either Party is required to disclose the Confidential Information of the other Party by regulations, laws or legal processes, including the rules or regulations of FDA, any similar Regulatory Authorities in countries other than the United States, the United States Securities and Exchange Commission or any stock exchange or listing entities, such Party shall, if practicable under the circumstances, provide to such other Party, prior to such intended disclosure, a copy of the proposed text of any such written disclosure or the proposed content of any such non-written disclosure, and the disclosing Party shall consider in good faith any comments received by it from such other Party with respect to such proposed disclosure and shall disclose only such Confidential Information of such other Party as is so required to be disclosed. The Parties agree and acknowledge that each Party is subject to the disclosure requirements under the Securities Exchange Act of 1934 and related laws and regulations. Therefore, in addition to the foregoing obligations, if a Party is required to publicly disclose the other Party's Confidential Information in accordance with such laws or regulations, the Party subject to such disclosure obligations shall, at least two (2) Business Days prior to such intended disclosure (unless impracticable under the circumstances), provide to such other Party a copy of the proposed text of any such disclosure, so as to permit such other Party to publicly disclose the Confidential Information on or before the date on which the Party originally subject to such disclosure obligations publicly discloses the Confidential Information in accordance with such laws or regulations. The confidentiality and limited-usage obligations set forth in this Section 9.1 and in the Confidentiality Agreement shall survive the expiration or termination of this Agreement and shall continue for seven (7) years after such expiration or termination.

9.2 Related Party, Employee, Consultant and Advisor Obligations. Except as set forth in Section 9.1, each Party may provide or permit access to the Confidential Information received by such party from such Party only to the receiving Party's Related Parties, and to the employees, consultants, advisors and subcontractors of such Party and its Related Parties, who have a need to know such Confidential Information to assist such Party and its Related Parties with the Development, Manufacture and Commercialization of Product in accordance with this Agreement and who are subject to the obligations of confidentiality and limited-usage with respect to such Confidential Information no less strict than the obligations of confidentiality and limited-usage imposed on such Party as set forth in Section 9.1; provided that Dyax and CMIC should each remain responsible for any failure by its Related Parties, and its and its Related Parties' respective employees, consultants, advisors and subcontractors, to treat such Confidential Information as required under this Section 9.2.

9.3 Publicity; Terms of Agreement.

- (a) Following the Effective Date, the Parties shall at a mutually agreeable time issue a mutually agreeable joint press release regarding the subject matter of this Agreement. After issuance of such initial joint press release, neither Party shall issue any other press release or public announcement regarding the execution or terms of this Agreement without the prior written approval of the other Party, which approval shall not be unreasonably withheld, conditioned or delayed, except that a Party may (i) issue such press release or public announcement regarding the execution or terms of this Agreement if the contents of such press release or public announcement have previously been made public other than through a breach of this

Agreement by the issuing Party; and (ii) issue such press release or public announcement regarding the execution or terms of this Agreement if required by the applicable regulations or laws, including the rules or regulations of FDA, the United States Securities and Exchange Commission or similar Regulatory Authorities in a countries other than the United States or of any stock exchange or listing entities; provided that, with respect to the press releases and public announcements made pursuant to the foregoing clause (ii), the Party subject to such requirement includes in the press releases or public announcements only such information relating to Compound, Product or this Agreement as is required by such applicable regulations or laws, and shall comply with the last three (3) sentences of Section 9.1.

- (b) In addition, if at any time a Party is legally required to file a copy of this Agreement with the Securities and Exchange Commission (or its counterpart in any country other than the United States), the Party shall attempt to obtain confidential treatment of such economic and trade secret information as included herein for which such treatment is reasonably available in accordance with the applicable laws and regulations and the SEC's (or its counterpart's) practice. To that end, the Party shall, at least fifteen (15) days in advance of any such filing, provide the other Party with a draft set of redactions to this Agreement for which confidential treatment should be so sought from them, and shall incorporate such other Party's reasonable comments as to the additional information, which it would like to redact, into the above economic and trade secret information, and shall seek from them the confidential treatment for such additional information.
- (c) Either Party may further disclose the terms of this Agreement which have been publicly disclosed pursuant to Sections 9.3(a) or (b). Otherwise, the terms of this Agreement shall be treated as Confidential Information of both Parties. Such undisclosed terms may be disclosed by a Party to its prospective and actual licensees, Sublicensees, employees, officers, consultants, subcontractors, agents, accountants, lawyers, advisers, bankers, lenders and investors who are bound to the obligations of confidentiality and limited-usage substantially equivalent in scope and extent to or no less strict than those set forth in this Article IX.

9.4 Publications. During the Term, if a Party desires to publicly disclose any New Information in scientific journals or publications or through scientific presentations, the Party shall provide the other Party with an advance copy of any such proposed abstracts, posters, scientific presentations and scientific journals or publications incorporating such New Information prior to submission for publication. With regard to such abstracts, posters, and scientific presentations, the advance copy shall be provided by the Party to the other Party at least fifteen (15) days prior to submission for public disclosure. With regard to such scientific journals or publications, the advance copy shall be provided by the Party to the other Party at least thirty (30) days prior to submission for public disclosure. The other Party shall have a reasonable opportunity to recommend to the Party any changes to such advance copies it reasonably believes are necessary to prevent any specific material adverse effect to it or the Product being Developed, Manufactured or Commercialized hereunder as a result of the public disclosure (such recommendation of changes to include a description of such specific material adverse effect), to which the Party shall give due consideration. The disputes concerning the public disclosure shall be referred to Executive Officers for resolution pursuant to Section 13.1 and, if not resolved as provided for in Section 13.1, shall be resolved as provided for in Sections 13.2 and 13.3. For the purposes of this Section 9.4, "New Information" shall mean any and all ideas, inventions, data, writings, protocols, discoveries, improvements, trade secrets, materials or other proprietary information which has not been previously disclosed to the public, which may arise, be conceived or developed by the Parties or their Related Parties during the Term in the course of performing this Agreement and which is specifically related to the Development, Manufacture or Commercialization of Product.

## **ARTICLE X**

### **REPRESENTATIONS AND WARRANTIES**

10.1 Representations of Authority. Each Party represents and warrants to the other Party that, as of the Effective Date, it has the full corporate right, power and authority to enter into this Agreement and to perform its obligations under this Agreement; that it has the right to grant to the other Party the licenses and sublicenses granted to the other Party pursuant to this Agreement; and that this Agreement has been duly executed by such Party.

10.2 Consents. Each Party represents and warrants to the other Party that, except for any Regulatory Approvals, pricing and/or reimbursement approvals, manufacturing approvals and/or similar approvals necessary for the Development, Manufacture or Commercialization of Product, all the necessary consents, approvals and authorizations of all the government authorities and other persons required to be obtained by it as of the Effective Date in connection with the execution, delivery and performance of this Agreement have been obtained by the Effective Date.

10.3 No Conflict. Each Party represents and warrants to the other Party that, notwithstanding anything to the contrary in this Agreement, the execution and delivery of this Agreement by such Party, the performance of such Party's obligations hereunder and the licenses and sublicenses to be granted by such Party pursuant to this Agreement (a) do not conflict with or violate any requirements of any laws, rules or regulations existing as of the Effective Date and applicable to such Party and (b) do not conflict with, violate, breach or constitute a default under any contractual obligations of such Party or any of its Affiliates existing as of the Effective Date.

10.4 Enforceability. Each Party represents and warrants to the other Party that, as of the Effective Date, this Agreement constitutes a legal and valid obligation binding upon such Party and is enforceable against such Party in accordance with the terms and conditions hereof, except as such enforceability may be limited by applicable insolvency and other applicable laws affecting creditors' rights generally or by the availability of equitable remedies.

10.5 No Debarment. Each Party represents and warrants to the other Party that neither such Party nor any of its Affiliates has been debarred or is subject to debarment under the applicable laws of any country in any Territory. Each Party agrees that neither it nor any of its Affiliates will use in any capacity, in connection with the Development, Manufacture or Commercialization of Product, any person who has been debarred under the applicable laws of any country in any Territory. Each Party agrees to inform the other Party in writing immediately if such Party or any person used by such Party or any of its Affiliates to perform services hereunder is debarred or is the subject of a conviction, or if any action, suit, claim, investigation or legal or administrative proceeding is pending or, to the best of such Party's Knowledge, is threatened, relating to the debarment or conviction of such Party or any person used in any capacity by such Party or any of its Affiliates in connection with the Development, Manufacture or Commercialization of Product.

10.6 Additional Representations and Warranties of Dyax. Dyax represents and warrants to CMIC that, as of the Effective Date:

- (a) Dyax has not granted, and will not grant during the Term, any rights, licenses or interests in or to Dyax Intellectual Property or any other intellectual property in the way that would conflict with any of the rights or licenses granted by Dyax to CMIC under this Agreement;
- (b) except for RCT License Agreement, there is no agreement between Dyax and any Third Party that imposes an obligation to pay royalties or any other amounts to such Third Party based on the Development, Manufacture or Commercialization of Product in Field in CMIC Territory;
- (c) Exhibit B sets forth a complete and correct list of all the Dyax Patent Rights existing as of the Effective Date that claim Compound, Product, its formulation or method of manufacture or use; except for the Dyax Patent Rights licensed under RCT License Agreement, Dyax is the sole and exclusive owner (as listed in the records of the relevant governmental entities) of all the rights, titles and interests in and to Existing Dyax Patent Rights and any other Dyax Intellectual Property;
- (d) Dyax has not granted and shall not grant any lien, security interest, mortgage or other encumbrance (excluding any licenses) with respect to any Dyax Intellectual Property, and has not permitted and shall not permit any lien, security interest, mortgage or other encumbrance (excluding any licenses) to attach to any Dyax Intellectual Property;
- (e) Dyax has obtained the effective assignment of all the rights, titles and interests of any and all Third Parties (including officers and employees) in and to Existing Dyax Patent Rights (and all the Inventions claimed thereunder); all the inventors of any Dyax Patent Rights have executed or will have executed effective assignments of such inventions to Dyax, and all such assignments are and shall be valid and enforceable;
- (f) the issued Existing Dyax Patent Rights are in full force and to the Knowledge of Dyax: (i) all the necessary registration, maintenance and renewal fees and any other payment due and owed

with respect to such Patent Rights have been fully paid and all the necessary documents and certificates have been filed with the relevant governmental entities for the purpose of maintaining such Patent Rights; (ii) such Patent Rights disclose the patentable subject matters under 35 U.S.C. Section 101 and their counterparts under the laws of the jurisdictions outside the United States; and (iii) Dyax and each of its Affiliates have complied with the required duty of candor and good faith in dealing with the U.S. Patent and Trademark Offices and similar governmental entities in other countries (collectively, the "Patent Offices"), including the duty to disclose to the Patent Offices all the information required to be disclosed under all the applicable laws and regulations;

- (g) there are no claims or demands of any Third Party or any actions, suits or other proceedings (including re-examination, opposition or interference proceedings) pending or threatened against Dyax or any of its Affiliates with respect to Dyax Intellectual Property; and
- (h) to the Knowledge of Dyax, the development, manufacture, commercialization, use or sale of Product (as it exists on the Effective Date) in the HAE Indication as contemplated hereunder will not infringe any valid and enforceable Patent Right or other intellectual property rights of any Third Party.

10.7 No Warranties. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH HEREIN, NEITHER PARTY MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, TO THE OTHER PARTY, AND, EXCEPT AS OTHERWISE EXPRESSLY SET FORTH HEREIN, EACH PARTY HEREBY DISCLAIMS ALL IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NON-INFRINGEMENT WITH RESPECT TO COMPOUND AND PRODUCT. EACH PARTY HEREBY DISCLAIMS ANY REPRESENTATION OR WARRANTY THAT THE DEVELOPMENT, MANUFACTURE AND COMMERCIALIZATION OF PRODUCT PURSUANT TO THIS AGREEMENT WILL BE SUCCESSFUL.

## **ARTICLE XI** **INDEMNIFICATION, DAMAGES AND INSURANCE**

11.1 By CMIC. CMIC shall defend, indemnify and hold harmless Dyax, its Affiliates and licensees and their respective directors, officers, employees and agents from and against all claims, demands, liabilities, damages, penalties, fines, costs and expenses, including reasonable attorneys' and expert fees and costs, and reasonable costs or amounts paid to settle (collectively, "Losses"), arising from or occurring as a result of a Third Party's claim (including any Third Party product liability or infringement claim), action, suit, judgment for or settlement with such Third Party to the extent that such Losses are due to or based upon:

- (a) the negligence, recklessness, bad faith, intentional wrongful acts or omissions or violations of the applicable laws or regulations by or of CMIC, its Related Parties or their respective directors, officers, employees or agents in relation to this Agreement; or
- (b) the breach by CMIC of the terms of, or the inaccuracy of any representation or warranty made by it in this Agreement; or
- (c) other activities conducted by CMIC or its Related Parties under this Agreement to Develop, Manufacture or Commercialize Product in Field in CMIC Territory;

except to the extent that such Losses arise out of, and are allocable to any cause set forth in Section 11.2(a) or (b) or (c).

11.2 By Dyax. Dyax shall defend, indemnify and hold harmless CMIC, its Affiliates or Sublicensees and their respective directors, officers, employees and agents from and against all Losses arising from or occurring as a result of a Third Party's claim (including any Third Party product liability or infringement claim), action, suit, judgment for or settlement with such Third Party to the extent that such Losses are due to or based upon:

- (a) the negligence, recklessness, bad faith, intentional wrongful acts or omissions or violations of the applicable laws or regulations by or of Dyax, its Related Parties or their respective directors, officers, employees or agents in relation to this Agreement; or

- (b) the breach by Dyax of the terms of, or the inaccuracy of any representation or warranty made by it in this Agreement; or
- (c) other activities conducted by Dyax or its Related Parties under this Agreement to Develop, Manufacture or Commercialize Product in Field in Dyax Territory or outside Field in all countries of the world;

except to the extent that such Losses arise out of, and are allocable to any cause set forth in Section 11.1(a), (b) or (c).

11.3 Claims for Indemnification.

- (a) A Person entitled to indemnification under Section 11.1 or 11.2 (the "Indemnified Party") shall give prompt written notification to the Party from whom such indemnification is sought (the "Indemnifying Party") of the commencement of any action, suit or proceeding relating to a Third Party claim for which such indemnification may be sought or, if earlier, upon the assertion of any such claim against the Indemnified Party by a Third Party (it being understood and agreed, however, that the failure by the Indemnified Party to give notice of a Third Party's claim as provided for in this Section 11.3 shall not relieve the Indemnifying Party of its indemnification obligation under this Article XI except and only to the extent that the Indemnifying Party is actually prejudiced as a result of such failure to give notice).
- (b) Within thirty (30) days after delivery of such notice, the Indemnifying Party may, upon written notice to the Indemnified Party, assume control of the defense of such action, suit, proceeding or claim with counsel reasonably satisfactory to the Indemnified Party. If the Indemnifying Party does not assume control of such defense, the Indemnified Party shall control such defense.
- (c) The Party not controlling such defense may participate therein at its own expense; provided that, if the Indemnifying Party assumes control of such defense and the Indemnified Party reasonably concludes, based on advice from its counsel, that the Indemnifying Party and the Indemnified Party have conflicting interests with respect to such action, suit, proceeding or claim, the Indemnifying Party shall be responsible for the reasonable fees and expenses of counsel to the Indemnified Party solely in connection therewith; provided further that in no event shall the Indemnifying Party be responsible for the fees and expenses of more than one counsel in any one jurisdiction for all the Indemnified Parties.
- (d) The Party controlling such defense shall keep the other Party advised of the status and development of such action, suit, proceeding or claim and the defense thereof and shall consider reasonable recommendations made by the other Party with respect thereto.
- (e) The Indemnified Party shall not agree to any settlement of such action, suit, proceeding or claim without the prior written consent of the Indemnifying Party, which shall not be unreasonably withheld, delayed or conditioned. The Indemnifying Party shall not, without the prior written consent of the Indemnified Party, agree to any settlement of such action, suit, proceeding or claim or consent to any judgment in respect thereof that does not include a complete and unconditional release of the Indemnified Party from any and all liabilities and obligations with respect thereto or that imposes any liabilities or obligations on the Indemnified Party.

11.4 No Consequential or Punitive Damages. NEITHER PARTY HERETO SHALL BE LIABLE FOR INDIRECT, INCIDENTAL, CONSEQUENTIAL, SPECIAL, EXEMPLARY, OR PUNITIVE DAMAGES ARISING OUT OF THIS AGREEMENT OR THE EXERCISE OF ITS RIGHTS HEREUNDER, OR FOR LOST PROFITS ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF SUCH DAMAGES; PROVIDED THAT NOTHING IN THIS SECTION 11.4 IS INTENDED TO LIMIT OR RESTRICT (A) THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF EITHER PARTY WITH RESPECT TO THIRD PARTY CLAIMS, OR (B) ANY CLAIMS WITH RESPECT TO A BREACH OF A PARTY'S OBLIGATIONS OF CONFIDENTIALITY OR LIMITED-USAGE IN ARTICLE IX.

11.5 Product Liability Insurance. During the Term and for a period of three (3) years after the expiration of this Agreement or the earlier termination hereof, CMIC shall obtain and/or maintain, at its sole cost and expense, product liability insurance (including any self-insured arrangements); provided that clinical trial insurance policies shall be required from CMIC only while the clinical trials hereunder are ongoing. The product liability insurance or self-insured arrangements shall insure against all reasonably anticipated liability for personal injury, physical injury, property damage or any other injury or damage arising in connection with the manufacture, sale, distribution or marketing of Product in CMIC Territory. Such insurance shall not be construed to create a limit of CMIC's liability under the terms of this Agreement. CMIC shall provide Dyax with a copy of the certificate of such insurance and/or self insurance or other evidence of such insurance and/or self-insurance, upon request. Furthermore, CMIC shall use Commercially Reasonable Efforts to provide Dyax with written notice at least thirty (30) days prior to the cancellation of, non-renewal of or material change to, such insurance and/or self-insurance that materially adversely affects the rights of Dyax hereunder.

## ARTICLE XII TERM AND TERMINATION

12.1 Term. Unless terminated earlier in accordance with this Article XII, this Agreement shall remain in force for the period commencing on the Effective Date and ending on the expiration of the last Royalty Term to expire under this Agreement (the "Term").

### 12.2 Termination Rights.

- (a) Termination for Convenience. CMIC shall have the right to terminate this Agreement at any time after the Effective Date on six (6) months prior written notice to Dyax.
- (b) Termination For Breach.
  - (i) Upon any material breach of this Agreement by a Party (the "Breaching Party"), the other Party (the "Non-Breaching Party") may terminate this Agreement by providing written notice to the Breaching Party specifying the nature of such material breach (a "Termination Notice").
  - (ii) The termination hereof as provided for in Section 12.2(b)(i) above shall become effective sixty (60) days following receipt of a Termination Notice by the Breaching Party unless the Breaching Party cures such specified material breach during such sixty (60) day grace period. Notwithstanding the foregoing, (i) if such material breach, by its nature, is incurable, the Non-Breaching Party may terminate this Agreement immediately upon receipt of a Termination Notice by the Breaching Party and (ii) if such material breach (other than a payment breach), by its nature, is curable, but not within the foregoing grace period, then the grace period shall be extended if the Breaching Party provides a written plan for curing such material breach to the Non-Breaching Party and uses Commercially Reasonable Efforts to cure such material breach in accordance with such written plan; provided that no such extension shall exceed ninety (90) days without the written consent of the Non-Breaching Party.
  - (iii) Notwithstanding the provisions of Sections 12.2(b)(i) and (ii), if the Non-Breaching Party gives a Termination Notice to the Breaching Party pursuant to Section 12.2(b)(i), and if, as of the end of the grace period set forth in Section 12.2(b)(ii), the Parties are engaged in an arbitration pursuant to Section 13.3 in which the Breaching Party disputes the basis for termination hereof pursuant to Section 12.2(b)(i), then this Agreement shall be terminated thirty (30) days after whichever comes earlier, (A) or (B) below;
    - (A) the arbitrator of such arbitration issues an award upholding the basis for termination hereof, or

- (B) the Breaching Party elects to end such dispute, and concedes that its breach hereof as specified in a Termination Notice should be the basis for termination hereof;

unless the Breaching Party cures its breach hereof within thirty (30) days of such earlier event.

- (c) Termination for Bankruptcy. A Party may terminate this Agreement should the other Party:
- (i) commit an act of bankruptcy;
  - (ii) be declared bankrupt;
  - (iii) voluntarily file or have filed against it a petition for bankruptcy or reorganization (unless such petition is dismissed within sixty (60) days of such filing or such petition is for a reorganization under Chapter 11 of the Bankruptcy Code or any relevant foreign equivalent thereof and such Party is not in default at the time of the filing of such petition or at any time during such reorganization of any of its obligations under this Agreement); or
  - (iv) enter into a procedure of winding up to dissolution, or should a trustee or receiver be appointed for its business assets or operations.

All the rights and licenses granted under or pursuant to this Agreement are, and shall otherwise be deemed to be, for the purposes of Section 365(n) of the Bankruptcy Code, license rights to "intellectual property" as defined under Section 101(60) of the Bankruptcy Code. The Parties agree that any Party, as a licensee hereunder, shall retain and may fully exercise all of its rights and elections under the Bankruptcy Code or any relevant foreign equivalent thereof.

- (d) Challenges of Patent Rights. If a Party or any of its Related Parties (the "Challenging Party") should (i) commence or participate in any action or proceeding (including any patent opposition or re-examination proceeding), or otherwise assert in writing any claim, challenging or denying the validity of any of the Patent Rights licensed to the Challenging Party hereunder or any claim thereof or (ii) actively assist any other Person in bringing or prosecuting any action or proceeding (including any patent opposition or re-examination proceeding) challenging or denying the validity of any of such Patent Rights or any claim thereof, the other Party shall have the right to give notice to the Challenging Party (which notice shall be given, if at all, within sixty (60) days after the other Party first learns of the foregoing) to the effect that the licenses granted to the Challenging Party to such Patent Rights shall terminate in thirty (30) days following such notice and, unless the Challenging Party withdraws or causes to be withdrawn all such challenge(s) within such thirty (30) day period, such licenses shall terminate.

12.3 Consequences of Termination.

- (a) Termination by Dyax for Cause.
- (i) Without limiting any other legal or equitable remedies that Dyax may have, if Dyax terminates this Agreement in accordance with Section 12.2(b), (c) or (d) then:
    - (A) CMIC's obligations under Section 5.1(b) shall survive for a period of one (1) year after such termination;
    - (B) CMIC shall, as promptly as practicable, transfer to Dyax or Dyax's designee all the records and materials in CMIC's possession or control containing the Confidential Information of Dyax;
    - (C) to the extent necessary and permitted under the applicable laws, CMIC shall appoint Dyax as CMIC's and/or CMIC's Related Parties' agent for all the

Product-related matters involving the Regulatory Authorities in CMIC Territory until all the Regulatory Approvals and other regulatory filings for Product have been transferred from CMIC and/or CMIC's Related Parties to Dyax or its designee;

- (D) if the effective date of such termination is after First Commercial Sale, to the extent necessary and permitted under the applicable laws, CMIC shall appoint Dyax as its exclusive distributor of Product in CMIC Territory and grant Dyax the right to appoint the sub-distributors of Product, until such time as all the Regulatory Approvals in CMIC Territory have been transferred from CMIC and/or CMIC's Related Parties to Dyax or its designee;
  - (E) CMIC shall transfer to Dyax or Dyax's designee the possession and ownership of all the Regulatory Approvals and pricing and reimbursement approvals in CMIC's possession and ownership relating to Product in CMIC Territory subject to reimbursement by Dyax of all the costs and expenses incurred by CMIC or its Related Parties for obtaining such approvals; the amount to be reimbursed by Dyax to CMIC under this Section 12.3(a)(i)(E) shall be first set off any outstanding amounts due from CMIC to Dyax under Article VII;
  - (F) at Dyax's request and subject to Dyax acquiring the relevant Regulatory Approvals under Section 12.3(a)(i)(E) above, CMIC shall provide reasonable assistance to allow the transfer to Dyax of any Third Party agreements relating to the Commercialization of Product in CMIC Territory to which CMIC is a party, to the extent that such transfer is not expressly prohibited by the terms of such Third Party agreements;
  - (G) CMIC shall grant Dyax an exclusive license, with the right to grant sublicenses through multiple tiers, under the CMIC Development Data that relates solely to Product, to Develop, Manufacture and/or Commercialize Product (or conduct the Regulatory Activities related thereto) in Field and throughout the world. The license granted pursuant to this Section 12.3(a)(i)(G) shall be royalty-free, fully-paid and perpetual; provided that, if and to the extent that any such license includes any sublicense of Third Party's intellectual property, then such sublicense shall be subject to such Third Party's consent and subject to the terms and conditions of the license between CMIC and such Third Party, and Dyax shall be responsible for the payment to such Third Party of any and all the fees, payments and royalties due under such license between CMIC and such Third Party as a result of the practice by Dyax and its Related Parties of such Third Party's so sublicensed intellectual property.
- (b) Termination by CMIC for Convenience. If CMIC terminates this Agreement in accordance with Section 12.2(a), then:
- (i) the provisions of Section 12.3(a)(i)(A)-(F) shall apply; and
  - (ii) CMIC shall grant to Dyax (x) an exclusive license, with the right to grant sublicenses, under the CMIC Development Data that relates solely to Product, to develop, manufacture and/or commercialize products containing Compound (or conduct the regulatory activities thereto) in and outside Field and throughout the world and (y) a non-exclusive license, with the right to grant sublicenses, under all the other CMIC Development Data, to develop, manufacture and/or commercialize products containing Compound (or conduct the regulatory activities thereto) in and outside Field and throughout the world. The licenses granted pursuant to this Section 12.3(b)(ii) shall be royalty-free, fully-paid and perpetual; provided that, if and to the extent that any such license includes any sublicense of Third Party's intellectual

property, then such sublicense shall be subject to such Third Party's consent and subject to the terms and conditions of the license between CMIC and such Third Party, and Dyax shall be responsible for the payment to such Third Party of any and all the fees, payments and royalties due under such license between CMIC and such Third Party as a result of the practice by Dyax and its Related Parties of such Third Party's so sublicensed intellectual property.

- (c) Termination by CMIC for Cause. Without limiting any other legal or equitable remedies that CMIC may have, if CMIC has the right to terminate this Agreement in accordance with Section 12.2(b), (c) or (d), then CMIC may, by notice to Dyax, elect to continue this Agreement or to terminate this Agreement, with the consequences set forth in either Section 12.3(c)(i) or Section 12.3(c)(ii), as applicable.
- (i) If CMIC elects to continue this Agreement: (A) effective as of the date when CMIC has obtained the right to terminate this Agreement, the payments payable by CMIC to Dyax pursuant to Section 7.5 hereof shall be reduced, as liquidated damages to be paid to CMIC by Dyax, and not as a penalty to be paid to CMIC by Dyax, to fifty percent (50%) of the amounts that otherwise would have been payable to Dyax by CMIC; and (B) all the other provisions of this Agreement shall remain in full force and effect without change.
- (ii) If CMIC elects to terminate this Agreement, as of the effective date of such termination, all the rights and obligations of the Parties under this Agreement shall terminate except as set forth in Section 12.4.

12.4 Survival. On the occasion of any expiration or termination of this Agreement, (a) all the financial obligations owed under Article VII as of the effective date of such expiration or termination shall remain in effect, (b) all the obligations to pay damages in connection with any material breach of this Agreement that has not been cured or otherwise resolved or settled as of the effective date of such expiration or termination shall remain in effect, and (c) the provisions set forth in Article XIII and in Sections 4.8(a), 4.8(b), 4.9, 5.5, 7.7, 7.8, 7.9, 7.10, 7.11, 7.12, 8.1, 9.1, 9.2, 9.3, 10.7, 11.1, 11.2, 11.3, 11.4, 12.3, 12.4, 14.1 and 14.13, and all other provisions contained in this Agreement that by their terms survive expiration or termination of this Agreement, shall survive such expiration or termination. In addition, if this Agreement is not terminated according to Section 12.2 but expires according to Section 12.1, the licenses granted in Sections 3.1, 3.2 and 8.8(c) shall survive as perpetual, fully paid-up, non-royalty-bearing licenses, and any exclusive license in such Sections shall convert to a non-exclusive license. The provisions set forth in Section 4.8 shall remain in effect as long as the Pharmacovigilance Agreement remains in effect or until the date the Pharmacovigilance Agreement otherwise provides for. The provisions set forth in Section 6.2 shall remain in effect as long as the Quality Agreement remains in effect or until the date the Quality Agreement otherwise provides for. The provisions set forth in Sections 6.1, 6.3, 6.4 and 6.6 shall remain in effect as long as the Supply Agreement remains in effect or until the date the Supply Agreement otherwise provides for.

### **ARTICLE XIII** **DISPUTE RESOLUTION**

13.1 Referral to Executive Officers. If for any reason the JSC cannot resolve any matter referred to it, either Party may refer such matter to Executive Officers for resolution. If after discussing such matter, or any other matter to be resolved pursuant to this Section 13.1 pursuant to this Agreement, in good faith and attempting to find a mutually satisfactory resolution to it, Executive Officers fail to come to consensus on it within thirty (30) Business Days after the date on which it is referred to Executive Officers, the provisions of Section 13.2 shall apply. The resolutions reached through the provisions of Section 13.1 or 13.2 shall be binding on the Parties.

13.2 Final Decision-Making Authority Allocated to a Single Party. If Executive Officers fail to come to consensus on any matter referred to them according to Section 13.1 (other than the matters referred to the JSC under Sections 3.4, 4.3 and 4.4) within the period for resolution set forth in Section 13.1, then:

- (a) on any matter solely relating to the Development, Regulatory Approval, packaging and labeling and Commercialization of Product in Field in CMIC Territory, CMIC shall have the final decision-making authority; provided that:
  - (i) with respect to any matter that Dyax reasonably concludes could adversely impact on any Regulatory Approval of Product outside of CMIC Territory (including the timing of such Regulatory Approval), Dyax shall have the final decision-making authority; and
  - (ii) with respect to any matter relating to any reformulation of Product, Dyax shall have the final decision-making authority;
- (b) on any matter solely relating to the Development, Regulatory Approval, Manufacturing, and Commercialization of Products in Field in Dyax Territory or outside Field in any country of the world, Dyax shall have the final decision-making authority;
- (c) on any matter that is reasonably likely to materially and adversely impact on the safety profile of Product in or outside Field (including matters relating to Product formulation and safety), Dyax shall have the final decision-making authority; and
- (d) notwithstanding the foregoing provisions of this Section 13.2, neither Party shall have the final decision-making authority pursuant to this Section 13.2 with respect to any matters (i) over which the other Party is expressly allocated the final decision-making authority elsewhere in this Agreement and (ii) for which this Agreement expressly provides that a decision shall not be made without the approval or consent of the other Party.

13.3 Arbitration. Any dispute arising out of or relating to this Agreement that is not finally resolved through the provisions of Section 13.1 or 13.2, including the interpretation of this Agreement and any breach or alleged breach of this Agreement, shall be resolved through binding arbitration as described below; provided that the specific matters for which this Agreement expressly provides that a decision shall not be made without the approval or consent of one or both of the Parties shall not be subject to resolution under this Section 13.3. Furthermore, the following procedures shall apply to all the arbitration proceedings pursuant to this Agreement:

- (a) A Party may submit such dispute to arbitration by notifying the other Party, in writing, to that effect. Within thirty (30) days after receipt of such notice by the other Party, the Parties shall designate in writing a single arbitrator to resolve the dispute; provided that, if the Parties cannot agree on such arbitrator within such thirty (30)-day period, the arbitrator shall be selected by the International Court of Arbitration of the International Chamber of Commerce ("ICC"). The arbitrator shall be a lawyer knowledgeable and experienced in the law concerning the subject matter of the dispute and a technical expert in the applicable field if the subject matter of the dispute involves a technical issue, and shall not be an employee, consultant, agent, officer, director or stockholder of either Party or its Related Parties.
- (b) Within thirty (30) days after the designation of the arbitrator, the arbitrator and the Parties shall meet, at which time the Parties shall be required to set forth in writing all the disputed issues and their proposed ruling on the merits of each such issue.
- (c) The arbitrator shall set a date for a hearing, which shall be no later than forty-five (45) days after the submission of written proposals pursuant to Section 13.3(b), to discuss each of the issues identified in such proposals by the Parties. The Parties may be accompanied or represented by counsel in the arbitration. Except as provided for herein, the arbitration shall be governed by the Arbitration Rules of the ICC applicable at the time of the notice of arbitration pursuant to Section 13.3(a); provided that the arbitration shall be conducted by a single arbitrator.
- (d) The arbitrator shall use his or her best efforts to rule on each disputed issue within thirty (30) days after the completion of the hearings described in Section 13.3(c). The determination of the arbitrator as to the resolution of any dispute shall be binding and conclusive upon both Parties. All the rulings of the arbitrator shall be in writing and shall be delivered to the Parties.

- (e) The (i) attorneys' fees of the Parties in the arbitration, (ii) fees of the arbitrator and (iii) costs and expenses of the arbitration shall be borne by the Parties as determined by the arbitrator.
- (f) Any arbitration pursuant to this Section 13.3 (including the meeting under (b) and the hearing under (c) of this Section 13.3) shall be conducted in English in Paris, France.
- (g) Nothing in this Section 13.3 shall be construed as limiting in any way the right of a Party to seek injunctive relief with respect to any actual or threatened breach of this Agreement from, or to bring an action in aid of arbitration in, a court in accordance with Section 14.1. Should any Party seek such injunctive relief, then for the purposes of determining whether to grant such injunctive relief, the dispute underlying the request for such injunctive relief may be heard by a court in accordance with Section 14.1.
- (h) The arbitrator shall not award the damages excluded pursuant to Section 11.4.
- (i) The Parties agree to continue performing under this Agreement in accordance with its provisions pending the final resolution of any dispute through the arbitration as provided for in this Section 13.3, and, without limiting the foregoing, shall continue to cooperate and participate in the committees provided for in this Agreement.

**ARTICLE XIV  
MISCELLANEOUS**

14.1 Choice of Law; Jurisdiction. This Agreement shall be governed by and interpreted under the laws of the Commonwealth of Massachusetts excluding: (a) its conflicts of laws principles; (b) the United Nations Conventions on Contracts for the International Sale of Goods; (c) the 1974 Convention on the Limitation Period in the International Sale of Goods; and (d) the Protocol amending such 1974 Convention, done at Vienna April 11, 1980. Subject to Section 13.3, each Party shall submit to the non-exclusive jurisdiction of the state and federal courts sitting in Boston, Massachusetts, United States with respect to any actions or proceedings (other than those described in Section 13.3) arising out of or relating to this Agreement. Each Party shall waive any defense of inconvenient forum to the maintenance of any action or proceeding so brought and shall waive any bond, surety or other security that might be required of the other Party with respect thereto. Each Party may serve a process on the other Party by sending or delivering a copy of the process to such other Party at the address and in the manner provided for in Section 14.2. Nothing in this Section 14.1, however, shall affect the right of any Party to serve a legal process in any other manner permitted by law.

14.2 Notices. Any notice or report required or permitted to be given or made under this Agreement by either Party to the other Party shall be in writing and shall be deemed to have been delivered: (a) upon personal delivery; or (b) ten (10) days after deposit in the mail by air or five (5) Business Days following deposit with a reputable courier; or (c) in the case of notices provided by facsimile (which notice shall be followed immediately by an additional notice pursuant to clause (a) or (b) above) upon completion of transmission to the addressee's facsimile numbers; such delivery to be made to the following addresses (or such other addresses or facsimile numbers as may be furnished in writing by either Party to the other Party as provided for in this Section 14.2):

If to Dyax:

Dyax Corp.  
300 Technology Square  
Cambridge, Massachusetts 02139  
U.S.A.  
Attention: Chief Executive Officer  
Facsimile No.: (617) 225-7708

With a copy to:

Dyax Corp.  
300 Technology Square  
Cambridge, Massachusetts 02139  
U.S.A.  
Attention: General Counsel  
Facsimile No.: (617) 252-9944

If to CMIC:

CMIC Co., Ltd.  
Kongo Bldg., 7-10-4 Nishigotanda, Shinagawa-ku  
Tokyo 141-0031  
Japan  
Attention: Head of Licensing  
Facsimile No.: +81-3-5745-7073

With a copy to:

CMIC Co., Ltd.  
Kongo Bldg., 7-10-4 Nishigotanda, Shinagawa-ku  
Tokyo 141-0031  
Japan  
Attention: Legal Counsel, New Business Development  
Facsimile No.: +81-3-5745-7073

14.3 Construction. This Agreement has been prepared jointly by both Parties and shall not be strictly construed against either Party. Any reference in this Agreement to an Article, Section, clause, Exhibit shall be deemed to be a reference to a Article, Section, clause, or Exhibit, of or to, this Agreement. Except where the context otherwise requires, (a) any definition of or reference to any agreement, instrument or other document refers to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein), (b) any reference to any laws refers to such laws as from time to time enacted, repealed or amended, (c) the word "here" in the words "herein," "hereof", "hereunder," and any other word "here" followed by such suffix refers to this Agreement in its entirety and not to any particular provision of this Agreement, and (d) the words "include," "includes" and "including" shall be deemed to be followed by the phrase "but not limited to," "without limitation" or other phrase of a similar meaning.

14.4 Severability. If, under the applicable law or regulation, any provision of this Agreement is invalid or unenforceable, or otherwise directly or indirectly affects the validity of any other material provision(s) of this Agreement (such invalid or unenforceable provision, a "Severed Clause"), it is mutually agreed that this Agreement shall endure except for Severed Clauses. Consulting one another, the Parties shall use their Commercially Reasonable Efforts to agree upon a valid and enforceable provision that is a reasonable substitute for a Severed Clause in view of the intent of this Agreement.

14.5 Captions. All the captions herein are for convenience only and shall not be interpreted as having any substantive meaning.

14.6 Integration. This Agreement (together with all Exhibits), constitutes the entire agreement between the Parties hereto with respect to the subject matter hereof and supersedes all previous agreements between the Parties, whether written or oral. This Agreement may be amended only in writing signed by the properly authorized representatives of each of both Parties.

14.7 Independent Contractors; No Agency. Neither Party shall have any responsibility for the employment, dismissal or compensation of the other Party's employees, officers and directors or for any employee benefits or other social-welfare systems for the other Party. No employee, officer, director or representative of a Party shall have any authority to bind or obligate the other Party for any sum or in any manner whatsoever, or to create or impose any contractual or other liability on the other Party without such other Party's written approval. For all purposes, and notwithstanding any provision of this Agreement to the contrary, either Party's legal relationship with the other Party under this Agreement shall be that of an independent contractor.

14.8 Assignment; Successors. Neither Dyax nor CMIC may assign this Agreement in whole or in part, any rights or obligations hereunder, without the prior written consent of the other Party; provided that:

- (a) either Party may assign this Agreement to its Affiliate for the period that the Affiliate remains an Affiliate of the assigning Party on the condition that the assigning Party shall remain

primarily liable for the prompt and punctual payment and performance of all such assigned obligations of the Affiliate;

- (b) this Agreement may be assigned by CMIC in connection with a sale or transfer of all or substantially all of CMIC's business or assets, to which this Agreement relates, to any Third Party who is not a Product Competitor;
- (c) this Agreement may be assigned by Dyax to a Third Party in connection with a sale or transfer of all or substantially all of Dyax's business or assets to which this Agreement relates.

This Agreement shall be binding upon, and shall inure to the benefit of, all the successors and assigns of this Agreement, provided that such succession or assignment is permitted hereunder.

14.9 Execution in Counterparts; Facsimile Signatures. This Agreement may be executed in counterparts, each of which counterparts, when executed and delivered, shall be deemed to be an original, and all of which counterparts, taken together, shall constitute one and the same instrument even if both Parties have not executed the same counterpart. Even though a copy of this Agreement is signed by a Party and transmitted by facsimile, such transmitted copy shall be deemed to be an original counterpart signed by the Party.

14.10 Waiver. The waiver by either Party hereto of any right hereunder, or of the failure of the other Party to perform this Agreement, or of a breach hereof by the other Party shall not be deemed a waiver by such Party of any other right hereunder or of any other breach or failure hereof by such other Party whether of a similar nature or otherwise.

14.11 Performance by Affiliates. To the extent that this Agreement imposes the obligations on Affiliates of a Party, the Party agrees to cause such Affiliates to perform the obligations. Either Party may use one or more of its Affiliates to perform its obligations and duties hereunder and the Affiliates of a Party are expressly granted certain rights herein; provided that each such Affiliate shall be bound by the corresponding obligations of such Party and the Parties shall remain liable hereunder for the prompt payment and performance of all their respective obligations hereunder.

14.12 Force Majeure. Neither Party shall be held liable to the other Party nor be deemed to have defaulted under or breached the Agreement for failure or delay in performing any obligation under this Agreement when such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party, which include embargoes, war, acts of war (whether declared or not), insurrections, riots, civil commotions, strikes, lockouts or other labor disturbances, fire, floods, or other acts of God, or acts, omissions or delays in acting by any governmental authority or the other Party. The affected Party shall notify the other Party of such force majeure circumstances as soon as reasonably practical, and shall promptly undertake all the reasonable efforts necessary to cure such force majeure circumstances.

14.13 Export Control. This Agreement is made subject to any restrictions on the export of products or technical information from the United States of America or other countries which might be imposed upon or related to Dyax or CMIC from time to time. Each Party agrees that it shall not export, directly or indirectly, any technical information acquired by it from the other Party under this Agreement or any products using such technical information to a location or in a manner that at the time of such export requires an export license or other governmental approval, without first obtaining the written consent to do so from the appropriate agency or other governmental entity.

14.14 Costs. Each Party shall bear its own legal costs of and incidental to the preparation, negotiation and execution of this Agreement.

IN WITNESS WHEREOF, Dyax and CMIC have caused this Agreement to be duly executed by their authorized representatives under seal, effective as of the Effective Date.

**DYAX CORP.**

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

Name: Gustav Christensen

Title: President and Chief Executive Officer

**CMIC CO. LTD.**

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

Name: Kazuo Nakamura, Ph.D.

Title: Chairman and CEO

EXHIBIT A

Amino Acid Sequence of DX-88

Position #	1	5	10	15
DX-88	Glu-Ala-Met-His-Ser-Phe-Cys-Ala-Phe-Lys-Ala-Asp-Asp-Gly-Pro-			
Position #	20	25	30	
DX-88	Cys Arg-Ala-Ala-His-Pro-Arg-Trp-Phe-Phe-Asn-Ile-Phe-Thr-Arg-			
Position #	35	40	45	
DX-88	Gln-Cys-Glu-Glu-Phe-Ile-Tyr-Gly-Gly-Cys-Glu-Gly-Asn-Gln-Asn-			
Position #	50	55	60	
DX-88	Arg-Phe-Glu-Ser-Leu-Glu-Glu-Cys-Lys-Lys-Met-Cys-Thr-Arg-Asp			

EXHIBIT B

Existing Dvax Patent Rights

DX-88								
MATTER		SERIAL	PATENT	PUBL	TITLE	STATUS	ISSUE	EXPIRATION
094003	US	11/323,261	7,276,480	20070249807	PREVENTION AND REDUCTION OF BLOOD LOSS	ISSUED	10/2 /2007	6 /6 /2023
094005	US	11/860,853			PREVENTION AND REDUCTION OF BLOOD LOSS	ABANDONED		7 /30/2009
094007	US	11/930,012		20090082267	PREVENTION AND REDUCTION OF BLOOD LOSS	ALLOWED		6 /6 /2023
094011	US	11/931,373		20080200646	PREVENTION AND REDUCTION OF BLOOD LOSS	PUBLISHED		6 /6 /2023
094AU1	AU	2003243394	2003243394		PREVENTION AND REDUCTION OF BLOOD LOSS	ISSUED	9 /25/2008	6 /6 /2023
094CA1	CA	2488558			PREVENTION AND REDUCTION OF BLOOD LOSS	PENDING		6 /6 /2023
094EP2	EP	07023364.8		EP1941867	PREVENTION AND REDUCTION OF BLOOD LOSS	PUBLISHED		6 /6 /2023
094HK2	HK	08114131.3		1119955	PREVENTION AND REDUCTION OF BLOOD LOSS	PUBLISHED		6 /6 /2023
094JP2	JP	2010-004265			PREVENTION AND REDUCTION OF BLOOD LOSS	PENDING		6 /6 /2023
096001	US	08/208,264	6,057,287		KALLIKREIN-BINDING "KUNITZ DOMAIN" PROTEINS AND ANALOGUES THEREOF	ISSUED	5 /2 /2000	8 /18/2015
096002	US	09/421,097	6,333,402		KALLIKREIN-BINDING "KUNITZ DOMAIN" PROTEINS AND ANALOGUES THEROF	ISSUED	12/25/2001	1 /11/2014
096003	US	10/016,329			KALLIKREIN-BINDING "KUNITZ DOMAIN" PROTEINS AND ANALOGUES THEREOF	ABANDONED		11/20/2006
096004	US	09/136,012	5,994,125		KALLIKREIN-INHIBITING "KUNITZ DOMAIN" PROTEINS AND ANALOGUES THEREOF	ISSUED	11/30/1999	1 /11/2014
096005	US	11/365,438	7,628,983	20060264603	KALLIKREIN-BINDING "KUNITZ DOMAIN" PROTEINS AND ANALOGUES THEREOF	ISSUED	12/8 /2009	2 /11/2015
096006	US	12/580,903			KALLIKREIN-BINDING "KUNITZ DOMAIN" PROTEINS AND ANALOGUES THEREOF	PENDING		1 /11/2014
096AT1	AT	95909223.0	E 275 583	EP0739355	KALLIKREIN-BINDING "KUNITZ DOMAIN" PROTEINS AND ANALOGUES THEREOF	ISSUED	9 /8 /2004	1 /11/2015
096BE1	BE	95909223.0	0739355	EP0739355	KALLIKREIN-BINDING	ISSUED	9 /8 /2004	1 /11/2015

CONFIDENTIAL DOCUMENT  
EXECUTION COPY

DX-88								
MATTER		SERIAL	PATENT	PUBL	TITLE	STATUS	ISSUE	EXPIRATION
					"KUNITZ DOMAIN" PROTEINS AND ANALOGUES THEREOF			
096CA1	CA	2180950	2180950		KALLIKREIN-INHIBITING "KUNITZ DOMAIN" PROTEINS AND ANALOGUES THEREOF	ISSUED	3 /29/2005	1 /11/2015
096CH1	CH	95909223.0	0739355	EP0739355	KALLIKREIN-BINDING "KUNITZ DOMAIN" PROTEINS AND ANALOGUES THEREOF	ISSUED	9 /8 /2004	1 /11/2015
096DE1	DE	95909223.0	EP0739355	EP0739355	KALLIKREIN-BINDING "KUNITZ DOMAIN" PROTEINS AND ANALOGUES THEREOF	ISSUED	9 /8 /2004	1 /11/2015
096DK1	DK	95909223.0	0739355	EP0739355	KALLIKREIN-BINDING "KUNITZ DOMAIN" PROTEINS AND ANALOGUES THEREOF	ISSUED	9 /8 /2004	1 /11/2015
096EP1	EP	95909223.0	0739355	EP0739355	KALLIKREIN-BINDING "KUNITZ DOMAIN" PROTEINS AND ANALOGUES THEREOF	ISSUED	9 /8 /2004	1 /11/2015
096EP2	EP	04019920.0		EP1484339	KALLIKREIN-BINDING "KUNITZ DOMAIN" PROTEINS AND ANALOGUES THEREOF	ABANDONED		11/8 /2008
096EP4	EP	10164197.5			KALLIKREIN-BINDING "KUNITZ DOMAIN" PROTEINS AND ANALOGUES THEREOF	PENDING		1 /11/2015
096ES1	ES	95909223.0	0739355	EP0739355	KALLIKREIN-BINDING "KUNITZ DOMAIN" PROTEINS AND ANALOGUES THEREOF	ISSUED	9 /8 /2004	1 /11/2015
096FR1	FR	95909223.0	0739355	EP0739355	KALLIKREIN-BINDING "KUNITZ DOMAIN" PROTEINS AND ANALOGUES THEREOF	ISSUED	9 /8 /2004	1 /11/2015
096GB1	GB	95909223.0	0739355	EP0739355	KALLIKREIN-BINDING "KUNITZ DOMAIN" PROTEINS AND ANALOGUES THEREOF	ISSUED	9 /8 /2004	1 /11/2015
096GR1	GR	95909223.0	0739355	EP0739355	KALLIKREIN-BINDING "KUNITZ DOMAIN" PROTEINS AND ANALOGUES THEREOF	ISSUED	9 /8 /2004	1 /11/2015
096HK2	HK	05104679.5		1071899A	KALLIKREIN-BINDING "KUNITZ DOMAIN" PROTEINS AND ANALOGUES THEREOF	PUBLISHED		1 /11/2015
096IE1	IE	95909223.0	0739355	EP0739355	KALLIKREIN-BINDING "KUNITZ DOMAIN" PROTEINS AND ANALOGUES THEREOF	ISSUED	9 /8 /2004	1 /11/2015
096IT1	IT	95909223.0	0739355	EP0739355	KALLIKREIN-BINDING "KUNITZ DOMAIN" PROTEINS AND ANALOGUES THEREOF	ISSUED	9 /8 /2004	1 /11/2015
096JP1	JP	7-518726	3805785	9511131	KALLIKREIN-BINDING "KUNITZ DOMAIN" PROTEINS AND	ISSUED	5 /19/2006	1 /11/2015

CONFIDENTIAL DOCUMENT  
EXECUTION COPY

DX-88								
MATTER		SERIAL	PATENT	PUBL	TITLE	STATUS	ISSUE	EXPIRATION
					ANALOGUES THEREOF			
096LT1	LT	95909223.0	0739355	EP0739355	KALLIKREIN-BINDING "KUNITZ DOMAIN" PROTEINS AND ANALOGUES THEREOF	ABANDONED	9 /8 /2004	1 /11/2015
096LU1	LU	95909223.0	0739355	EP0739355	KALLIKREIN-BINDING "KUNITZ DOMAIN" PROTEINS AND ANALOGUES THEREOF	ISSUED	9 /8 /2004	1 /11/2015
096MC1	MC	95909223.0	0739355	EP0739355	KALLIKREIN-BINDING "KUNITZ DOMAIN" PROTEINS AND ANALOGUES THEREOF	ISSUED	9 /8 /2004	1 /11/2015
096NL1	NL	95909223.0	0739355	EP0739355	KALLIKREIN-BINDING "KUNITZ DOMAIN" PROTEINS AND ANALOGUES THEREOF	ISSUED	9 /8 /2004	1 /11/2015
096PT1	PT	95909223.0	0739355	EP0739355	KALLIKREIN-BINDING "KUNITZ DOMAIN" PROTEINS AND ANALOGUES THEREOF	ISSUED	9 /8 /2004	1 /11/2015
096SE1	SE	95909223.0	0739355	EP0739355	KALLIKREIN-BINDING "KUNITZ DOMAIN" PROTEINS AND ANALOGUES THEREOF	ISSUED	9 /8 /2004	1 /11/2015
096US1	US	08/676,125	5,795,865		KALLIKREIN-INHIBITING "KUNITZ DOMAIN" PROTEINS AND ANALOGUES THEREOF	ISSUED	8 /18/1998	8 /18/2015
096WO1	WO	PCT/US95/00299		WO9521601	KALLIKREIN-BINDING "KUNITZ DOMAIN" PROTEINS AND ANALOGUES THEREOF	NAT PHASE		
143001	US	11/716,278		20070213275	FORMULATIONS FOR ECALLANTIDE	PUBLISHED		3 /10/2026
143AU1	AU	2007226698			FORMULATIONS FOR ECALLANTIDE	PENDING		3 /9 /2027
143CA1	CA	2643693		CA2643693	FORMULATIONS FOR ECALLANTIDE	PUBLISHED		3 /9 /2027
143EP1	EP	07758271.6		EP2001500	FORMULATIONS FOR ECALLANTIDE	PUBLISHED		3 /9 /2027
143HK1	HK	09100264.0		1119964	FORMULATIONS FOR ECALLANTIDE	PUBLISHED		3 /9 /2027
143IN1	IN	PCT/US07/63703		7659/DELNP/2008	FORMULATIONS FOR ECALLANTIDE	PUBLISHED		3 /9 /2027
143JP1	JP	2008-558556		2009529542	FORMULATIONS FOR ECALLANTIDE	PUBLISHED		3 /9 /2027
143P01	US	60/781,444			FORMULATIONS FOR ECALLANTIDE (Large Entity)	EXPIRED		3 /10/2007
143WO1	WO	PCT/US07/063703		WO07106746	FORMULATIONS FOR ECALLANTIDE	NAT PHASE		