EX-10.5 8 a2236778zex-10\_5.htm EX-10.5

**Exhibit 10.5**

**ELANCO UK AH LIMITED**

**AND**

**ELI LILLY EXPORT S.A.**

**TOLL MANUFACTURING AND SUPPLY  
AGREEMENT**

**Dated as of September 24, 2018**

**TABLE OF CONTENTS**

|  |  |  |
| --- | --- | --- |
| **ARTICLE** |  | **PAGE** |
|  |  |  |
| ARTICLE I Definitions | | 1 |
| 1.01 | Definitions | 1 |
|  | |  |
| ARTICLE II General Terms of Supply | | 7 |
| 2.01 | Agreement to Manufacture Product | 7 |
| 2.02 | Manufacture of Product | 7 |
| 2.03 | Key Personnel | 8 |
| 2.04 | Technical Transfer Services | 9 |
| 2.05 | Forecasting and Yield | 9 |
| 2.06 | Orders | 10 |
| 2.07 | Delivery | 11 |
| 2.08 | Title and Risk | 12 |
| 2.09 | Acceptance and Rejection of Product | 12 |
| 2.10 | Use of Intellectual Property | 12 |
| 2.11 | Disaster Recovery and Business Continuity Plan | 13 |
|  | |  |
| ARTICLE III Joint Manufacturing Committee | | 13 |
| 3.01 | Joint Manufacturing Committee | 13 |
|  | |  |
| ARTICLE IV Tolling Fee | | 13 |
| 4.01 | Tolling Fee | 13 |
|  | |  |
| ARTICLE V Payment | | 15 |
| 5.01 | Product Payments | 15 |
| 5.02 | Exit Payments | 15 |
| 5.03 | Payment Guidelines | 15 |
|  | |  |
| ARTICLE VI Quality Control | | 16 |
| 6.01 | Quality Control | 16 |
| 6.02 | Product Recall | 16 |
| 6.03 | Complaints and Returns | 16 |
| 6.04 | Regulatory Responsibility | 16 |
| 6.05 | Stability Testing | 16 |
|  | |  |
| ARTICLE VII Books and Records; Audits and Inspections | | 17 |

i

|  |  |  |
| --- | --- | --- |
| 7.01 | Books and Records | 17 |
| 7.02 | Quality Audits | 17 |
| 7.03 | Financial Audits | 17 |
| 7.04 | Regulatory Inspections | 18 |
|  | |  |
| ARTICLE VIII Representations and Warranties | | 18 |
| 8.01 | Representations and Warranties | 18 |
| 8.02 | Supplier’s Representations, Warranties and Covenants | 18 |
| 8.03 | No Further Representations or Warranties | 19 |
| ARTICLE IX Indemnification; Limitation of Liability; Conduct of Third Party Claims | | 19 |
| 9.01 | Indemnification | 19 |
| 9.02 | Limitation of Liability | 20 |
| 9.03 | Conduct of Third Party Claims | 21 |
| 9.04 | Insurance | 22 |
|  | |  |
| ARTICLE X Term | | 22 |
| 10.01 | Term and Termination | 22 |
|  | |  |
| ARTICLE XI Confidentiality | | 23 |
| 11.01 | Confidentiality | 23 |
|  | |  |
| ARTICLE XII Further Assurances | | 24 |
| 12.01 | Further Assurances | 24 |
|  | |  |
| ARTICLE XIII Miscellaneous Provisions | | 24 |
| 13.01 | Counterparts; Entire Agreement; Conflicting Agreements | 24 |
| 13.02 | No Construction Against Drafter | 25 |
| 13.03 | Governing Law | 25 |
| 13.04 | Assignment | 25 |
| 13.05 | No Third-Party Beneficiaries | 25 |
| 13.06 | Notices | 26 |
| 13.07 | Severability | 26 |
| 13.08 | Force Majeure | 27 |
| 13.09 | Headings | 27 |
| 13.10 | Waivers of Default | 27 |
| 13.11 | Specific Performance | 27 |
| 13.12 | Amendments | 27 |
| 13.13 | Interpretation | 28 |

ii

|  |  |  |
| --- | --- | --- |
| 13.14 | Waiver of Jury Trial | 28 |
| 13.15 | Submission to Jurisdiction; Waivers | 28 |

iii

**TOLL MANUFACTURING AND SUPPLY AGREEMENT**

**THIS TOLL MANUFACTURING AND SUPPLY AGREEMENT** (this “***Agreement***”), dated as of September 24, 2018 (the “***Effective Date***”), is entered into by and between Elanco UK AH Limited, a corporation organized under the laws of the United Kingdom (the “***Supplier***”), and Eli Lilly Export S.A., a company organized under the laws of Switzerland (the “***Purchaser***”) (Supplier and Purchaser hereinafter referred to individually as a “***Party***” or collectively as the “***Parties***”).

**RECITALS**

**WHEREAS**, Eli Lilly and Company Limited (“***Historical Supplier***”), an Affiliate of Eli Lilly and Company (“***Lilly***”) historically manufactured Product at the Facility for delivery to Purchaser;

**WHEREAS**, pursuant to that certain Master Separation Agreement by and between Lilly and Elanco Animal Health Incorporated (“***Elanco***”), dated on or about the date hereof (the “***Separation Agreement***”), and the Ancillary Agreements, Lilly has transferred the Animal Health Business to Elanco in contemplation of the Separation and IPO;

**WHEREAS**, the transactions contemplated by the Separation Agreement include (i) the transfer to Elanco of the assets previously used by Historical Supplier to manufacture Product and (ii) control of the Facility; and

**WHEREAS**, Supplier, an Affiliate of Elanco, has agreed to continue to provide certain manufacturing services to Purchaser, an Affiliate of Lilly, with respect to Product at the Facility until the manufacture and Delivery of Product for and to Purchaser has been successfully transferred to a New Product Supplier in accordance with the terms of this Agreement.

**NOW, THEREFORE**, the Parties agree as follows:

**ARTICLE I**

**DEFINITIONS**

**1.01**                        **Definitions**

Capitalized terms used herein and not otherwise defined herein shall have the meanings ascribed to such terms in the Separation Agreement.  In this Agreement, the following words and expressions shall have the following meanings:

“***Affiliate***” of any Person means a Person that controls, is controlled by, or is under common control with such Person. As used in this definition, “***control***” means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of such entity, or the power to appoint and remove a majority of the directors, managers or persons holding similar power in respect of such entity, whether through ownership of voting securities or other interests, by contract or otherwise. It is expressly agreed that, from and after the Effective Date, solely for purposes of this Agreement, (i) no member of the Purchaser’s Group shall be deemed to be an Affiliate of any member of the Supplier’s Group and (ii) no member of the Supplier’s Group shall be deemed to be an Affiliate of any member of the Purchaser’s Group.

1

“***Agreement***” has the meaning set forth in the Preamble.

“***Annual Total Tolling Fee Margin***” means the planned annual total U.S. Dollar amount of the Tolling Fee Margin, as mutually agreed upon by the Parties.

“***Batch***” means a specific quantity of manufactured material processed either in one (1) process or a series of processes so that it is expected to be homogenous.

“***Binding Order***” has the meaning set forth in Section 2.05(c).

“***Binding Period***” means a period of six (6) months, beginning on the first day covered by the applicable Forecast.

“***Business Day***” means any day other than a Saturday, Sunday or a day on which banking institutions are authorized or obligated by Law to be closed in New York, New York.

“***Certificate of Analysis***” means a document identifying the results of the methods of analysis for a specific Batch of Product in the form agreed by the Parties.

“***cGMP***” means, to the extent applicable to the manufacture of Product, the then-current good manufacturing practices as set forth in applicable Laws relating to the manufacture of Product.

“***Claim***” means any demand, action, claim, dispute, suit, countersuit, arbitration, inquiry, proceeding or investigation by or before any Governmental Authority.

“***Claiming Party***” has the meaning set forth in Section 9.02(f).

“***Compliance Requirements***” means applicable Law, the Marketing Authorizations, the terms of the Quality Agreement, the instructions and requirements set forth in the MRD, the specifications for the Product (as provided in writing by Purchaser to Supplier), the Purchaser’s Global Quality Standards, the Purchaser’s Global Ethics and Compliance Policies and cGMP, each as may be amended or replaced from time to time.

“***Confidential Information***” means, with respect to a Party, all confidential and proprietary information of such Party, its Affiliates and its or their Representatives that is provided to the other Party, its Affiliates or its or their Representatives pursuant to this Agreement; provided that Confidential Information shall not include information that (i) is or becomes part of the public domain through no breach of this Agreement by the recipient Party or its Affiliates or its or their respective Representatives, (ii) was independently developed following the Effective Date by employees or agents of the recipient Party, its Affiliates or its or their respective Representatives who have not accessed or otherwise received the applicable information; provided that such independent development can be demonstrated by competent, contemporaneous written records of the recipient Party or any of its Affiliates or (iii) becomes available to the recipient Party or any of its Affiliates following the Effective Date on a non-confidential basis from a Third Party who is not known by such Person to be bound directly or indirectly by a confidentiality

2

agreement or other contractual, legal or fiduciary obligation of confidentiality to the disclosing Party of any of its Affiliates.

“***Currency***” means the lawful currency of the United States of America, or U.S.D., U.S. Dollar or $.

“***Currency Conversion Rate***” means the relevant exchange rate between the relevant currency of origin and U.S. Dollars as reported by *The Wall Street Journal (New York Edition)* on the date of the relevant invoice.

“***Default Interest***” means interest at a rate per annum equal to the Prime Rate plus five percent (5%).

“***Delivery***” means a delivery to Purchaser or its designated carrier of a Batch of Product by Supplier under Section 2.07 in accordance with the Shipping Terms, and “***Deliver***” and “***Delivered***” have corresponding meanings.

“***Effective Date***” has the meaning set forth in the Preamble.

***“Elanco”***has the meaning set forth in the Recitals.

“***Estimated Delivery Schedule***” is defined in Section 2.05(b).

“***Exit Expenses***” means any costs and expenses as they are incurred in connection with (i) the return or destruction of, or reimbursement for, unused Granules, raw materials, resins or intermediates, (ii) the decommissioning process and (iii) Facility employee termination costs.

“***Facility***” means the animal health manufacturing plant located at Speke Operations, Fleming Road, Speke, Liverpool, United Kingdom, L24 9LN.

“***For Cause Audit***” means an audit in the case of an emergency (such as material Product defects or regulatory actions) or material non-compliance with any of the Compliance Requirements.

“***Forecast***” has the meaning set forth in Section 2.05(a).

“***Governmental Authority***” means any U.S. federal, state or local or any supra-national or non-U.S. government, political subdivision, governmental, regulatory or administrative authority, instrumentality, agency, body or commission, self-regulatory organization or any court, tribunal, or judicial or arbitral body.

“***Granules***” means the starting granules fermented and developed by Lilly at its Puerto Rico facility (PR05) that are necessary to manufacture the Product.

***“Group”***means the Purchaser’s Group or the Supplier’s Group, as the context requires.

***“Historical Supplier”*** has the meaning set forth in the Recitals.

“***Improvements***” means improvements, developments, modifications and enhancements.

“***Intellectual Property***” means all rights, title and interest in or relating to intellectual property, whether protected, created or arising under the laws of the United States or any other foreign jurisdiction, including all: (a)(i) patent applications (along with all patents issuing thereon) and issued patents, invention disclosures, certificates of invention and statutory invention registrations; (ii) reissues, renewals, extensions, substitutions, continuations, continuations-in-part, and divisions, all results of oppositions, reexaminations, supplemental examinations,

3

supplementary protection certificates, and other review procedures (including ex parte reexamination, inter partes review, and post grant review) with respect to (i), and (iii) rights to claim priority with respect to (i) and (ii); (b) Know-How; (c) trademarks, service marks, names, corporate names, trade names, certification marks, service names, brand names, brand marks, trade dress rights, trade styles, slogans, identifying symbols, logos, emblems, monograms and signs or insignia, and other similar designations of source or origin and all applications and registrations therefor and all reissues, extensions and renewals of any of the foregoing, together with the goodwill symbolized by any of the foregoing; (d) Internet domain names; (e) works of authorship, copyrights, database and design rights, whether or not registered, published or unpublished, and registrations and applications therefor along with all reversions, renewals and extensions thereof; (f) software, data and databases and (g)(i) all rights in and to all income, royalties, damages and payments previously, now or hereafter due or payable, (ii) all Claims, causes of action, rights of recovery and rights of set-off of any kind against any Person, and (iii) the right to recover for past, present and future infringement against any Person, in each case of (i) to (iii) with respect to the foregoing (a) through (f).

“***JMC***” has the meaning set forth in Section 3.01.

“***Know-How***” means all existing and available technical information, know-how and data, including inventions (whether patentable or not), patent disclosures, discoveries, trade secrets, specifications, instructions, processes and formulae, including all biological, chemical, pharmacological, biochemical, toxicological, pharmaceutical, physical, safety, quality control, preclinical and clinical data (which includes anonymized data as it relates to individuals).

“***Law***” means any United States or non-United States federal, national, international, multinational, supranational, state, provincial, local or similar law (including common law and privacy and data protection laws), statute, ordinance, regulation, rule, code, order, treaty (including any income tax treaty), license, permit, authorization, registration, approval, consent, decree, injunction, judgment, notice of liability, request for information, binding judicial or administrative interpretation or other requirement or rule of law or legal process, in each case, enacted, promulgated, issued, entered or otherwise put into effect by a Governmental Authority or any rule or requirement of any national securities exchange.

***“Lilly”*** has the meaning set forth in the Recitals.

“***Local Value Added***” means all direct costs, and an allocable portion of indirect costs, incurred by Supplier pursuant to the fulfillment of Supplier’s obligations under this Agreement.

“***Losses***” means any and all damages, losses, deficiencies, Liabilities, penalties, judgments, settlements, payments, fines, charges, interest, costs and expenses, whether or not resulting from Third Party Claims, including the costs and expenses of any and all Claims and demands, assessments, judgments, settlements and compromises relating thereto and the costs and expenses of attorneys’, accountants’, consultants’ and other professionals’ fees and expenses incurred in the investigation or defense thereof or the enforcement of rights hereunder.

“***Marketing Authorizations***” means marketing authorizations issued, or applications for marketing authorizations, with respect to the Product and all supplements, amendments and revisions thereto.

4

“***Measure***” means any quarantine, stop-sale, field alert, withdrawal or recall concerning any Product Delivered by Supplier under this Agreement.

“***MRD***” means the mutually agreed Manufacturing Responsibilities Document to be entered into by the Parties within thirty (30) calendar days after the Effective Date that sets forth written instructions regarding the manufacture of the Product and other technical matters including testing procedures and Delivery of the Product under this Agreement.

“***New Product Supplier***” means a third party manufacturer designated by Purchaser to manufacture Product.

“***Order***” means an order for Product submitted through a Purchase Order.

“***Parties***” has the meaning set forth in the Preamble.

“***Party***” has the meaning set forth in the Preamble.

“***Person***” means an individual, a general or limited partnership, a corporation, a trust, a joint venture, an unincorporated organization, a limited liability entity, any other entity and any Governmental Authority.

“***Preamble***” means the preamble to this Agreement.

“***Prime Rate***” means the rate last quoted as of the time of determination by *The Wall Street Journal*as the “Prime Rate” in the United States or, if *The Wall Street Journal* ceases to quote such rate, the highest per annum interest rate published by the Federal Reserve Board in Federal Reserve Statistical Release H.15 (519) (Selected Interest Rates) as the “bank prime loan” rate as of such time, or, if such rate is no longer quoted therein, any similar rate quoted therein (as determined by Purchaser) or any similar release by the Federal Reserve Board (as determined by Purchaser).

“***Product***” means Humatrope drug substance.

“***Purchase Order***” means a purchase order for Product given by Purchaser under Section 2.06 to Supplier.

“***Purchaser***” has the meaning set forth in the Preamble.

“***Purchaser’s Global Ethics and Compliance Policies***” means the Global Policy on Compliance and Global Policy on Ethical Interactions with External Parties disseminated within the Purchaser’s Group’s organization detailing required compliance and ethics behavior.

“***Purchaser’s Global Quality Standards***” means requirements developed and disseminated within the Purchaser’s Group’s organization for the design, execution, and monitoring of product quality.

“***Purchaser’s Group***” means Purchaser and its current and future Affiliates (but excludes any member of Supplier’s Group).

5

“***Quality Agreement***” means the mutually agreed Quality Agreement to be entered into by the Parties within thirty (30) calendar days after the Effective Date.

“***Recitals***” means the recitals to this Agreement.

“***Representatives***” means, when used with respect to any Person, such Person’s directors, officers, employees, agents, accountants, attorneys, consultants and other advisors and representatives.

“***Separation Agreement***” has the meaning set forth in the Recitals.

“***Shipping Terms***” means “Ex Works” (as defined in Incoterms 2010).

“***Specified Delivery Date***” has the meaning set forth in Section 2.06(b)(ii).

“***Starting Material Reimbursement Price***” means a U.S. Dollar amount per gram of Granules that is mutually agreed upon by the Parties.

“***Supplier***” has the meaning set forth in the Preamble.

“***Supplier’s Bank Account***” means the bank account information provided by Supplier to Purchaser within thirty (30) calendar days after the Effective Date.

“***Supplier’s Group***” means Supplier and its current and future Affiliates (but excludes any member of Purchaser’s Group).

“***Surviving Provisions***” means Article I, Section 2.10(c), Section 2.10(d), Article V, Article VI, Section 7.01, Section 8.01, Section 10.01(d), Section 10.01(e), Article IX, Article XI, Article XII, and Article XIII.

“***Technical Transfer Services***” means services to support the transfer of manufacturing and Delivery of Product from Supplier to the New Product Supplier including transfer of technical documentation, specifications and procedures.

“***Term***” has the meaning set forth in Section 10.01.

“***Territory***” means worldwide.

“***Third Party Claim***” has the meaning set forth in Section 9.03.

“***Tolling Fee***” means the consideration per gram of Product due to Supplier for the manufacture of Product at the Facility and Delivery thereof to Purchaser, as mutually agreed upon by the Parties.

“***Tolling Fee Margin***” has the meaning set forth in Section 4.01(c).

6

**ARTICLE II**

**GENERAL TERMS OF SUPPLY**

**2.01**                        **Agreement to Manufacture Product**

**(a)**                                 Subject to and in accordance with the terms and conditions of this Agreement, during the Term, Supplier shall manufacture the Product at the Facility for Delivery exclusively to Purchaser or its designated Affiliates.  During the Term, Supplier shall not (and shall cause its Affiliates not to) develop, assist in the development of, manufacture, assist in the manufacture of, Deliver, supply, distribute or sell Product for or to any Person (including Supplier or its Affiliates) other than Purchaser or its designated Affiliates.

**(b)**                                 Subject to Section 2.04, Supplier shall manufacture the Product at the Facility in the physical form that Product was manufactured by Supplier for Purchaser immediately prior to the Effective Date, unless otherwise agreed in writing by the Parties.

**(c)**                                  Supplier may not sub-contract all or any part of the manufacture or Delivery of the Product or any of its rights or obligations under this Agreement to any Person (including to any Affiliates) without Purchaser’s prior written consent (such consent to be granted or withheld in Purchaser’s sole discretion); provided, however, that Supplier may sub-contract all or any part of Delivery of the Product to any sub-contractors used by Historical Supplier in the delivery of the Product to Purchaser in the twelve (12) months immediately preceding the Effective Date.

**(d)**                                 Purchaser and its Affiliates shall have the right to use, sell, distribute or otherwise exploit the Product for any purpose in the Territory.

**2.02**                        **Manufacture of Product**

**(a)**                                 Supplier shall manufacture the Product at the Facility and shall Deliver the Product to Purchaser in accordance with the Compliance Requirements (including the Anti-Bribery Commitments for Lilly Procurement Contracts, as revised by Purchaser or its Affiliate from time to time and published at https://www.lilly.com/suppliers/new-and-existing-suppliers/supplier-notifications or otherwise made available to Supplier).  Supplier shall also obtain and maintain in force during the Term all licenses, permissions, authorizations, consents and permits needed to manufacture and Deliver the Product in accordance with the terms of this Agreement.

**(b)**                                 Supplier shall be responsible for procuring all materials (including raw materials and the ordering of Granules as set forth in Section 2.05(e)) used in the manufacture of Product at the Facility and shall be the importer of record for any such materials.  Except as otherwise set forth herein, Supplier shall bear all costs and expenses associated with or resulting from such manufacture and Delivery of Product to Purchaser (including procurement of all necessary materials other than the Granules).

7

**(c)**                                  Supplier may not make any changes (including technical, manual or analytical changes) to the Product or the manufacturing or Delivery process of Product (as such processes existed immediately prior to the Effective Date) without Purchaser’s prior written consent (such consent to be granted or withheld in Purchaser’s sole discretion) unless any such change: (i) is required under the Compliance Requirements (including applicable Law); or (ii) is the result of a non-discriminatory, universal change with respect to the Facility or the Animal Health Business that does not affect the manufacture or Delivery of the Product (including its production or quality).  Except as otherwise set forth herein, Supplier shall bear all costs and expenses associated with or resulting from any such change.

**(d)**                                 The cost and expenses of consumables required to maintain compliance with the Compliance Requirements shall be borne by Supplier.

**(e)**                                  Any capital expenditure required to maintain compliance with the Compliance Requirements shall be borne by Supplier if such capital expenditure relates to manufacturing of products other than or in addition to the Product or the amount of such capital expenditure is below a U.S. Dollar amount that the Parties mutually agree in writing is a *de minimis* expense.  If such capital expenditure relates exclusively to the manufacturing of the Product and the amount of capital expenditure is greater than such agreed *de minimis* amount, the Parties will engage in a good faith discussion as to which Party should bear such amount of capital expenditure prior to the payment of any such capital expenditure.

**2.03**                        **Key Personnel**

**(a)**                                 During the Term, Supplier shall not, without Purchaser’s prior written consent, alter the assignment of any senior technical employee or contractor who has historical and technical knowledge of the manufacturing process of the Product at the Facility and, as of the Effective Date, is employed or contracted at the Facility.  In addition, at all times during the Term, Supplier shall employ or contract at least one (1) employee or contractor that has technical knowledge of the manufacturing process of the Product at the Facility to ensure the successful manufacture and Delivery of Product to Purchaser in accordance with the terms of this Agreement.

**(b)**                                 The Parties shall discuss in good faith any retention strategy (including the offer of a retention package) to be offered to any employee or contractor of Supplier to the extent such strategy, in Supplier’s good faith belief, is required in connection with Supplier’s obligations under Section 2.03(a).  Such good faith discussion will take place prior to the implementation of any such strategy and will include a discussion as to which Party shall bear the costs and expenses of offering and implementing any such strategy.

**(c)**                                  Upon Purchaser’s reasonable prior notice, Supplier shall allow up to two (2) Representatives of Purchaser to have access to the Facility at any given time during the Term solely for purposes related to the manufacture and Delivery of the Product; provided, however, that such access shall be limited to normal working hours at the Facility.

8

**2.04**                        **Technical Transfer Services**

**(a)**                                 Subject to Section 2.04(b), from time to time during the Term Supplier shall (or shall procure that any of its Affiliates shall), if requested by Purchaser, provide Technical Transfer Services to the New Product Supplier.  If so requested, Supplier (or its Affiliate) and Purchaser shall, and Purchaser shall cause the New Product Supplier to, meet to discuss and agree on a plan that sets out the respective obligations of the Parties and the New Product Supplier in relation to those Technical Transfer Services.  The Parties shall (and shall cause each of their Affiliates to and in the case of Purchaser, the New Product Supplier to) act reasonably when working together to produce a plan in relation to any Technical Transfer Services under this Section 2.04(a).

**(b)**                                 If the New Product Supplier receives more than two hundred (200) hours in aggregate of Technical Transfer Services from Supplier or its Affiliates in respect of the Product, Purchaser shall reimburse Supplier for any direct out-of-pocket costs and expenses incurred by Supplier or its Affiliates in the provision of any such Technical Transfer Services in excess of that two hundred (200) hour threshold, together with a margin of 10 percent (10%).

**2.05**                        **Forecasting and Yield**

**(a)**                                 Beginning on October 1, 2018 and on the first (1st) day of each calendar quarter thereafter during the Term, Purchaser shall give Supplier a written, rolling forecast of the amount of Product (in grams) it will purchase during the Term (each such forecast, a “***Forecast***”).  Each such Forecast shall break down the quantity (in grams) Purchaser expects to be Delivered each month.  Purchaser shall act in good faith when forecasting its requirements for Product.

**(b)**                                 Within thirty (30) calendar days of Supplier’s receipt of each Forecast, the Parties shall discuss in good faith the amount (in grams) of Product to be Delivered during each month of the Binding Period and agree on the same (the “***Estimated Delivery Schedule***”).

**(c)**                                  The amount of Product included in a Forecast for the Binding Period shall be deemed to be binding upon the Parties, committing the Purchaser to purchase and the Supplier to sell such amount of Product, as broken down per month in the relevant Forecast, and Purchaser shall issue a Purchase Order for that Binding Period accordingly (each such Purchase Order, a “***Binding Order***”).

**(d)**                                 Any change to a Binding Order or the Estimated Delivery Schedule may only be made with the written consent of both Parties.  This consent shall not be unreasonably withheld by either Party.

**(e)**                                  Based on Purchaser’s Forecasts, Supplier may, in good faith, order reasonably sufficient amounts of materials (including the Granules in accordance with Section 2.05(f)) used in the manufacture of the Product to fulfill Purchaser’s requirements for Product during the applicable Binding Period.  Purchaser shall bear the good faith costs and expenses incurred or committed with respect to any of these materials to the extent they are not,

9

or cannot be, used due to a change in Purchaser’s Forecasts, or any change in the Compliance Requirements or industry requirements.

**(f)**                                   Subject to and in accordance with the terms and conditions of this Agreement, Purchaser shall deliver (or procure the delivery of) the Granules to Supplier in accordance with Supplier’s orders for such Granules, free of charge, solely for use in Supplier’s manufacture of Product pursuant to this Agreement.  All Granules delivered under this Agreement by Purchaser shall be shipped on the basis of the Shipping Terms.  Delivery of the Granules shall be completed on delivery of such Granules in accordance with the Shipping Terms and receipt thereof by Supplier.  Except as otherwise set forth herein, Purchaser shall bear all costs and expenses associated with or resulting from delivery of the Granules to Supplier; provided, however, that (subject to Section 9.02) Supplier shall bear all costs and expenses associated with or resulting from the loss or impairment of the Granules once such Granules have been delivered to Supplier in accordance with this Section 2.05(f) (including reimbursement of any costs and expenses borne by Purchaser to replace such lost or impaired Granules).

**(g)**                                 For each one-thousand (1,000) grams of Granules that Purchaser delivers to Supplier in accordance with Section 2.05(f), Supplier shall manufacture one hundred fifty (150) grams of Product and if Supplier is not in good faith able to do so, it shall reimburse Purchaser for the cost and expense of manufacturing any additional Granules required for Supplier to achieve the above-referenced yield in this Section 2.05(g).

**2.06**                        **Orders**

**(a)**                                 Purchase orders that were placed with Supplier by or on behalf of Purchaser or its Affiliates before the Effective Date and are unfulfilled as at the Effective Date shall be fulfilled in accordance with the terms of the Transitional Services Agreement.

**(b)**                                 Each Purchase Order shall:

(i)             be consistent with the quantities of Product set out in the then current Estimated Delivery Schedule and set forth such quantities in grams; and

(ii)          specify the date on which Delivery of the Order is required (the “***Specified Delivery Date***”).

**(c)**                                  By the first (1st) day of each calendar quarter, Purchaser shall issue a Purchase Order to Supplier for the amount of Product falling within the Binding Period of the most recent Estimated Delivery Schedule, for which a Purchase Order has not yet been issued under Section 2.05(c).

**(d)**                                 Purchaser shall assign an Order number to each Order it submits and notify Supplier of such Order number.  Supplier and Purchaser shall use the relevant Order number in all subsequent correspondence relating to the Order.

10

**2.07**                        **Delivery**

**(a)**                                 Subject to this Section 2.07, Supplier shall Deliver the Product by the Specified Delivery Date in accordance with each Purchase Order and shall bear all costs and expenses related to such Delivery.  Unless otherwise agreed, Deliveries of Product shall be made by forwarders used by Historical Supplier within the twelve (12) months immediately preceding the Effective Date, provided that Purchaser or Supplier may request the replacement of a forwarder (*e.g.*, for reasonable quality reasons) in which case the Parties shall discuss and agree in good faith on a solution acceptable for both Parties. All transport packaging and preparation for Delivery will be done in accordance with the standards used at the Facility immediately prior to the Effective Date, the Compliance Requirements and applicable good storage and good distribution practices, including the use of data loggers, packaging dimensions and transport protection.  Any change thereof shall be deemed a change to be handled and reimbursed in accordance with Section 2.02(c).

**(b)**                                 If Supplier or Purchaser becomes aware of any unexpected problem that may require the Specified Delivery Date to be rescheduled, it shall promptly inform the other Party and submit a commercially reasonable proposal for a new delivery date.  Supplier and Purchaser shall cooperate to agree upon such new delivery date in good faith.  If Supplier is unable to fulfill the applicable Purchase Order within three (3) months after the Specified Delivery Date or another mutually agreed delivery date, as applicable, Purchaser may, in its sole discretion, without incurring any cost, expense, or penalty, cancel such Purchase Order.

**(c)**                                  All Product Delivered under this Agreement by Supplier shall be shipped on the basis of the Shipping Terms and Delivery of Product shall be completed upon delivery of the Product in accordance with the Shipping Terms.

**(d)**                                 Supplier shall have no liability for any failure or delay in Delivering an Order to the extent that the failure or delay is caused by Purchaser’s failure to deliver Granules in accordance with Section 2.05(g).

**(e)**                                  Each delivery of an Order shall be accompanied by a delivery note from Supplier showing the Order number, the date of the Order and the quantity of Product (in grams) included in the Order.

**(f)**                                   If, in respect of an Order, Supplier Delivers up to and including 10 percent (10%) more or less than the quantity of the Product set forth in that Order:

(i)             Purchaser shall not be entitled to reject the Order, but a pro rata adjustment shall be made to the amount of the Order invoice; and

(ii)          the Delivery shall be deemed to be a complete fulfillment of the Order, and no amount of Product shall be considered outstanding from the Order.

11

**2.08**                        **Title and Risk**

Purchaser shall own all right, title and interest in, to and under the Granules, and does not grant to Supplier under this Agreement any right in, to or under such Granules except as expressly set forth in Section 2.05(f).

**2.09**                        **Acceptance and Rejection of Product**

**(a)**                                 The Product Delivered by Supplier under this Agreement shall be accompanied by a Certificate of Analysis.

**(b)**                                 Purchaser shall notify Supplier within thirty (30) Business Days from the date of Delivery of each Order whether the Product so Delivered conforms to the Certificate of Analysis. If Purchaser does not notify Supplier within such period, it shall be deemed to have accepted the Order of Product Delivered to it and Purchaser can no longer file a Claim in respect of such Order of Product, except in respect of any latent defects that are not apparent from a reasonable physical inspection of such Order of Product, in which case Purchaser shall have thirty (30) Business Days from the date of discovery of the latent defect to notify Supplier as to the non-conformance of such Order of Product to the Certificate of Analysis.

**(c)**                                  If Purchaser notifies Supplier that the Product does not meet the specifications set out in the Certificate of Analysis in accordance with Section 2.09(b), Supplier shall carry out a good faith analysis from the control sample of the notified Batch of the Product and if Supplier is satisfied after analysis of the control sample that there are manufacturing defects in the Batch notified by Purchaser, Supplier shall replace the quantity of that notified Batch free of charge and reimburse Purchaser for the related Starting Material Reimbursement Price.  Once Supplier has complied with its obligations under this Section 2.09(c), it shall have no further liability to Purchaser in respect of the Product’s failure to comply with the Certificate of Analysis.

**(d)**                                 If Supplier’s analysis of the control sample is different than Purchaser’s analysis, then either Party may refer the matter for final analysis to a third party specialized laboratory of international reputation reasonably acceptable to both Parties.  Any determination by the laboratory shall be final and binding on Supplier and Purchaser.  The cost and expense of the independent laboratory including testing charges, shall be borne by the Party whose Certificate of Analysis has not been upheld by the independent laboratory.

**2.10**                        **Use of Intellectual Property**

**(a)**                                 Each Party hereby grants (and shall cause its Affiliates, as applicable, to grant) to the other Party a limited, non-exclusive, non-sublicensable, revocable, royalty-free license under such granting Party’s Group’s Intellectual Property during the Term solely to enable the other Party to fulfill its obligations under this Agreement.

**(b)**                                 Except as expressly set forth in this Agreement, neither Party grants the other Party any right or license in, to or under such Party’s Group’s Intellectual Property, whether by implication, estoppel or otherwise.

12

**(c)**                                  Purchaser shall own all right, title and interest in, to and under any Improvements made to the Product, whether made individually by a Party or jointly by the Parties.  Supplier shall promptly disclose to Purchaser any such Improvements to the Product and hereby assigns and agrees to promptly assign to Purchaser all right, title or interest in, to or under any such Improvements to the Product.

**(d)**                                 The Parties shall jointly own all right, title and interest in, to and under any Improvements made to the manufacturing process of the Product, whether made individually by a Party or jointly by the Parties, with each Party having an equal fifty percent (50%) ownership in such Improvement.

**2.11**                        **Disaster Recovery and Business Continuity Plan**

At all times during the Term, Supplier shall maintain and adequately support a disaster recovery and business continuity program that ensures the continuous operation and, in the event of an interruption, the recovery of all material business functions needed to meet Supplier’s obligations under this Agreement.

**ARTICLE III  
JOINT MANUFACTURING COMMITTEE**

**3.01**                        **Joint Manufacturing Committee**

Within thirty (30) calendar days following the Effective Date, the Parties shall establish a Joint Manufacturing Committee to oversee the manufacturing and Delivery of Product under this Agreement (the “***JMC***”).  The JMC shall be composed of five (5) Representatives from each Party or its Affiliates (each Representative as selected by such Party in its sole discretion), and shall meet (whether in person or by teleconference) twice per calendar year starting from the Effective Date to ensure the orderly fulfillment of both Parties’ obligations under this Agreement.

**ARTICLE IV  
TOLLING FEE**

**4.01**                        **Tolling Fee**

**(a)**                                 Supplier shall invoice Purchaser, and Purchaser shall pay the Tolling Fee for the Product, in the Currency (as converted through the Currency Conversion Rate).

**(b)**                                 The Tolling Fee is based on Delivery in accordance with the Shipping Terms, and is inclusive of all applicable Taxes, all of which shall be listed separately on each invoice issued under Section 5.01; provided, however, that for the avoidance of doubt, each Party shall bear its own income Tax costs with respect to the activities covered by this Agreement.  The Tolling Fee is inclusive of all costs and expenses of the supply chain

13

or Delivery and insurance of the Product (including raw materials, components, utilities, equipment or services which are used in the manufacture or Delivery of Product), which such costs and expenses shall be borne by Supplier.

**(c)**                                  The Tolling Fee shall be sufficient for Supplier to be reimbursed for its Local Value Added plus a reasonable arm’s length mark-up (the “***Tolling Fee Margin***”), with such:

(i)           Local Value Added to be calculated on the basis of standard costs and planned variances consistent with the fees paid by Purchaser to Historical Supplier for the Product in the twelve (12) months immediately prior to the Effective Date; and

(ii)        Tolling Fee Margin to be mutually agreed upon by the Parties.

**(d)**                                 During the fourth (4th) calendar quarter of each calendar year during the Term and in any event by December 1 of each such calendar year, Supplier shall provide Purchaser with a report containing a good faith reconciliation estimate of such the Tolling Fee previously invoiced for supply of Product during such year and actual Local Value Added plus the Tolling Fee Margin for such Product. The Parties shall thereafter discuss and agree on any balancing payment that may be due from either Party to the other so that the Tolling Fee paid for supply in that calendar year is as close as practicable to the amount equal to Supplier’s Local Value Added plus the Tolling Fee Margin.  The Party owed a balancing payment, as agreed by the Parties, shall then provide the other Party with an invoice for such balancing payment by January 31 of the subsequent calendar year, with such balancing payment being made within sixty (60) calendar days of the date of receipt of such invoice. The elements of such reconciliation shall be calculated based on certain variances calculated in accordance with U.S. GAAP consistently applied, including the following variances set forth in (i) through (iv); provided, however, that such variances shall not be included to the extent the subject variance is a result of Supplier’s gross negligence (in which case Supplier shall be solely responsible for the costs associated with such variance(s) and such variance(s) shall not be included in calculating the relevant true-up surcharge):

(i)           expense variances relative to the underlying Tolling Fee calculation;

(ii)        unabsorbed expenses not considered as part of the Tolling Fee calculation;

(iii)     manufacturing losses (but not the cost of replacement Batches or related Starting Material Reimbursement Price); and

(iv)    production variances such as use, yield and purchase price variances.

**(e)**                                  By October 1 of each calendar year during the Term, the Parties shall mutually agree upon a new Tolling Fee to be effective for the duration of the following calendar year beginning on January 1 of such following calendar year.

14

**ARTICLE V**

**PAYMENT**

**5.01**                        **Product Payments**

Supplier shall issue an invoice in the Currency (as converted through the Currency Conversion Rate) to Purchaser on the date of Delivery of any Order of Product and Purchaser shall pay the full amount of each such invoice issued to it by Supplier within sixty (60) calendar days of the date of its receipt of such invoice; provided, however, that Purchaser may withhold payment of any amount that it may reasonably dispute in good faith until such dispute is resolved (including as the result of the Product’s non-compliance with the Compliance Requirements).

**5.02**                        **Exit Payments**

**(a)**                                 Beginning on October 1, 2018 and on the first (1st) day of each calendar month thereafter during the Term until Supplier has been reimbursed in full, Supplier shall issue a pro-rated invoice (based on the length of the then-current Term) to Purchaser in the Currency (as converted through the Currency Conversion Rate) for reimbursement of the accelerated depreciation on the HGH Assets, which such total amount of depreciation shall be agreed upon by the Parties in good faith by October 1, 2018.  Purchaser shall pay the full amount of each such invoice issued to it by Supplier within sixty (60) calendar days of the date of its receipt of such invoice; provided, however, that Purchaser may withhold payment of any amount that it may reasonably dispute in good faith until such dispute is resolved.

**(b)**                                 Upon the termination or expiration of this Agreement, Supplier shall issue an invoice to Purchaser in the Currency (as converted through the Currency Conversion Rate) for any Exit Expenses it has incurred under this Agreement for which it has not yet been reimbursed by Purchaser.  Purchaser shall pay the full amount of each such invoice issued to it by Supplier within sixty (60) calendar days of the date of its receipt of such invoice; provided, however, that Purchaser may withhold payment of any amount that it may reasonably dispute in good faith until such dispute is resolved.

**5.03**                        **Payment Guidelines**

**(a)**                                 Any payment to be made pursuant to this Agreement by Purchaser shall be made to Supplier’s Bank Account in the Currency, without any deduction of transmission fees, bank charges or early payment discounts or rebates (unless otherwise agreed by the Parties in writing).

**(b)**                                 Payment under Section 5.03(a) shall be in immediately available funds by electronic transfer by the due date for payment.  Receipt of the amount due shall be an effective discharge of the relevant payment obligation.

**(c)**                                  If any sum due for payment in accordance with this Agreement is not paid by the due date for payment (and such payment is not the subject of a good faith dispute), the Party

15

in default shall pay Default Interest on that sum from but excluding the due date to and including the date of actual payment calculated on a daily basis until such payment is settled.

**ARTICLE VI  
QUALITY CONTROL**

**6.01**                        **Quality Control**

The Parties shall enter into the Quality Agreement within thirty (30) calendar days after the Effective Date. The Quality Agreement shall, as may be revised and amended from time to time as mutually agreed by the Parties, describe certain quality expectations and responsibilities relating to the manufacture, release testing, quality control testing (including stability testing) and quality oversight and supply of the Product to Purchaser.

**6.02**                        **Product Recall**

In respect of any Measure in the Territory related to Product that is required or recommended by a Governmental Authority or reasonably deemed advisable by any member of the Purchaser’s Group in good faith, such Measure shall be promptly implemented, directed and administered by the Purchaser’s Group in a manner which is appropriate, reasonable and in accordance with applicable Law and Supplier shall reasonably cooperate in good faith with the Purchaser’s Group in connection with such implementation, direction or administration.  Subject to Section 9.01(b), all costs and expenses related to a Measure shall be borne by the Purchaser’s Group.

**6.03**                        **Complaints and Returns**

**(a)**                                 From the Effective Date, the Purchaser’s Group shall be responsible for handling any complaints associated with the Product and dealing with and processing any returns of Product and Supplier shall reasonably cooperate in good faith with the Purchaser’s Group in connection with resolution of any such complaints and returns.

**(b)**                                 Each Party shall notify the other promptly after receiving any complaint in relation to, or return of, the Product and provide the other Party with a complete copy of the complaint and all other relevant information.

**6.04**                        **Regulatory Responsibility**

All matters related to the Parties’ regulatory responsibilities, including regulatory communications and quality assurance, shall be governed by this Agreement or the Quality Agreement.

**6.05**                        **Stability Testing**

Supplier shall perform or procure the performance of stability testing of all Product manufactured at the Facility in accordance with the Quality Agreement to confirm the Product’s

16

compliance with the Compliance Requirements.  Supplier’s obligation as set forth in this Section 6.05 shall apply to all Batches of Product manufactured under this Agreement (and any Product manufactured by Historical Supplier at the Facility) and shall extend beyond the duration of the Term solely to the extent required in connection with the completion of the stability testing of any such Batch of Product.  Purchaser shall bear all costs and expenses associated with or resulting from any such stability testing conducted under this Section 6.05.

**ARTICLE VII**

**BOOKS AND RECORDS; AUDITS AND INSPECTIONS**

**7.01**                        **Books and Records**

At its own expense, Supplier shall create and maintain all books and records as required by this Agreement or the Compliance Requirements that relate to this Agreement and to Supplier’s performance hereunder (for any period prescribed by such Compliance Requirement or otherwise as set forth in this Agreement), and such books and records shall be sufficient to demonstrate that all changes in the Tolling Fee or any other expenses invoiced to Purchaser hereunder are accurate and proper in both kind and amount.

**7.02**                        **Quality Audits**

**(a)**                                 Supplier will allow Purchaser to reasonably audit Supplier and the Facility for the purposes of evaluating and verifying compliance with the Compliance Requirements.  Any audit undertaken pursuant to this Section 7.02(a) shall be subject to the following conditions: (i) Supplier shall be given no less than two (2) Business Days’ prior notice of any For Cause Audit, and no less than fifteen (15) Business Days’ prior notice of any other proposed audit; (ii) each such audit shall be conducted during normal working hours and shall take no longer than three (3) Business Days, so long as Supplier furnishes all information requested by Purchaser in a timely fashion; and (iii) each Party shall bear its own costs and expenses incurred in connection with any such audit.

**(b)**                                 Purchaser may exercise its audit rights under Section 7.02(a) once per calendar year during the Term or otherwise on a frequency as mutually agreed by the Parties and additionally, as may be necessary, in the case of For Cause Audits.

**7.03**                        **Financial Audits**

**(a)**                                 Supplier will allow a Purchaser-appointed auditor to reasonably inspect (and, upon request, Supplier will furnish copies of) the books and records which Supplier is required to create or maintain under Section 7.01 for the purposes of evaluating and verifying the accuracy of and changes in the Tolling Fee.  Any audit undertaken pursuant to this Section 7.03(a) shall be subject to the following conditions:  (i) Supplier shall be given no less than fifteen (15) Business Days’ prior notice of any such proposed audit; (ii) each such audit shall be conducted during normal working hours and shall take no longer than three (3) Business Days, so long as Supplier furnishes all books and records requested by Purchaser in a timely fashion; and (iii) such audit shall

17

be performed by an internationally recognized independent auditor reasonably acceptable to both Parties acting under such obligations of confidentiality owed to Supplier as Supplier may reasonably require.

**(b)**                                 Purchaser may exercise its audit rights under Section 7.03(a) once per calendar year during the Term and additionally upon its reasonable belief that the Tolling Fee has been incorrectly calculated or invoiced.

**(c)**                                  Purchaser shall bear all costs and expenses incurred in connection with any audit under this Section 7.03; provided, however, that if any such audit correctly identifies overpricing or overcharges (of any nature) by Supplier to Purchaser, any adjustments or payments owed to Purchaser shall be made by Supplier to Purchaser within a reasonable amount of time (not to exceed ninety (90) calendar days) from presentation of the audit findings to Supplier and Supplier shall also reimburse Purchaser for all reasonable costs and expenses incurred by Purchaser in connection with such audit inspection.

**7.04**                        **Regulatory Inspections**

Supplier shall notify Purchaser within three (3) Business Days of the date of any notification received by it from any Governmental Authority to conduct an inspection of the Facility.

**ARTICLE VIII**

**REPRESENTATIONS AND WARRANTIES**

**8.01**                        **Representations and Warranties**

Each of Purchaser and Supplier represents and warrants to the other that: (a) it has the requisite corporate power and authority to enter into and perform its obligations under this Agreement; (b) it has taken all corporate actions necessary on its part required to execute and deliver this Agreement, to consummate the transactions contemplated hereby and to perform its obligations hereunder; and (c) this Agreement has been duly executed and delivered on behalf of such Party, and assuming that this Agreement constitutes a valid and binding obligation of the other Party, this Agreement constitutes a legal, valid and binding obligation of such Party that is enforceable against it in accordance with its terms, except as such enforceability may be limited by bankruptcy, insolvency, reorganization, moratorium or other similar applicable Laws affecting or relating to the enforcement of creditors’ rights generally, and general principles of equity, regardless of whether asserted in a proceeding in equity or at Law.

**8.02**                        **Supplier’s Representations, Warranties and Covenants**

Supplier represents, warrants and covenants to be, at all time during this Agreement, in possession of any and all approvals, permits and other documents required by all legislative and regulatory requirements on health, safety, working conditions and environment which are applicable to equipment and activities related to the manufacturing of the Product at the Facility and necessary to operate such equipment and activities at the Facility.  Upon Purchaser’s request, Supplier shall provide Purchaser with any document evidencing such possession.

18

**8.03**                        **No Further Representations or Warranties**

Other than as expressly set forth in this Article VIII, neither Party makes any representation or warranty under this Agreement and all further representations and warranties are excluded to the maximum extent permitted under applicable Law.

**ARTICLE IX**

**INDEMNIFICATION; LIMITATION OF LIABILITY; CONDUCT OF THIRD PARTY CLAIMS**

**9.01**                        **Indemnification**

**(a)**                                 Purchaser shall indemnify, defend and hold harmless Supplier and its Affiliates against all Losses (including Supplier’s own Losses and those resulting from Third Party Claims) resulting from, or otherwise relating to:

(i)           Purchaser’s gross negligence or willful misconduct in connection with this Agreement;

(ii)        any breach by Purchaser of any of its representations and warranties and any material breach by Purchaser of its obligations under this Agreement;

(iii)     any Third Party Claim that any method of manufacturing implemented by Supplier at the request of and as directed by Purchaser (regardless of whether such request or direction was made prior to or after the Effective Date) infringes, misappropriates or otherwise violates any third party’s Intellectual Property rights;

(iv)    any violation of the Compliance Requirements by Purchaser or its Affiliates in its or their performance under this Agreement; or

(v)       any product liability Claims arising from manufacturing defects in any Batch of Granules delivered to Supplier;

in each case except to the extent such Losses result from, or otherwise relate to, circumstances that give rise to Supplier’s liability in accordance with Section 9.01(b).

**(b)**                                 Supplier shall indemnify, defend and hold harmless Purchaser and its Affiliates against all Losses (including Purchaser’s own Losses and those resulting from Third Party Claims) resulting from, or otherwise relating to:

(i)           Supplier’s gross negligence or willful misconduct in connection with this Agreement;

(ii)        any breach by Supplier of any of its representations and warranties and any material breach by Supplier of its obligations under this Agreement;

19

(iii)     any violation of the Compliance Requirements by Supplier or its Affiliates in its or their performance under this Agreement;

(iv)    any Third Party Claim that any method of manufacturing implemented by Supplier after the Effective Date without Purchaser’s consent infringes, misappropriates or otherwise violates any third party’s Intellectual Property rights; or

(v)       any product liability Claims arising from manufacturing defects in the Product Delivered hereunder except to the extent such Claims result from defects in the Granules.

**9.02**                        **Limitation of Liability**

**(a)**                                 Notwithstanding anything contained in this Agreement, neither Party shall be liable to the other for any Losses for any punitive, incidental, special or indirect damages or for any consequential damages or damages for loss of future profits, revenue or income, diminution in value or loss of business reputation or opportunity, whether in contract, tort or otherwise, that arise under or in connection with this Agreement (including under any Purchase Order).

**(b)**                                 Except as otherwise set forth in this Agreement, with respect to any particular Batch of Product, the total liability of each Party under or in connection with this Agreement for all claims (including Claims), whether in contract, tort or otherwise in relation to any such particular Batch of Product, shall not exceed the U.S. Dollar amount of the Tolling Fee Margin applicable to such Batch.

**(c)**                                  Except as otherwise set forth in this Agreement, the total aggregate liability of each Party under or in connection with this Agreement for all claims (including Claims), whether in contract, tort or otherwise in relation to the Product, shall not exceed the Annual Total Tolling Fee Margin; provided, however, that for any such claims that arise in calendar year 2018, the relevant Annual Total Tolling Fee Margin shall be pro-rated on a three (3) month basis.

**(d)**                                 The limitations in Sections 9.02(a) through 9.02(c) shall not apply to:

(i)           Purchaser’s obligation to make payments under Sections 5.01 or 5.02 of this Agreement;

(ii)        Supplier’s obligation to reimburse Purchaser pursuant to Section 2.09(c) of this Agreement;

(iii)     either Party’s obligation to make any payment under Section 2.02(e), Section 2.03(b) or Section 2.09(d);

(iv)    any liability arising from fraud, breach of Article XI, gross negligence, willful misconduct or personal injury; or

20

(v)       any other liability that cannot be excluded by applicable Law.

**(e)**                                  The limitations in Section 9.02(b) shall not apply to Third Party Claims subject to indemnification under Sections 9.01(a) or 9.01(b), it being understood by the Parties that Section 9.02(a) shall not act to limit a Party’s obligation to provide such indemnification, regardless of the character or nature of the Losses asserted by the third party in the Third Party Claim subject to such indemnification.

**(f)**                                   Subject to Section 9.03, a Party (the “***Claiming Party***”) shall notify the other in writing within thirty (30) calendar days of the date on which it becomes aware of any grounds for any Claim against the other.  Failure to give notice within thirty (30) calendar days shall not affect the validity of any Claim, but in the absence of notification, the other Party’s liability for any loss or damage for the Claim shall not exceed any liability it would have incurred for the loss or damage if the Claiming Party had duly notified the other Party on or before the thirtieth (30th) calendar day after becoming aware of the grounds for the Claim.

**(g)**                                 The Claiming Party shall, for any Loss that may give rise to a Claim against the other Party, take all reasonable steps to avoid and mitigate that Loss, including by pursuing any relevant third party, or claiming under any relevant insurance policy or bond in respect of the loss or damage.

**9.03**                        **Conduct of Third Party Claims**

If either Party becomes aware of any claim or potential claim by a third party (a “***Third Party Claim***”), or of any other matter or circumstance, which in either case might result in a Claim being made against such Party, such Party shall:

**(a)**                                 promptly (and in any event within ten (10) Business Days of becoming aware of it) give notice of the Third Party Claim or other matter or circumstance to the other Party and ensure that the other Party and its Representatives are given all reasonable information and facilities to investigate such Third Party Claim, matter or circumstance;

**(b)**                                 not (and ensure that each of its Affiliates shall not) admit liability or make any agreement or compromise in relation to the Third Party Claim without prior written approval of the other Party; and

**(c)**                                  subject to the notifying Party or its relevant Affiliates being indemnified by the other Party against all reasonable out of pocket costs and expenses incurred in respect of that Third Party Claim, ensure that it and each of its Affiliates shall:

(i)           take any action as the other Party may reasonably request to avoid, resist, dispute, appeal, compromise or defend the Third Party Claim;

(ii)        allow the other Party (if it elects to do so) to take over the conduct of all proceedings or negotiations arising in connection with the Third Party Claim (provided that the other Party may not admit liability nor make any agreement or compromise in relation to the Third Party Claim without prior written

21

approval of the notifying Party, such approval not to be unreasonably withheld, unless the agreement or compromise imposes no ongoing obligations or liability on the notifying Party); and

(iii)     provide any information and assistance as the other Party may reasonably require in connection with the preparation for and conduct of any proceedings or negotiations relating to the Third Party Claim.

**9.04**                        **Insurance**

At all times during the Term for the Product, each Party shall maintain sufficient self-insurance or insurance with a reputable insurer in an amount appropriate for the business and Product that is the subject of this Agreement, and its obligations under this Agreement.

**ARTICLE X**

**TERM**

**10.01**                 **Term and Termination**

**(a)**                                 Subject to Section 10.01(c), this Agreement shall commence on the Effective Date and shall remain in effect through December 31, 2020 (the “**Term**”) unless earlier terminated in accordance with Section 10.01(b).

**(b)**                                 This Agreement may be terminated upon the written agreement of both Parties.

**(c)**                                  If, by March 31 of each calendar year during the Term (beginning with March 31, 2020 and ending, at the latest and if applicable, on March 31, 2022), the New Product Supplier has failed to reasonably demonstrate to Purchaser’s satisfaction that it (i) is capable of manufacturing Product (in compliance with the Compliance Requirements) at the volume that Historical Supplier manufactured Product for Purchaser in the twelve (12) months immediately preceding the Effective Date or (ii) has received all necessary approvals from applicable Governmental Authorities to manufacture and Deliver Product to Purchaser, Purchaser shall have the right to extend the Term for additional one (1) year periods (for a maximum of three (3) additional one (1) year periods).  Any such one (1) year extensions, if timely elected by Purchaser, shall extend the duration of the Term accordingly and any references to the Term in this Agreement shall thereafter include the period of any such extensions.

**(d)**                                 The Surviving Provisions, together with any other Section or Article reasonably intended to survive expiration or termination, shall survive expiration or termination of this Agreement.

**(e)**                                  Supplier hereby covenants and agrees that it shall not (and shall cause its Affiliates not to):

22

(i)           for a period of five (5) years after the expiration of termination of this Agreement, develop, assist in the development of, manufacture, assist in the manufacture of, deliver, supply, distribute or sell any product (including any active pharmaceutical ingredient) that is competitive to the Product; and

(ii)        during the Term, conduct manufacturing of any product at the W10 or B118 buildings of the Facility other than the Product without Purchaser’s prior written consent.

**ARTICLE XI**

**CONFIDENTIALITY**

**11.01**                 **Confidentiality**

**(a)**                                 Each Party shall keep confidential any Confidential Information of the other Party disclosed in connection with this Agreement or its implementation, except as expressly agreed upon in writing by the other Party.

**(b)**                                 The confidentiality obligations in Section 11.01(a) shall not apply to information which any Party can demonstrate is required to be disclosed by applicable Law or the rules of any stock exchange or any Governmental Authority provided that in this event the Party which is obliged to disclose shall to the extent permitted by applicable Law use its commercially reasonable efforts to consult with the other Party in advance as to its form, content and timing.

**(c)**                                  Each of Supplier and Purchaser undertakes that it (and its Affiliates) shall only disclose Confidential Information to its Representatives if it is reasonably required for purposes connected with this Agreement and only if the Representatives are informed of the confidential nature of the Confidential Information and the confidentiality obligations related thereto.  Each of Supplier and Purchaser undertakes that it (and its Affiliates) shall not use or permit the use of, any Confidential Information of the other Party, except in furtherance of such Party’s (or its Affiliate’s) exercise of its rights and the performance of such Party’s (or its Affiliate’s) obligations under this Agreement.

**(d)**                                 If this Agreement terminates or expires, except as and solely to the extent required to remain in compliance with applicable Law, each Party shall as soon as practicable on request by the other Party:

(i)           return to the other Party all written documents and other materials relating to the Product or this Agreement (including any Confidential Information) which the other Party (or its Representatives) has provided to it (or its Representatives), or which has been provided on the other Party’s (or its Representatives’) behalf, without keeping any copies of them;

(ii)        destroy all information or other documents derived from the other Party’s Confidential Information; and

23

(iii)     so far as it is practicable to do so, expunge the other Party’s Confidential Information from any of its computers, word processors or other devices.

**ARTICLE XII**

**FURTHER ASSURANCES**

**12.01**                 **Further Assurances**

In addition to the actions specifically provided for elsewhere in this Agreement, each of the Parties will cooperate with each other and shall use its (and shall cause its Affiliates to use their) commercially reasonable efforts, prior to, on and after the Effective Date, to take, or cause to be taken, all actions, and to do, or cause to be done, all things, reasonably necessary, proper or advisable under applicable Laws, regulations and agreements to implement and give effect to this Agreement.

**ARTICLE XIII**

**MISCELLANEOUS PROVISIONS**

**13.01**                 **Counterparts; Entire Agreement; Conflicting Agreements**

**(a)**                                 This Agreement may be executed in one (1) or more counterparts, all of which shall be considered one (1) and the same agreement, and shall become effective when one (1) or more counterparts have been signed by each Party and delivered to the other Party.  Execution of this Agreement or any other documents pursuant to this Agreement by facsimile or other electronic copy of a signature shall be deemed to be, and shall have the same effect as being, executed by an original signature.

**(b)**                                 This Agreement, the Quality Agreement, the Separation Agreement, the other Ancillary Agreements, the exhibits, the schedules and appendices hereto and thereto contain the entire agreement between the Parties with respect to the subject matter hereof, supersede all previous agreements, negotiations, discussions, writings, understandings, commitments and conversations with respect to such subject matter and there are no agreements or understandings between the Parties with respect to such subject matter other than those set forth or referred to herein or therein.

**(c)**                                  In the event of any inconsistency between this Agreement and any other agreement entered into in connection with the Transaction (including the Separation Agreement), the Separation Agreement shall prevail.  In the event and to the extent that there shall be a conflict between the provisions of this Agreement and the provisions of the Separation Agreement, the Separation Agreement shall control.

**(d)**                                 If there is any conflict between the terms of this Agreement and the Quality Agreement, this Agreement shall prevail, with respect to non-quality related terms, and the Quality Agreement shall govern with respect to all quality related terms.  If any provisions of

24

the Quality Agreement or this Agreement are inconsistent with the terms of the Compliance Requirements, the Compliance Requirements shall prevail.

**13.02**                 **No Construction Against Drafter**

The Parties acknowledge that this Agreement and all the terms and conditions contained herein have been fully reviewed and negotiated by the Parties.  Having acknowledged the foregoing, the Parties agree that any principle of construction or rule of Law that provides that, in the event of any inconsistency or ambiguity, an agreement shall be construed against the drafter of the agreement shall have no application to the terms and conditions of this Agreement.

**13.03**                 **Governing Law**

This Agreement shall be governed by and construed and interpreted in accordance with the Laws of Switzerland, without regard to the conflict of laws principles thereof that would result in the application of any Law other than the Laws of Switzerland.

**13.04**                 **Assignment**

**(a)**                                 This Agreement shall be binding upon and inure to the benefit of the Parties hereto and their respective successors and permitted assigns; provided, however, that no Party hereto may assign its respective rights or delegate its respective obligations under this Agreement without the express prior written consent of the other Party hereto.

**(b)**                                 Notwithstanding Section 13.04(a), Supplier may assign all or any part of its rights under this Agreement to any third party acquirer of (i) the whole or a substantial part of Supplier’s equity or business or (ii) the Facility; provided, however, that such acquirer agrees in writing to be bound by the terms and conditions of this Agreement and Purchaser is provided with written notice sixty (60) calendar days prior to any such assignment.

**(c)**                                  Notwithstanding Section 13.04(a), Purchaser shall be entitled to assign all or any part of its rights under this Agreement to one or more of its Affiliates, provided that if such assignee subsequently is anticipated to cease being a member of Purchaser’s Group, Purchaser shall ensure that it shall re-assign all such rights to Purchaser or to another continuing member of Purchaser’s Group.

**13.05**                 **No Third-Party Beneficiaries**

Except for the indemnification rights under this Agreement as set forth in Article IX, (a) the provisions of this Agreement are solely for the benefit of the Parties hereto and are not intended to confer upon any Person (including employees of the Parties hereto) except the Parties any rights or remedies hereunder, and (b) there are no third party beneficiaries of this Agreement and this Agreement shall not provide any third person (including employees of the Parties hereto) with any remedy, claim, liability, reimbursement, claim of action or other right in excess of those existing without reference to this Agreement.

25

**13.06**                 **Notices**

All notices or other communications under this Agreement shall be in writing and shall be deemed to be duly given when (a) delivered in person or (b) deposited in the United States mail or private express mail, postage prepaid, addressed as follows:

If to Purchaser, to:

Eli Lilly Export S.A.  
Air Center

16 Chemin des Coquelicots

1214 Vernier/Geneva, Switzerland  
Attention:                                         Chief Financial Officer

With a copy to:

Eli Lilly and Company

Lilly Corporate Center

Indianapolis, Indiana 46285

Attention:                                         General Counsel

If to Supplier to:

Elanco UK AH Limited  
Speke Operations

Fleming Road, Liverpool, L24 9LN

Speke, United Kingdom  
Attention:                                         Chief Financial Officer

With a copy to:

Elanco Animal Health Incorporated

2500 Innovation Way

Greenfield, Indiana 46140

Attention:                                         General Counsel

Any Party may, by written notice to the other Party, change the address to which such notices are to be given.

**13.07**                 **Severability**

If any provision of this Agreement or the application thereof to any Person or circumstance is determined by a court of competent jurisdiction to be invalid, void or unenforceable, the remaining provisions hereof or the application of such provision to Persons or circumstances or in jurisdictions other than those as to which it has been held invalid or unenforceable, shall remain in full force and effect and shall in no way be affected, impaired or invalidated thereby, so long as the economic or legal substance of the transactions contemplated hereby is not

26

affected in any manner adverse to any Party.  Upon such determination, the Parties shall negotiate in good faith in an effort to agree upon a suitable and equitable provision to effect the original intent of the Parties as closely as possible in a mutually acceptable manner in order that the rights and obligations contemplated by this Agreement be fulfilled as originally contemplated to the greatest extent possible.

**13.08**                 **Force Majeure**

No Party shall be deemed in default of this Agreement to the extent that any delay or failure in the performance of its obligations under this Agreement results from any cause beyond its reasonable control and without its fault or negligence, such as acts of God, acts of civil or military authority, embargoes, epidemics, war, riots, insurrections, fires, explosions, earthquakes, floods, unusually severe weather conditions, or labor problems, or, in the case of computer systems, any failure in electrical or air conditioning equipment.  In the event of any such excused delay, the time for performance shall be extended for a period equal to the time lost by reason of such delay.

**13.09**                 **Headings**

The table of contents and article, section and paragraph headings contained in this Agreement are for reference purposes only and shall not affect in any way the meaning or interpretation of this Agreement.

**13.10**                 **Waivers of Default**

Waiver by any Party of any default by the other Party of any provision of this Agreement shall not be deemed a waiver by the waiving Party of any subsequent or other default, nor shall it prejudice the rights of the other Party.

**13.11**                 **Specific Performance**

In the event of any actual or threatened default or breach of, any of the terms, conditions and provisions of this Agreement, the Party or Parties who are or are to be thereby aggrieved shall be entitled to seek an injunction or injunctions to prevent breaches of this Agreement and to enforce specifically the terms and provisions hereof, in each case (a) without the requirement of posting any bond or other indemnity and (b) in addition to any other remedy to which it or they may be entitled, at Law or in equity.  Such remedies shall be cumulative with and not exclusive of and shall be in addition to any other remedies which any Party may have under this Agreement, or at Law or in equity or otherwise, and the exercise by a Party hereto of any one remedy shall not preclude the exercise of any other remedy.

**13.12**                 **Amendments**

No provision of this Agreement shall be deemed waived, amended, supplemented or modified by any Party, unless such waiver, amendment, supplement or modification is in writing and signed by the authorized representative of the Party against whom it is sought to enforce such waiver, amendment, supplement or modification.

27

**13.13**                 **Interpretation**

Interpretation of this Agreement (except as specifically provided in this Agreement, in which case such specified rules of construction shall govern with respect to this Agreement) shall be governed by the following rules of construction: (a) words in the singular shall be held to include the plural and vice versa, and words of one gender shall be held to include the other gender as the context requires; (b) references to the terms Article, Section, paragraph and Exhibit are references to the Articles, Sections, paragraphs and Exhibits to this Agreement unless otherwise specified; (c) the terms “hereof”, “herein”, “hereby”, “hereto” and derivative or similar words refer to this entire Agreement, including the Schedules and Exhibits hereto; (d) references to “$” shall mean U.S. dollars; (e) the word “including” and words of similar import shall mean “including without limitation,” unless otherwise specified; (f) the word “or” shall not be exclusive; (g) references to “written” or “in writing” include in electronic form; (h) provisions shall apply, when appropriate, to successive events and transactions; (i) a reference to any Person includes such Person’s permitted successors and permitted assigns; (j) any reference to “days” means calendar days unless Business Days are expressly specified; and (k) when calculating the period of time before which, within which or following which any act is to be done or step taken pursuant to this Agreement, the date that is the reference date in calculating such period shall be excluded and, if the last day of such period is not a Business Day, the period shall end on the next succeeding Business Day.

**13.14**                 **Waiver of Jury Trial**

SUBJECT TO SECTIONS 13.11 AND 13.15 HEREIN, EACH OF THE PARTIES HEREBY WAIVES TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW ANY RIGHT IT MAY HAVE TO A TRIAL BY JURY WITH RESPECT TO ANY COURT PROCEEDING DIRECTLY OR INDIRECTLY ARISING OUT OF AND PERMITTED UNDER OR IN CONNECTION WITH THIS AGREEMENT.  EACH OF THE PARTIES HEREBY (A) CERTIFIES THAT NO REPRESENTATIVE, AGENT OR ATTORNEY OF THE OTHER PARTY HAS REPRESENTED, EXPRESSLY OR OTHERWISE, THAT SUCH OTHER PARTY WOULD NOT, IN THE EVENT OF LITIGATION, SEEK TO ENFORCE THE FOREGOING WAIVER AND (B) ACKNOWLEDGES THAT IT HAS BEEN INDUCED TO ENTER INTO THIS AGREEMENT AND THE TRANSACTIONS CONTEMPLATED BY THIS AGREEMENT, AS APPLICABLE, BY, AMONG OTHER THINGS, THE MUTUAL WAIVERS AND CERTIFICATIONS IN THIS SECTION 13.14.

**13.15**                 **Submission to Jurisdiction; Waivers**

With respect to any Claim relating to or arising out of this Agreement, each Party to this Agreement irrevocably (a) consents and submits to the exclusive jurisdiction of the courts of Switzerland, (b) waives any objection which such Party may have at any time to the laying of venue of any Claim brought in any such court, waives any claim that such Claim has been brought in an inconvenient forum and further waives the right to object, with respect to such Claim, that such court does not have jurisdiction over such Party and (c) consents to the service of process at the address set forth for notices in Section 13.06 herein; provided, however, that such manner of service of process shall not preclude the service of process in any other manner permitted under applicable Law.

[*Signature Page Follows*]

28

**IN WITNESS WHEREOF**, each of Supplier and Purchaser have duly executed this Agreement as of the date first written above.

|  |  |  |
| --- | --- | --- |
| **ELI LILLY EXPORT S.A., as Purchaser** | |  |
|  | |  |
| By: | /s/ Philip L. Johnson |  |
| Name: | Philip L. Johnson |  |
| Title: | Vice President |  |
|  | |  |
| **ELANCO UK AH LIMITED, as Supplier** | |  |
|  | |  |
| By: | /s/ Nilesh Sukumar Ambani |  |
| Name: | Nilesh Sukumar Ambani |  |
| Title: | Director |  |

29