

foiapa

From: Mark Edwards <medwards@biosciadvisors.com>
Sent: Friday, May 18, 2018 8:21 PM
To: foiapa
Subject: FOIA Request

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MAY 21 2018

Office of
FOIA Services

I would like to request access to Exhibits 10.7 thru 10.10 to the Form F-1, as amended, filed by GW Pharmaceuticals PLC on 3/19/2013. Confidential treatment was sought as to certain portions when initially filed with the Commission.

In the event that confidential treatment has not expired or has been extended, I further request that you send me the expiration date(s) from the relevant CT order(s) so I will know when I should resubmit my request.

I authorize up to \$61 in search and retrieval fees. Please send the exhibit(s) by PDF if possible.

Sincerely,

Mark

Mark G Edwards
Managing Director
Bioscience Advisors
2855 Mitchell Dr., Suite 103
Walnut Creek, CA 94598
medwards@biosciadvisors.com
925 954-1397



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

Office of FOIA Services

June 18, 2018

Mr. Mark G. Edwards
Bioscience Advisors
2855 Mitchell Dr., Suite 103
Walnut Creek, CA 94598

RE: Freedom of Information Act (FOIA), 5 U.S.C. § 552
Request No. 18-04408-E

Dear Mr. Edwards:

This letter is in response to your request, dated and received in this office on May 21, 2018, for access to Exhibits 10.7 thru 10.10 to the Form F-1, as amended, filed by GW Pharmaceuticals PLC on March 19, 2013.

The search for responsive records has resulted in the retrieval of 32 pages of records that may be responsive to your request. They are being provided to you with this letter.

As shown on the enclosed invoice, the processing fee is \$45.75 in accordance with our fee schedule. You may use our [Online Payment](#) option to pay by debit or credit card. If paying by mail, checks or money orders should be made payable to the SEC and a copy of the invoice should be mailed to our payment address: Enterprise Services Center, HQ Bldg., Room 181, AMZ-341, 6500 South MacArthur Boulevard, Oklahoma City, OK 73169. Please refer to the following link for detailed instructions on how to remit payments. <http://www.sec.gov/about/offices/ofm.htm>

If you have any questions, please contact me at reidk@sec.gov or (202) 551-3504. You may also contact me at foiapa@sec.gov or (202) 551-7900. You also have the right to seek assistance from Lizzette Katilius as a FOIA Public Liaison or contact the Office of Government Information Services (OGIS) for dispute resolution services. OGIS can be reached at 1-877-684-6448 or Archives.gov or via e-mail at ogis@nara.gov.

Sincerely,

Kay Reid

Kay Reid
FOIA Lead Research Specialist

Enclosures

10.7

BAYER AG

and

GW PHARMA LTD

SUPPLY AGREEMENT

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SUPPLY AGREEMENT

THIS SUPPLY AGREEMENT ("Agreement") is made the 20th day of May 2003 between BAYER AG, Bayer HealthCare, Division Pharma, having its registered office at Bayerwerk, 51368 Leverkusen, Germany ("Bayer") and GW PHARMA LIMITED having its registered office at Porton Down Science Park, Salisbury, Wiltshire SP4 0JQ ("GW").

WHEREAS, GW is the owner of all right, title and interest in certain patents and know-how relating to certain cannabinoid products and desires to grant a licence to the rights to sell and distribute such cannabinoid products in the Territory;

WHEREAS, Bayer and its Affiliates have experience in the market development, marketing, promotion and sale of pharmaceutical products and desires to obtain a licence to the rights to sell and distribute such cannabinoid products in the Territory and GW is willing to grant to Bayer such rights;

WHEREAS, GW and Bayer entered into a License and Distribution Agreement, a Loan Agreement and a Subscription Option Agreement as of the date hereof; and

WHEREAS, Bayer wishes to purchase the Products manufactured by GW for sale and distribution in the Territory and GW wishes to supply such Products to Bayer.

NOW, THEREFORE, THE PARTIES HEREBY AGREE AS FOLLOWS:

1. DEFINITIONS

- 1.1. "Affiliate(s)" shall have the meaning defined in the License and Distribution Agreement.
- 1.2. "Agreement" shall mean this supply agreement together with all its appendices including without limitation the Quality Agreement (the "Appendi(x)(ces)").
- 1.3. "Authorised Contractors" shall mean **Humber Growers Limited; Botanix Limited and CP Pharmaceuticals Limited**.
- 1.4. "Bayer Sales" shall mean the sales of units of Product ex warehouse reported by Bayer in each Country.
- 1.5. "Commercial Year" shall mean the twelve (12) month period in each Country beginning with the month following the Launch date and each subsequent twelve (12) month period.
- 1.6. "Contract Governance Committee" shall have the meaning defined in the License and Distribution Agreement.
- 1.7. "Controlled Drugs Authority" shall have the meaning defined in the License and Distribution Agreement.
- 1.8. "Country" shall mean each country within the Territory.
- 1.9. "Country Commercialisation Committee(s)" shall have the meaning defined in the License and Distribution Agreement.
- 1.10. "Delivery" shall mean the Products either available for collection by Bayer or its appointed carrier for transporting to the Bayer nominated warehouse; or available for delivery by GW or its appointed carrier to the Bayer nominated warehouse as notified by Bayer and "Deliver" and "Delivered" shall be construed accordingly.

- 1.11. "Effective Date" shall mean the date upon which this Agreement is effective and shall be the date of this Agreement first above written.
- 1.12. "Estimated Supply Prices" shall mean the List Prices for the Products in a Country less the wholesaler discount agreed in writing from time to time between the Parties based on the agreed standard prevailing wholesaler discount in the Country in question multiplied by the relevant Supply Price percentage as stated in **Appendix 1** to this Agreement.
- 1.13. "Good Manufacturing Practice" or "GMP" shall mean the regulatory standards and principles and guidelines of Good Manufacturing Practice as in force from time to time relating to the production of medicinal products established by the applicable Governmental Authority applicable anywhere in the Territory including, without limitation, the Guidelines on Good Manufacturing Practice of Medicinal Products for Human Use published by the European Commission, as the same may be amended from time to time. GMP includes Good Distribution Practice ("GDP") as defined by Directive 2001/83/EC for the purposes of this Agreement.
- 1.14. "Governmental Authority" shall have the meaning defined in the License and Distribution Agreement.
- 1.15. "Gross Sales" shall mean the gross amounts invoiced by Bayer in respect of the sales of the Products in the Territory under this Agreement by Bayer or its Affiliates to third parties at an arm's length open market price.
- 1.16. "IMS" shall mean Intercontinentall Medical Statistics or any other agreed source.
- 1.17. "IMS Sales" shall mean the total IMS reported sales of Product in each Country.
- 1.18. "Indication" shall have the meaning defined in the License and Distribution Agreement.
- 1.19. "Intermediates" shall mean the raw materials and components used in the three stages of Manufacture of the Products.
- 1.20. "Laboratory" shall mean the independent testing laboratory agreed between the parties for the testing of disputed shipments pursuant to Clause 9.
- 1.21. "Launch Conditions" shall have the meaning defined in the License and Distribution Agreement.
- 1.22. "Latent Defect" shall mean a defect in a Product existing at the time of receipt by Bayer which is not discovered by visual inspection and which is not attributable to the storage of a Product by Bayer.
- 1.23. "Launch" shall have the meaning specified in the License and Distribution Agreement.
- 1.24. "Launch Stocks" shall mean those stocks of the Products Manufactured by GW or Authorised Contractors on its behalf as specifically ordered for Launch by Bayer.
- 1.25. "Licence and Distribution Agreement" shall mean the agreement of even date for the licensing and distribution of the rights to the Products.
- 1.26. "Licence to Manufacture" shall mean the conditional rights to manufacture granted to Bayer under Clause 2.4 of the Licence and Distribution Agreement and more particularly described in Clause 8.2 of this Agreement.
- 1.27. "List Price(s)" shall mean with respect to the UK Territory the prices that pharmacists are paid for the Products by the Governmental Authorities in a Country or the nearest equivalent price in other Countries of the Territory.
- 1.28. "Manufacture" shall mean the planning, purchasing, cultivating, extracting, manufacture, processing, compounding, storage, filling, packaging, labelling, leafleting, testing, sample retention, stability testing, release, QP certification and

despatch of the Products (or procurement of the same) and "Manufactured" and "Manufacturing" shall be construed accordingly.

- 1.29. "Manufacturing Know-How" shall mean the technical information and know-how in the possession or under the control of GW relating to the Manufacture and formulation of the Products.
- 1.30. "Manufacturing Licence" shall mean all licences necessary for or in connection with the Manufacture of the Products at the Manufacturing Site(s).
- 1.31. "Manufacturing Site" shall mean the manufacturing facility of GW or such other manufacturing facility of GW or of any Authorised Contractor appointed by GW under this Agreement applicable to the Manufacture of the Products.
- 1.32. "Marketing Authorisation(s)" shall have the meaning defined in the License and Distribution Agreement.
- 1.33. "Net Sales" shall have the meaning defined in the License and Distribution Agreement.
- 1.34. "Net Selling Price" shall mean Net Sales per unit of Product.
- 1.35. "Out of Stock Situation" shall have the meaning specified in Clause 8.2.4.
- 1.36. "Party(ies)" shall have the meaning defined in the License and Distribution Agreement.
- 1.37. "Person Day" shall mean eight (8) hours work by a representative of GW qualified to assist in transfer of the Manufacturing Know-How.
- 1.38. "Products" shall have the meaning defined in the License and Distribution Agreement.
- 1.39. "Qualified Person" (or "QP") shall mean the person responsible for releasing or certifying each batch of the Products for sale.
- 1.40. "Quality Agreement" shall mean the agreement to be entered into between GW and the Authorised Contractors and the agreement to be entered into between GW and Bayer as required by the Governmental Authority relating to the Manufacture, storage or distribution of the Products to be attached hereto as **Appendix 3** in accordance with the requirements of Council Directive 2001/83/EEC.
- 1.41. "Specifications" shall mean the specifications applicable to the Products in accordance with a Marketing Authorisation, drafts of which are attached as **Appendix 2** to this Agreement.
- 1.42. "Supply Price(s)" shall mean the prices of the Products set out in **Appendix 1** to this Agreement.
- 1.43. "Technical Manager(s)" shall mean the person nominated in writing by Bayer and the person nominated in writing by GW who will be responsible for technical matters relating to the implementation of this Agreement (and such other persons as may from time to time be substituted by either Party for such persons).
- 1.44. "Territory" shall have the meaning defined in the License and Distribution Agreement.
- 1.45. "Trade Mark" shall mean such trade mark as Bayer may from time to time request GW to affix during Manufacture of the Products as set out in **Appendix 5** of the License and Distribution Agreement.
- 1.46. "UK Territory" shall have the meaning defined in the License and Distribution Agreement.
- 1.47. "Wholesale Dealer's Licence" shall mean the consent, licence or approval granted by a Governmental Authority in a Country required in order to supply medicinal products on a wholesale basis.

1.48. In this Agreement unless it is inconsistent with the context a reference to a statutory provision includes a reference to:

- (i) a statutory amendment, modification, substitution, consolidation or re-enactment (whether before or after the date of this Agreement);
- (ii) statutory instruments or subordinate legislation or orders made under the statutory provision; and
- (iii) statutory provisions of which the statutory provision is an amendment, modification, substitution, consolidation or re-enactment.

Unless the context of this Agreement otherwise requires,

- (i) words of one gender includes the other gender;
- (ii) words using the singular or plural number also include the plural or singular number respectively;
- (iii) the terms "hereof", "herein", "hereby" and derivative or similar words refer to this entire Agreement; and
- (iv) the terms "Clause" and "Appendix" refer to the specified Clause and Appendix of this Agreement.

When this Agreement refers to a number of days, unless otherwise specified (as business days in which case reference shall be made to normal UK working days), such number shall refer to calendar days. When this Agreement refers to a number of years and/or months, unless otherwise specified, such number shall refer to calendar years and/or months.

2. SUPPLIER'S OBLIGATIONS

2.1. In accordance with the terms of this Agreement and subject to Clause 16.2, GW shall Manufacture Bayer's requirements for the Products as ordered from time to time by Bayer in accordance with **Appendix 5** except in circumstances where GW is unable to supply Bayer with its requirements for the Products in accordance with this Agreement in which case the provisions of Clause 8.2 below shall apply.

2.2. GW shall Manufacture the Products at the Manufacturing Site(s) in accordance with Good Manufacturing Practice, the Specifications, the Manufacturing Licence, approvals of a Governmental Authority and all laws and regulations relevant to the Manufacture of the Products. Without prejudice to the foregoing, GW shall not change any Manufacturing Site in which the Products are Manufactured, or the Intermediates, process or plant used in the Manufacture of the Products without first notifying Bayer in advance in writing and obtaining Bayer's prior written consent which shall not be unreasonably withheld. In the event that Bayer responds to such written notice with questions or concerns, the Parties shall promptly meet and discuss any alternative course of action. Bayer acknowledges that GW, as the holder of the Marketing Authorisation, may be required to make any such changes without delay particularly if such changes relate to regulatory requirements or safety concerns.

2.3. Any changes in the Specifications for the Products must be agreed in writing by both Parties. Consent from Bayer shall not be unreasonably withheld or delayed.

3. ORDERS FOR PRODUCTS

3.1. Subject to Clause 16.2, Bayer shall purchase its entire requirement of Product from GW.

3.2. The provisions relating to orders for Products applicable to the UK Territory are set out in **Appendix 5.A**. The Parties undertake to negotiate in good faith as part of the Launch Conditions adjustments required to such provisions for countries added to the

Territory under the Territory Option Procedure set out in Clause 3 of the License and Distribution Agreement. Such adjusted provisions shall be attached as **Appendix 5.B etc.** for each Country concerned.

4. DELIVERY OF PRODUCTS

The provisions relating to Delivery of Products applicable to the UK Territory are set out in **Appendix 6.A**. The Parties undertake to negotiate in good faith as part of the Launch Conditions adjustments required to such provisions for countries added to the Territory under the Territory Option Procedure set out in Clause 3 of the License and Distribution Agreement. Such adjusted provisions shall be attached as **Appendix 6.B. etc.** for each Country concerned.

5. PASSING OF PROPERTY AND RISK IN PRODUCTS

- 5.1. The property and risk in the Products shall remain with GW until Delivery at which point they shall pass to Bayer.
- 5.2. Neither payment by nor passage of property or risk in the Products to Bayer shall be deemed to constitute acceptance of the Products, with respect to which the provisions of Clause 9.4 below shall apply.

6. PRICE OF PRODUCTS

- 6.1. The Supply Prices for the Products for the duration of this Agreement are set out in **Appendix 1** to this Agreement.
- 6.2. In the event that the Net Selling Price for any or all of the Products in a Country within the EEA declines by more than **twenty five** percent (**25%**) from the Net Selling Price at the time of Launch or **ten** percent (**10%**) below the lowest ex factory price of Products within other countries within the EEA, whichever is lower, the Parties shall promptly meet and discuss with a view to agree upon a revised Supply Price during the period of the reduced Net Selling Price. In the event of a decline in the Net Selling Price for a Product resulting in the Supply Price falling below GW's cost of Manufacture for the Products, the Parties shall promptly meet and discuss with a view to agree upon a revised Supply Price during the period of the reduced Net Selling Price. GW shall not be obliged to supply Bayer at a price below its cost of Manufacture with the exception of supplies of goods free of charge specified in **Appendix 1.C**.

7. INVOICE AND PAYMENT

- 7.1. The following terms shall apply:
 - 7.1.1 Upon Delivery, GW shall raise an invoice as to total amount due assuming the Products are sold at the Estimated Supply Prices; such invoice shall be faxed or e-mailed at the invoice date to Bayer with a following hard copy by post.
 - 7.1.2 Bayer shall undertake the following reconciliations per Commercial Year: (a) a reconciliation of amounts at the end of September each year and (b) a reconciliation of amounts at the end of the third quarter of each Commercial Year, both based on amounts invoiced at the Estimated Supply Prices and the Net Sales made during the period between each reconciliation. Bayer shall send the full details of the reconciliation to GW within forty-five (45) days of the end of each reconciliation period. Any underpayments shall be paid to GW against the provision by GW of an invoice in respect of such sum and any overpayment made by Bayer shall be repaid by GW sent with an accompanying statement. Payments to be made to either Party shall be made within sixty (60) days following the reconciliation.
 - 7.1.3 **Appendix 1.C** shall apply in the event that Product is sold to wholesalers and/or pharmacies in the Territory by authorised wholesalers and/or retailers

importing Product from outside the Territory provided that (a) Clause 7.1.3 shall not apply as long as (i) Bayer Sales are above 95% of IMS Sales within two reconciliation periods (understood as a full twelve (12) month period) mentioned in Clause 7.1.2 above and/or (ii) Net Sales are equal to or exceed the Net Sales in each Commercial Year detailed in **Appendix 1**, and (b) this Clause 7.1.3 shall cease to apply if Bayer exercises its Territory Option according to Clause 3 for the entire EEA.

- 7.2. Each invoice issued by GW hereunder in each Country shall specify:
- (a) the order number;
 - (b) the Estimated Supply Prices and Supply Price percentage in respect of the Products Delivered;
 - (c) the Batch Number or Order Reference of the Products Delivered;
 - (d) the quantity of the Products Delivered;
 - (e) the currency (provided that the Parties shall in good faith agree on the currency applicable to the invoices relating to each of the countries within the Territory); and
 - (f) the amount of VAT (as defined in Clause 7.5 below (if any)) due in respect of the invoiced amount.
- 7.3. Subject to Clause 7.5 below, payment with respect to each Country shall be made within thirty (30) days after the date of the invoice.
- 7.4. Bayer shall provide to GW on a monthly basis details of its Gross Sales and Net Sales in each Country and on a Product by Product basis to enable GW to verify the same within thirty (30) days from the end of each month.
- 7.5. All amounts in this Agreement are stated exclusive of Value Added Tax or other sales tax applicable in any Country or the Territory ("VAT"). If VAT, which is or may become properly payable or chargeable in respect of the payments, becomes payable by Bayer, then GW will promptly provide a valid VAT invoice to Bayer. If the VAT charged to and paid by Bayer is subsequently refunded by any relevant fiscal authorities to GW, then such refund shall be promptly forwarded to Bayer with a valid VAT credit note.
- 7.6. Bayer shall keep and shall cause its Affiliates to keep complete and accurate records of all Gross Sales and Net Sales of the Products in each Country and GW shall have the right, at GW's expense, through a certified public accountant or like person reasonably acceptable to Bayer, to examine such records during regular business hours during the life of this Agreement and for six (6) months after its termination; provided however that such examination shall not take place more often than once a year and shall not cover such records for more than the preceding two (2) years and provided further that such accountant shall report to GW only as to the accuracy of Net Sales. All such costs and expenses in connection with performing any such examination shall be paid by GW unless the examination discloses at least a **two (2%)** per cent shortfall, in which case Bayer will bear the full cost of such examination.
- 8. FAILURE TO SUPPLY; SECURITY OF SUPPLY**
- 8.1. Bayer shall notify GW as soon as reasonably practicable if there is an incomplete Delivery in any Country having regard to the permitted margin of **10% (ten percent)** variance in the Firm Order quantities as detailed in **Appendix 5** in accordance with the terms of this Agreement. If GW is notified by telephone or in person then such notification shall be confirmed by Bayer in writing. The alleged incomplete Delivery shall then be promptly investigated by the Parties and in the event that it is established that Delivery is in fact incomplete, GW shall then be obliged to rectify the

incomplete consignment within twenty (20) business days, from the later of the date of written notification or the Parties reasonably establishing that that Delivery is in fact incomplete.

- 8.2. If GW is unable, or anticipates that it will be unable, to supply the Products in accordance with any Firm Orders or Semi-Firm Orders placed in accordance with **Appendix 5** for any reason other than for reasons set out in Clause 16 of the Licence and Distribution Agreement incorporated by reference to this Agreement by Clause 19 of this Agreement, the following provisions shall apply:

8.2.1 In respect of the Products for which permitted shelf life is less than **eighteen (18)** months, GW shall, as soon as it becomes aware of the fact, give written notice to Bayer of the reasons for the shortfall.

8.2.2 In respect of the Products for which permitted shelf life is equal or greater than **eighteen (18)** months, GW shall, as soon as it becomes aware of the fact, and in any event not less than fourteen (14) days before the due Delivery date, give written notice to Bayer of the reasons for the shortfall. Bayer shall notify GW in the event that its stock levels fall below the forecasted level.

8.2.3 Upon service of the notice referred to in Clauses 8.2.1 and 8.2.2 above, the Parties shall enter into discussions in good faith with a view to alleviating its effects or agreeing alternative supply arrangements.

8.2.4 Clauses 8.2.5 to 8.2.9 shall only apply where Bayer can demonstrate to the reasonable satisfaction of GW that Bayer will as a result of such inability to supply be out of stock or where Bayer reasonably anticipates being out of stock of the Products during the period for which GW, other than for reasons of delay caused by the acts or omissions of a Governmental Authority, reasonably anticipates that supply of the Products by GW will be interrupted ("Out of Stock Situation"). For the avoidance of doubt, Clauses 8.2.4. to 8.2.7 shall not apply where Bayer is out of stock due to market demand being in excess of the Firm Order or Semi-Firm Order quantities or where the Out of Stock Situation arose as a result of Bayer not exercising prudent stock management disciplines.

8.2.5 Should the Parties have failed to have agreed remedial action in accordance with Clause 8.2.3 during a period of sixty (60) days and Bayer is or reasonably anticipates being out of stock during the continuing period of interruption reasonably anticipated by GW, then Bayer shall be entitled to take over the partial or total Manufacture of the Products.

- (i) Bayer shall have the right either to manage that stage of the Manufacture currently undertaken by one or more of the Authorised Contractors or GW or alternatively assume the Manufacture itself of that part of the Manufacturing process and this Agreement shall be amended appropriately to reflect the revised arrangements during which period Bayer shall assume the Licence to Manufacture, subject to appropriate regulatory approvals being obtained.
- (ii) Depending upon whether Bayer has partial or total responsibility, GW shall become a contractor to Bayer in respect of the first stage of the Manufacturing process and if necessary, at Bayer's request GW shall assign its contracts with the Authorised Contractors to Bayer.
- (iii) The Manufacturing Licence shall become a sole licence as provided by Clause 2.4 of the Licence and Distribution Agreement.
- (iv) During the period of Manufacture by Bayer the Supply Prices shall be adjusted by good faith negotiation between the Parties enabling GW to

receive payment for the Licence to Manufacture based on the Supply Prices but subject to deduction of Bayer's costs of Manufacture so as to reflect the reasonable costs of Manufacture incurred by Bayer under the revised Manufacturing arrangements required to fulfil Bayer's sales volumes of the Products for the Territory, and GW's costs relating to the Manufacture of the Products previously included by GW within the Supply Prices.

- 8.2.6 GW shall give reasonable assistance to Bayer in transferring Manufacturing to such location or third party as Bayer shall nominate from GW and any of the Authorised Contractors to Bayer on terms of confidence, including reasonable assistance with transferring GW's Manufacturing Know-How for Manufacture and Confidential Information provided that such third party shall be obliged to maintain the same degree of confidentiality as Bayer under this Agreement. In relation to the transfer of Manufacturing Know-How, GW shall provide ten (10) Person Days of assistance at no cost to Bayer. This Clause 8.2.6 shall apply mutatis mutandis whereby Bayer, at the end of the period referred to Clause 8.2.5 above shall retransfer Manufacturing to GW or any of the Authorised Contractors.
- 8.2.7 The Manufacturing Know-How and any other information supplied for the purposes of Manufacture shall be treated by Bayer as Confidential Information of GW and Bayer shall not disclose the same except to the third party referred to in Clause 8.2.6. Bayer shall procure that all third parties to which it discloses any such Confidential Information shall also keep it confidential on terms no less onerous than those contained in Clause 8 of the License and Distribution Agreement.
- 8.2.8 In circumstances where the Parties have reasonably agreed that the continuing period of interruption has ceased and GW wishes to assume the Manufacture of the Products and can reasonably demonstrate to Bayer that it is able to Manufacture the Products to a quality equivalent to that Manufactured by Bayer at the time of cessation, GW shall provide one (1) month's notice to Bayer during which period the Parties shall define the process for Manufacture to Bayer so as to ensure no interruption in supply to patients. Upon the resumption of Manufacture by GW, the rights granted under Clause 8.2.5 shall automatically cease and Bayer shall promptly return all Manufacturing information together with such Confidential Information and information provided for the purposes of Manufacture. Bayer shall use its best endeavours to assign back to GW those contracts previously assigned to Bayer with the Authorised Contractors for the purposes of Manufacture by Bayer.
- 8.2.9 Any Manufacture undertaken by Bayer under the provisions of Clause 8.2.5 of this Agreement would be to fulfil Bayer's requirements for the sale of the Products in the Territory. On request by GW, Bayer agrees to supply the Products on reasonable commercial terms to GW or any other party for sale outside the Territory.
- 8.3. Notwithstanding Clause 8.2 above, the Parties intend to minimise the effect of an Out of Stock Situation and to ensure a continuous and adequate supply of the Product to Bayer in accordance with the terms of this Agreement.
- 8.3.1 GW has prior to the Effective Date qualified and validated GW's site in Kent, Humber VHB's site and Botanix's site for the growing and extracting stage of the Manufacture of the Product and hereby agrees to qualify and validate, at its own cost and expense, a second site for extraction stage of the

Manufacture of the Product (the "Second Site") as soon as practicable after the Effective Date.

- 8.3.2 GW shall, within thirty (30) business days after the Second Site and – at Bayer's option – a second site for the packaging to be established by Bayer (the "Bayer Site") are qualified and validated, apply for and effect any changes, variations or amendments to any relevant Marketing Authorisation that may be required to ensure that the Second Site and the Bayer Site can be used immediately upon the occurrence of an Out of Stock Situation. Bayer shall provide to GW all reasonable co-operation and assistance that may be necessary to enable GW to carry out its obligations hereunder.
- 8.3.3 GW shall during the term of this Agreement at its own cost and expense prepare, maintain and update the Manufacturing Know How as necessary and as agreed between the Parties so that the Manufacturing Know How is at all times capable of being used to Manufacture or have Manufactured Product. If Bayer specifically requests at any time that the Manufacturing Know How be updated GW shall promptly do so at Bayer's cost and expense.
- 8.4. In the event of an Out of Stock Situation or where Bayer would be entitled to terminate this Agreement pursuant to Clause 16.4 upon GW compounding or making any arrangement with its creditors or having a receiver appointed over all or any part of its assets or going into liquidation (whether voluntary or otherwise) save as part of a bona fide reconstruction not involving insolvency or shall take or suffer to be taken any similar action as a result of its liability to pay its debts or its insolvency, then:
 - 8.4.1 the Manufacturing Know How shall be immediately released to Bayer;
 - 8.4.2 Bayer shall be granted a non-exclusive, royalty free, sub-licensable, irrevocable licence to use the Manufacturing Know How (as updated from time to time) to Manufacture or to have Manufactured the Product;
 - 8.4.3 GW shall in accordance with legislative and regulatory requirements transfer to Bayer or its nominee ownership of the Marketing Authorisation in the Territory. In the event that such transfer is not possible GW shall use reasonable endeavours to ensure that Bayer has the benefit of the Marketing Authorisation, and, to this end, consents to any Governmental Authority cross-referencing the data and information on file with any Governmental Authority as may be necessary to facilitate the granting to Bayer of second marketing authorisations in respect of the Product in the Territory; and
 - 8.4.4 GW agrees to complete whatever other procedures are reasonably necessary in relation to the same to enable Bayer (either itself or in conjunction with a third party) freely to Manufacture and sell the Product in the Territory. For this purpose, GW shall execute and deliver to Bayer on the Effective Date a power of attorney in the form attached hereto in **Appendix 4**. Bayer undertakes only to complete and use such power of attorney in the circumstances, if (a) Bayer notified GW in writing of such intended use of the power of attorney, and (b) GW did not provide the reasonably requested support promptly after receipt of such request, and (c) Bayer attempted to discuss and negotiate with GW in good faith a timely resolution, provided that such negotiation period shall not exceed ten (10) business days and, if longer, the period Bayer can reasonably wait until use of the power of attorney is required.

9. QUALITY OF PRODUCTS

- 9.1. GW shall ensure that each Delivery of the Products supplied to Bayer hereunder is accompanied by a Certificate of Analysis. The Products will be supplied in accordance with the requirements of the Quality Agreement between GW and Bayer and in compliance with the agreed Specifications and Acceptable Quality Levels

(AQLs) detailed therein. Bayer shall notify GW of any visually apparent defects in any quantity of the Products Delivered to it within eight (8) business days of the date of Delivery to Bayer's premises. Within eight (8) business days of receipt of the Products from GW ordered pursuant to this Agreement, Bayer shall have the right but not the obligation, to analyse or cause to be analysed, any shipment of the Products. If in Bayer's reasonable opinion such analysis reveals any defects in such shipment by reference to the Specifications, Bayer shall immediately notify GW in writing thereof and send samples of that shipment to GW.

- 9.2. Bayer shall notify GW in writing within thirty (30) business days of its visual inspection (or within five (5) business days of becoming aware of any Latent Defects) of any complaints or issues arising as to the quality of the Products and send a sample of the defective Product(s) to GW. Additionally if a potential defect may constitute a hazard to patient safety such reporting should be within twenty four (24) hours of Bayer becoming aware of such defect, initially by telephone and promptly followed up in writing.
- 9.3. If GW is satisfied and has agreed that the relevant shipment of the Products is defective due to GW's default, Bayer shall dispose of such defective shipment of the Products as GW shall direct in writing and at GW's reasonable expense and GW shall use its reasonable efforts to supply new Products to Bayer as soon as reasonably possible thereafter PROVIDED THAT if the Parties fail to agree whether the shipment is defective or, if defective whether the defect is due to GW's default, the matter shall be referred to the Laboratory to be tested in the presence of representatives of both the Parties within fourteen (14) days to determine whether the shipment complies with the Specifications. The costs of such testing shall be borne by GW in the event it is established by the Laboratory that the Products fail to comply with the Specifications. In circumstances where it is established by the Laboratory that the Products are within the Specifications Bayer shall bear the costs of such testing. If, notwithstanding the foregoing provision, GW has invoiced Bayer in respect of such Products GW shall credit BAYER with the value of such invoiced Products if the Products fail to comply with the Specifications. Pending the outcome of any such dispute, GW shall use its reasonable efforts to ensure that Bayer remains in stock of the Products.
- 9.4. Subject to Clause 9.2, in the absence of any notification in writing to the contrary by Bayer within twenty (20) business days of receipt of the Products by Bayer the Products shall be deemed to have been accepted by Bayer.
- 9.5. GW shall provide a reasonable volume of samples of the Products to Bayer for quality assurance purposes on a free of charge basis.

10. SUPPLY AND STORAGE OF MATERIALS AND PRODUCTS

- 10.1. GW shall be solely responsible for ordering the required quantities of Intermediates. GW shall purchase and use only Intermediates and use such procedures in the Manufacture of the Products, which comply with the requirements of the Marketing Authorisations and with Good Manufacturing Practice and where such Intermediates otherwise are fit for purpose. GW shall at all times ensure that all Intermediates and Products Manufactured by GW pursuant to this Agreement are stored and warehoused in compliance with the Manufacturing Licence and otherwise in accordance with Bayer's reasonable written requirements. GW shall operate a warehousing system which identifies all the Products according to type and status. GW shall comply with any reasonable written requirements of Bayer or a Governmental Authority relating to the security of controlled drugs and cold storage.
- 10.2. GW shall be responsible for ensuring that where Manufacture is contracted out to Authorised Contractors, such Authorised Contractors comply with the requirements of Clause 10.1 above.

- 10.3. Bayer or its Affiliates shall comply with the requirements of the Manufacturing Licence or any Wholesale Dealers Licence(s), GMP and otherwise in accordance with GW's reasonable written requirements in respect of the storage and warehousing of the Products. Bayer shall comply with any reasonable written requirements of GW or a Governmental Authority relating to the security of controlled drugs and cold storage.
- 10.4. Bayer shall be responsible for ensuring that, where warehousing, transport, storage and distribution is contracted out, its contractors will comply with the requirements of Clause 10.3 above.

11. MARKETING AUTHORISATIONS

- 11.1. GW undertakes to observe and comply with all requirements of the valid Marketing Authorisations and any amendments or additions thereto in so far as they apply to the Manufacture of the Products hereunder and have been disclosed by GW to Bayer or its Affiliates in writing.
- 11.2. GW undertakes to inform Bayer or its Affiliates of any amendments or additions to the Marketing Authorisations which are relevant to the performance by Bayer of its obligations under this Agreement at which time the Agreement shall be amended in accordance with the amendments or additions implemented by GW in the Manufacture of the Products to the extent required.

12. MANUFACTURE OF PRODUCTS

- 12.1. GW shall at its own cost obtain and throughout the term of this Agreement maintain all necessary Manufacturing Licences or procure that Manufacturing Licences are maintained by the Authorised Contractors and perform its, or procure the performance by the Authorised Contractors of their, obligations hereunder in accordance with the Manufacturing Licences and all applicable laws and legislation in the Territory. GW shall supply a copy of each such Manufacturing Licence to Bayer or its Affiliates free of charge on written request.
- 12.2. All personnel employed by GW or the Authorised Contractors in the Manufacture of the Products shall be suitably trained, experienced and competent for their respective functions with particular reference to performing their assigned duties in accordance with Good Manufacturing Practice. GW shall, or shall procure that the Authorised Contractors shall, keep written records of the training provided to such employees, copies of which shall be made available to Bayer on request.
- 12.3. GW covenants with Bayer not at any time during the term of this Agreement to carry out any other activities that may, to GW's knowledge at the time of the said activity, prejudice the quality, safety or efficacy of the Products.

13. LABELLING AND ARTWORK

- 13.1. GW shall Manufacture the Products incorporating such design, Trade Mark and artwork as may be agreed in writing from time to time between the Parties.
- 13.2. GW shall bear the initial costs in respect of preparation of artwork and labels for the Products for Launch in the UK. Bayer shall bear any subsequent costs for changes to artwork or labelling requested by Bayer during the term of this Agreement. Bayer shall bear the write-off costs in respect of packaging components, resulting from artwork or labelling changes requested by Bayer, provided that the volume of such components is no greater than that required to fulfil Bayer's then forecast Firm and Semi-Firm requirements for the affected Products.
- 13.3. GW shall bear the artwork and labelling costs arising from any artwork and labelling changes instigated by the Governmental Authority or arising for regulatory reasons implemented by GW as holder of a Marketing Authorisation.

- 13.4. Save as required by any applicable law or regulation and as provided for by Clause 11.2 of the Licence and Distribution Agreement, GW will not affix to any of the Products any trade mark (other than the Trade Mark unless otherwise agreed by GW and Bayer), business names, labels or signs other than as may previously have been approved in writing by Bayer (Bayer's agreement not to be unreasonably withheld or delayed).
- 13.5. Save as required by any applicable law or regulation, GW shall not make any change to the layout, content or appearance of any labelling of any of the Products without the prior written consent of Bayer (Bayer's agreement not to be unreasonably withheld or delayed).

14. HAZARDS

GW will inform and keep Bayer informed of all hazards, regulations and guidance (statutory or otherwise) which GW knows or believes to be associated with the use, handling, storage labelling, transport, treatment and disposal of the Products and GW will ensure that relevant consignments are safe, packaged, labelled so as to prevent any health risk to persons, property or the environment and properly marked with the appropriate internationally recognised danger symbols and that prominent hazard warnings appear on all packages and documents.

15. WARRANTIES AND INDEMNITY

- 15.1. GW hereby represents and warrants that:

- (a) the Products supplied hereunder shall conform to the Specifications; and
- (b) the Products shall be Manufactured in accordance with Good Manufacturing Practice and the processes set out in this Agreement;
- (c) it will convey good title to the Products supplied hereunder and that the Products will be delivered free from any lawful security, interest, lien or encumbrance.

- 15.2. Bayer hereby represents and warrants that the Products shall be stored and distributed in accordance with GDP and the processes set out in this Agreement.

16. DURATION AND TERMINATION

- 16.1. This Agreement shall continue for fifteen (15) years ("Initial Term"), unless (a) the License and Distribution Agreement is terminated earlier in which case this Agreement shall also terminate or (b) earlier terminated in accordance with this Clause 16. This Agreement shall continue for successive twelve (12) month periods thereafter unless Bayer terminates by serving at least twelve (12) months' written notice prior to the end of the Initial Term and prior to the end of each successive calendar year after such Initial Term.

- 16.2. Notwithstanding Clause 16.1, the obligation of Bayer according to **Appendix 5** to purchase its entire requirement of Product from GW shall only apply for a period of **five (5)** years from Launch of the Products in the Territory.

During the Initial Term, the following shall apply: Upon written request of GW of not less than **eighteen (18)** months prior to the end of such period, the Parties shall meet and discuss whether Bayer in its sole discretion wants to agree on a renewal for a period of further **five (5)** years on the same terms set forth above. Should Bayer agree to such renewal, the Parties shall agree on forecast for sales which shall form the basis for the calculation of the supply prices, as set out in **Appendix 1**. Should Bayer not agree to such renewal in writing within **six (6)** months following receipt of the request by GW, GW has the right but not the obligation to terminate this Agreement and the Licence and Distribution Agreement with a **eleven (11)** month written notice to be provided prior to the expiration of the respective **five (5)** year term. For the

avoidance of doubt, in the event that GW does not request a meeting in writing prior to the said **eighteen (18)** month period or does not provide the said eleven (11) months' written notice, the provisions contained in this Agreement relating to the obligation of Bayer to purchase the entire requirement of Product and the right of GW to terminate the Agreement shall be deemed to be deleted after expiry of the said **five (5)** year period and the Agreement shall continue thereafter in accordance with all remaining terms.

- 16.3. If either party to this Agreement shall commit any material breach excluding failure to supply or delayed in Delivery of this Agreement and not remedy the breach within sixty (60) days of notice from the other Party so to do (if capable of remedy) the other Party may terminate this Agreement immediately by notice in writing to the Party in breach.
- 16.4. If either Party shall compound or make any arrangement with its creditors or have a receiver appointed over all or any part of its assets or go into liquidation (whether voluntary or otherwise) save as part of a bona fide reconstruction not involving insolvency or shall take or suffer to be taken any similar action as a result of its liability to pay its debts or its insolvency it shall promptly so notify the other Party in writing giving particulars of the circumstances whereupon the other Party may terminate the Agreement immediately by notice (for the avoidance of doubt, Bayer may terminate the Agreement upon the occurrence of any of the circumstances described in this Clause 16.4 notwithstanding that GW may not have given notice to Bayer as required).
- 16.5. If Bayer ceases to sell the Products for a significant technical or regulatory reason (and a significant technical or regulatory reason for these purposes is agreed to include, without limitation, any adverse technical or regulatory impact for Bayer that is or may be attributable in whole or in significant part to the use by Bayer of the Product(s)) either Party may terminate this Agreement on giving six (6) months' notice provided, however, that the Party learning of such technical or regulatory impact shall immediately notify the other of the same, and, as appropriate, work together diligently and in good faith to remedy such impact during the notice period or such other period as the Parties shall agree in writing.

17. CONSEQUENCES OF TERMINATION

- 17.1. On termination of the Agreement GW shall, not later than seven (7) days after Bayer's request but at Bayer's cost:
- (a) Bayer shall notify GW of the amount of the Products in its possession and Bayer shall be permitted to sell those amounts of the Products for a period of up to one hundred (180) days after termination provided that Bayer shall pay the payments thereon at the time provided herein;
 - (b) each Party to return to the other Party all other documents provided to it, other than those documents provided as part of the Manufacturing Information if Bayer has assumed its rights to Manufacture under Clause 8.2.5;
 - (c) ensure that all copies (save one (1) for the purposes of demonstrating compliance with this Agreement) of Confidential Information, know-how and/or any information of a technical nature relating to the Products and the Manufacture of the Products or of a confidential nature and supplied by one Party to the other is returned or destroyed by GW at Bayer's option or Bayer at GW's option; and
 - (d) Bayer shall pay all sums due to GW under any invoices provided by GW in respect of supply of the Products hereunder.

- 17.2. On termination of the Agreement Bayer shall, not later than seven (7) days after GW's request return to GW all other documents provided to Bayer by GW; with the exception of any records required to be kept for the purposes of complying with GMP.
- 17.3. Termination of this Agreement or withdrawal of any of the Products from the Agreement shall be without prejudice to the continuation in force of Clauses 7 of this Agreement and Clauses 8 and 17 of the License and Distribution Agreement and any other obligations otherwise provided by this Agreement which have accrued. In addition, any other provision required to interpret and enforce the Parties' rights and obligations under this Agreement shall also survive, but only to the extent required for the full observation and performance of this Agreement. Furthermore, GW agrees to provide Bayer with all reasonable support with respect to any investigation reasonably required by Bayer or any Governmental Authority with respect to Manufacture of the Products carried out prior to such termination or withdrawal even after such termination or withdrawal provided that GW's reasonable costs in providing such assistance shall be at Bayer's cost unless the Agreement has been terminated by Bayer for a reason contained in Clause 17.2 above.
- 17.4. Termination or expiry of this Agreement shall not release either Party hereto from any liability or right of action which at the time of termination has already accrued to either Party hereto or which may thereafter accrue in respect of any act or omission prior to such termination. Such rights shall include but not be limited to the recovery of any monies due hereunder.

18. AUTHORISED CONTRACTORS

- 18.1. As at the Effective Date, GW has appointed and executed binding agreements with Authorised Contractors to carry out its obligations under this Agreement.
- 18.2. Notwithstanding Clause 10.2 above, GW shall remain liable to Bayer for the performance of all its obligations and shall ensure that the contracts between GW and such Authorised Contractor comply with and reflect the provisions of this Agreement. In particular, such contracts shall contain (a) a Quality Agreement, (b) the prior written approval of Authorised Contractors in respect of the assignment of the contracts to Bayer under Clause 8.2.5 above and (c) a satisfactory level of protection in the event an Authorised Contractor compounds or makes an arrangement with its creditors or has a receiver appointed over all or any part of its assets or goes into liquidation (whether voluntary or otherwise) save as part of a bona fide reconstruction not involving insolvency or shall take or suffer to be taken any similar action as a result of its liability to pay its debts or its insolvency during the term of this Agreement, including, but not limited, to GW's first right to acquire all or any of the facilities, equipment, materials and other assets and consumables used by Authorised Contractor in the performance of services relating to Products. It is understood by Bayer that such protection is always at the discretion of the administrator or receiver of the Authorised Contractor.
- 18.3 GW shall not without the prior written consent of Bayer (which shall not be unreasonably withheld or delayed) appoint any other contractor during the term of this Agreement to carry out its obligations hereunder. Clauses 18.1 and 18.2 shall apply accordingly.

19. REFERENCE


Clauses 8 and 15 to 24 of the License and Distribution Agreement shall also apply to this Supply Agreement.

IN WITNESS WHEREOF, the Parties, through their authorised officers, have executed this Agreement as of the date first written above.

Signed for and on behalf of
BAYER AG

Leverkusen, 20 May 2003


Dr. Dietrich Brocks
Head of International Cooperations
and Licensing Europe


Dr. Dirk Ehle
Law and Patents

Signed for and on behalf of
GW PHARMA LIMITED

Salisbury, 20 May 2003


Justin Gover
Managing Director


David Kirk
Finance Director

APPENDIX 1

THE SUPPLY PRICES

For Net Sales in each Commercial Year the Supply Prices are to be calculated as **forty percent (40%)** of Net Selling Price. For Net Sales in each Commercial Year above **fifty percent (50%)** of the Net Sales forecasts below for that Commercial Year, **five percent (5 %)** of the Net Selling Price shall be added to the Supply Price for the incremental quantity (for the avoidance of doubt, in respect of such incremental sales, the Supply Price is **forty five percent (45%)** of the Net Selling Price). Upon submission to the Medicinal Products Regulatory Authority to include the indication relief of cancer pain to the Indications the parties shall agree to an increased Net Sales Forecast to reflect the Net Sales for all Indications.

A. United Kingdom

Sales in the Territory of the Products

<u>Commercial Year</u>	<u>Net Sales in £'000</u>
1	8,141
2	17,851
3	25,130
4	33,064
5	35,023
6	37,421
7	38,211
8	38,335
9	38,348
10	38,361

B.

Agreed Net Sales forecasts for other Countries to be added to this Appendix in accordance with Clause 3 of the Licence and Distribution Agreement.

C.

In the event Bayer Sales within two reconciliation periods (understood as one twelve (12) month period) fall beneath the following percentages of IMS Sales Bayer shall receive from GW quantities of Product free of charge ("Free Goods") according to the table below. Such Free Goods shall be calculated as a percentage of Products sold by Bayer in each Country during the previous annual reconciliation period.

Bayer Sales as a percentage of IMS Sales	Percentage of Bayer Sales as Free Goods
95-80%	5%
79-60%	10%
59-50%	15%
49-40%	20%
39-25%	25%
<25	30%

The Free Goods shall be delivered within the next ordered quantities scheduled according to **Appendix 5** following the reconciliation.

APPENDIX 2

DRAFT SPECIFICATIONS OF PRODUCTS

<u>Test</u>	<u>Test Method</u>	<u>Limits</u>
Appearance:	In-house	Pale yellow / brown clear solution
Appearance of Container:	In-house	Amber glass vial with sealed on pump & actuator No visual evidence of leaking
Volume Variation:	In-house	Average net content is NLT labelled amount & net content of any single container NLT 90% of labelled amount.
Identification: - A	TLC	Spots have characteristic R_f and colours, compared with THC and CBD standards Positive for THC and CBD
- B	HPLC/UV	
Assay: - THC Content - CBD Content	In-house (HPLC/UV)	24.3 - 29.7mg/ml 22.5 - 27.5mg/ml
Other Cannabinoids: - CBN Content - Others (total) [THCA, CBC, CBDA, CBG, THCV]	In-house (HPLC/UV)	0.2 - 2.0% of the THC + CBD content 3.0 - 9.0% of the THC + CBD content
Spray Content Uniformity:	In-house	9 out of 10 actuations between 75-125% of average delivery for THC & CBD and none outside 65-135%

The drug product is a solution containing THC and CBD botanical extracts. The specification for the control of 27mg/ml THC and 25mg/ml CBD BDP has been provided.

Please note:

The BDP specification stated above is the proposed specification for commercial release of the finished product. Batch Analysis has been provided to show compliance with the existing in-house BDP specification. The specification for 'Other Cannabinoids' has been extended significantly as a result of the availability of additional qualitative standards that allow the identification of additional cannabinoids.

Analytical Procedures: The analytical procedures used in the control of BDP are in-house methods.

In-house methods:

- Appearance
- Volume Variation
- Identification (A - TLC)
- Identification, Assay and Other Cannabinoids
- Spray Content Uniformity (based on Ph.Eur. methodology for sampling & limits)

APPENDIX 3
QUALITY AGREEMENT

- to be attached -

APPENDIX 4
POWER OF ATTORNEY

THIS DEED is made on 20 May 2003 by GW Pharma Limited whose registered office is at Porton Down Science Park, Salisbury, Wiltshire SP4 0JQ ("GW")

WHEREAS, GW has become a party to an agreement of even date herewith with Bayer AG (the "Agreement") in relation to the supply of a medicinal product and is obliged, inter alia, pursuant to Clause 8.4.4 thereof to deliver to Bayer AG a power of attorney in the form of this Deed.

NOW THIS DEED WITNESSES AS FOLLOWS:

1. Appointment of Attorney

GW hereby irrevocably and unconditionally (and by way of security of the performance of its obligations under the Agreement) appoints Bayer AG as its attorney (the "Attorney") to execute and do in its name or otherwise and on its behalf all documents, acts and things which the Attorney shall in its absolute discretion consider necessary or desirable in order to implement GW's obligations under clause 8.4 of the Agreement.

2. Ratification

GW undertakes to ratify whatever Bayer AG, as its Attorney, shall lawfully do or cause to be done in accordance with this Power of Attorney.

3. Governing Law

This Deed shall be governed and construed in accordance with the laws of England.

IN WITNESS whereof GW Pharma Limited has executed this Deed the day and year first before written.

EXECUTED as a Deed by GW Pharma Limited

Acting by

Director

Director/Secretary

APPENDIX 5

ORDERS FOR PRODUCTS

The following provisions apply under the provisions of Clause 3 in relation to the following countries of the Territory:

PART A

UK Territory

1. Bayer or its Affiliate shall provide to GW by the first Day of each month with a forecast APPENDIX of demand for the Products for each Country for at least the following eighteen (18) months ("Forecast APPENDIX"). The Forecast APPENDIX shall be updated monthly. In addition and subject to Clauses 2 – 7 below, Bayer shall provide GW during the fourth (4th) quarter of each calendar year with an annual forecast for the following calendar year which shall serve as a basis for the ordering system and shall not contain binding orders but quantities corresponding to the first twelve (12) months of the Forecast APPENDIX. Against this annual forecast Bayer will formally call off the respective quantities.
2. The quantities of the Products detailed in the first **four (4)** months of each Forecast APPENDIX ("Firm Order Period") shall (to the extent set out in **Appendix 5**) constitute a binding commitment on Bayer in relation to each Country to purchase such quantities of the Products from GW on the terms and conditions of this Agreement ("Firm Order"). With respect to each Country Bayer shall issue to GW a Firm Order for the quantity of the Products ordered for the Firm Order Period not later than **ten (10)** weeks prior to the Delivery date specified therein. The Firm Order shall specify the arrangements for Delivery of the Products. The Parties agree that all Firm Orders for the Products placed by BAYER with GW under this Agreement shall be supplied on the terms of this Agreement.
3. In determining Firm Order quantities for each Country Bayer shall take account of Manufacturing batch sizes, such that Bayer must accept as fulfilled orders actual quantities of Products Manufactured which are within a margin of **+/- ten (10)** percent of the Firm Order quantity. In the event GW supplies quantities in an aggregated shortfall of more than **thirty (30)** percent, then GW shall be obliged to make up such shortfall quantities as early as possible. The initial Manufacturing batch sizes for the Products shall be **16,500 (sixteen thousand five hundred) vials (8ml gross vials)** and **9,200 (nine thousand two hundred) vials (14ml gross vial)** and any variance to this quantity shall be notified by GW to Bayer in writing.
4. The volumes detailed in the next **four (4)** months after the Firm Order Period of the Forecast APPENDIX (the "Semi-Firm Order Period", being months **5 to 8**) shall represent a semi-firm order for each Country, meaning that Bayer shall be obliged to order and purchase at least **70%** of the initial forecast for any month **8** forecast. For the avoidance of doubt the initial forecast for any month **8** forecast may not vary by more than thirty percent by the time that forecast becomes a Firm Order. GW shall hold sufficient stocks of intermediates to meet the forecast requirements during the Firm Order Period and up to **one hundred and thirty percent (130%)** of the forecast requirements detailed in the Semi-Firm Order Period. Both Parties shall conduct their businesses so as to minimise any stock write-offs. Bayer may ask GW for additional quantities to be manufactured and delivered by GW. GW shall use its reasonable efforts to comply with Bayer's additional demand. In any case GW shall give notice to

Bayer within ten (10) business days of the receipt of the written order of its ability to meet the additional quantity.

5. GW shall respond to each Firm Order received from Bayer within three (3) business days of receipt. The response shall include confirmation of the Delivery dates and quantity as set out in the Firm Order. In the event that discussion is required regarding the timings of production and Delivery then the relevant planning personnel from both Parties will negotiate in good faith and agree and confirm in writing an amended Forecast APPENDIX within four (4) business days of receipt by GW of the original Forecast APPENDIX except during the period 20th December to 6th January in each year when the periods of three (3) or four (4) business days referred to herein shall be replaced by eight (8) business days in each case.
6. It is understood that volumes detailed in relation to the remaining **ten (10)** months of the Forecast APPENDIX after the Firm Order Period and the Semi-Order Period constitute an estimate of the future Product requirement of Bayer and its Affiliates for each Country within the Territory and do not comprise any minimum purchase requirement or any binding commitment by Bayer or its Affiliates to purchase such volume of the Products.
7. Binding orders subject to approval in the Territory for Bayer's requirements of Launch Stocks shall be provided by Bayer for the UK within ten (10) business days of the Effective Date. The delivery date shall be agreed by the UK Country Commercialization Committee. Bayer shall notify GW in writing of the Delivery date for the Launch Stocks at least ten (10) weeks before due delivery date specified for Launch.

PART B

APPENDIX 6

DELIVERY OF PRODUCTS

The following provisions apply under the provisions of Clause 4 in relation to the following countries of the Territory:

PART A

UK Territory

1. GW shall procure that the Products Manufactured hereunder are Delivered in each Country in accordance with the provisions of this Agreement. The costs of Delivery of the Products from GW or the premises of its Authorised Contractor as appropriate to Bayer's nominated distribution centre or other nominated location in the Country in question shall be borne by Bayer.
2. With respect to Launch Stocks and for all the Products Manufactured with a maximum permitted shelf life of twelve (12) months, there shall be a minimum of ten (10) months' shelf life remaining on the Products at the date of Delivery requested by Bayer on each Bayer order. In the case of any of the Products with less than ten (10) months' shelf life, the Products shall be returned to GW at GW's reasonable cost and replaced with Product having the required shelf-life at no cost to Bayer, unless Bayer accepts these Products for sale.
3. In the event that the shelf-life permitted by a Governmental Authority applicable to a Country is extended beyond twelve (12) months or to any other period the Parties shall negotiate in good faith and agree in writing the revised shelf life remaining on the Products upon Delivery to Bayer and the date upon which the first Delivery shall be made of the Products with such extended shelf-life PROVIDED ALWAYS THAT at the date of Delivery requested by Bayer on each Bayer order the shelf life remaining on the Products at the date of Delivery shall be at least **seventy five percent (75%)** of the total shelf life available for the Products or **eighteen (18) months**. In the event that the said Governmental Authority approves an extension to the shelf-life beyond twelve (12) months or approval for the 14 ml vial (gross) size, the Parties shall develop an implementation and transition plan to minimise write-off costs for the 8 ml gross vial and to ensure minimum disruption to patients and any write-offs costs shall be shared equally. Bayer shall undertake to launch the 14 ml gross vial for the Products, upon agreement as to the transitional arrangements, and subject to approval by the Governmental Authority and availability of stocks of the Products from GW to satisfy Bayer's Firm Order requirements.
4. In the event of a delay caused by the acts or omissions of a Governmental Authority in a Country resulting in a delayed Launch beyond the Launch date to be agreed between the parties in writing and Bayer is not able to sell such part or all of the Launch Stocks, the Parties shall equally share GW's write-off costs of the destruction of any Launch Stocks of the Products calculated in accordance with **Appendix 5**. GW shall provide replacement stocks in respect of any destroyed Launch Stocks as soon as is reasonably practicable. If GW has invoiced Bayer with any proportion of such destroyed Launch Stocks GW shall credit Bayer with the invoiced value of that proportion of the Launch Stocks.
5. In the event that GW fails to deliver in response to the Firm Orders for the Products for a Country on the specified Delivery date by reason of delay, GW shall provide a

revised Delivery date. In the event that Delivery is more than ten (10) business days later than the original specified Delivery date, GW shall provide to BAYER an action plan to achieve the revised Delivery date. In circumstances where Delivery has not been achieved within twenty (20) business days from the original Delivery date and Bayer is able to demonstrate that it has thereby suffered a material stock shortage of the Products at its nominated distribution centre Bayer shall be entitled to a discount of the total invoiced Supply Prices for the affected delivery/ies for such late delivery commencing on the fifteenth (15th) Day from the original Delivery date on the following basis:

Number of business days Late	Discount in Supply Prices
15 - 30	2.5 %
31 - 40	5 %
> 40	10 %

For the avoidance of doubt the above discount rates shall not be applicable if the shortage of the Products is due to demand in excess of the Firm Orders or Semi-Firm Orders as the case may be.

PART B

AMENDMENT NUMBER 1
TO THE SUPPLY AGREEMENT

between GW PHARMA LIMITED ("GW") having its registered office at Porton Down Science Park, Salisbury, Wiltshire SP4 0JQ and BAYER HEALTHCARE AG, Division Pharma, having its registered office at Bayerwerk, 51368 Leverkusen, Germany ("Bayer")

WHEREAS, Bayer AG and GW executed a Supply Agreement as of the 20th day of May 2003;

WHEREAS, Bayer AG transferred its entire healthcare business including all contractual rights and obligations to its 100% subsidiary Bayer HealthCare AG with effect of October 1, 2003, as permitted in accordance with Clause 19 of the Supply Agreement and Clause 22.2 of the License and Distribution Agreement;

WHEREAS, Bayer decided to exercise its option under clause 3.1 of the License and Distribution Agreement for Canada;

WHEREAS, the Parties wish to agree upon the Supply Prices for Canada;

WHEREAS, in accordance with Clauses 3.2 and 4 of the Supply Agreement, the Parties will negotiate in good faith the provisions relating to orders for Products applicable to Canada as well as provisions relating to Delivery of Products applicable to Canada.

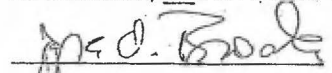
NOW, THEREFORE, THE PARTIES HEREBY AGREE AS FOLLOWS:

1. Appendix 1, Part B, for Canada is completed in the form attached to this Amendment.
2. This Amendment shall be executed in two counterparts, but shall not be effective until each party has executed at least one counterpart. Each counterpart shall constitute an original of this Amendment, but all counterparts shall together constitute but one and the same instrument.

IN WITNESS WHEREOF, the Parties, through their authorised officers, have executed this Agreement as of the date first written above.

Signed for and on behalf of
BAYER HEALTHCARE AG

Leverkusen, 4th November 2003



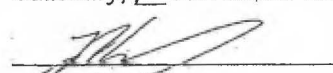
Dr. Dietrich Brocks
Head of International Cooperations
and Licensing Europe



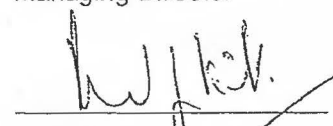
Dr. Alexander Bey
Law and Patents

Signed for and on behalf of
GW PHARMA LIMITED

Salisbury, 4th November 2003



Justin Gover
Managing Director



David Kirk
Finance Director

APPENDIX 1.B. for Canada

THE SUPPLY PRICES

In the event that only Milestone 1 or Milestone 3 as specified in Appendix 3 of the License and Distribution Agreement as amended for Canada by Amendment Number 1 has been achieved, for Net Sales in each Commercial Year, the Supply Prices are to be calculated as **thirty five percent (35%)** of Net Selling Price.

Immediately upon achievement of any additional Milestone listed in Appendix 3 of the License and Distribution Agreement as amended for Canada by Amendment Number 1, for Net Sales in each Commercial Year up to **fifty percent (50%)** of the Net Sales forecasts below, the Supply Prices are to be calculated as **thirty five percent (35%)** of Net Selling Price. For Net Sales in each Commercial Year above **fifty percent (50%)** and up to **one hundred percent (100%)** of the Net Sales forecasts below for that Commercial Year, **four percent (4 %)** of the Net Selling Price shall be added to the Supply Price for the incremental Net Sales (for the avoidance of doubt, in respect of such incremental Net Sales, the Supply Price is **thirty nine percent (39%)** of the Net Selling Price). In respect of Net Sales in each Commercial Year above **one hundred percent (100%)** of the Net Sales forecasts below for that Commercial Year, another **six percent (6 %)** of the Net Selling Price shall be added to the Supply Price for the incremental Net Sales (for the avoidance of doubt, in respect of such incremental sales, the Supply Price is **forty five percent (45%)** of the Net Selling Price); provided, however, that BAYER is not entitled to a Supply Price of **forty two percent (42%)** according to Appendix 3, number 6 of the License and Distribution Agreement as amended for Canada by Amendment Number 1.

B. Canada

Sales in Canada of the Products

Commercial Year	Net Sales in '000 Canadian Dollars
1	1.086
2	5.555
3	13.112
4	18.209
5	23.769
6	26.805
7	28.606
8	29.042
9	29.242
10	29.245

AMENDMENT NUMBER 2
TO THE SUPPLY AGREEMENT

between GW PHARMA LIMITED ("GW") having its registered office at Porton Down Science Park, Salisbury, Wiltshire SP4 0JQ and BAYER HEALTHCARE AG, Division Pharma, having its registered office at Bayerwerk, 51368 Leverkusen, Germany ("Bayer")

WHEREAS, Bayer and GW executed a Supply Agreement as of the 20th day of May 2003, as amended for Canada by Amendment Number 1 to the Supply Agreement and by Amendment Number 3 to the License and Distribution Agreement;

WHEREAS, Bayer and GW wish to amend the sales forecast for the UK Territory.

NOW, THEREFORE, THE PARTIES HEREBY AGREE AS FOLLOWS:

1. Appendix 1, Part A shall be replaced by Appendix 1, Part A, as attached to this Amendment.
2. This Amendment shall be executed in two counterparts, but shall not be effective until each party has executed at least one counterpart. Each counterpart shall constitute an original of this Amendment, but all counterparts shall together constitute but one and the same instrument.

IN WITNESS WHEREOF, the Parties, through their authorised officers, have executed this Agreement as of the date first written above.

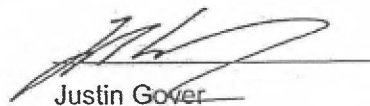
Signed for and on behalf of

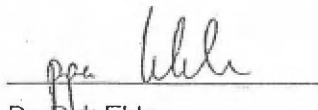
BAYER HEALTHCARE AG
Leverkusen, May 9, 2005

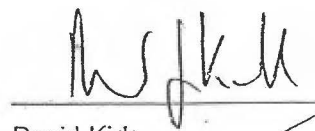
Signed for and on behalf of

GW PHARMA LIMITED
Salisbury, May 10, 2005


Dr. Horst Harenberg
Head of International Cooperations
and Licensing Europe


Justin Gover
Managing Director


Dr. Dirk Ehle
Law and Patents


David Kirk
Finance Director

Appendix 1**A. United Kingdom****Sales in the Territory of the Products**

Commercial Year	Net Sales in £'000's
1	3,445
2	5,914
3	14,199
4	20,077
5	23,778
6	24,614
7	26,414
8	27,392
9	28,472
10	29,317

Amendment # 3

to the Supply Agreement by and between Bayer Schering Pharma AG (formerly "Bayer AG, Bayer HealthCare, Division Pharma") and GW Pharma Limited dated May 20, 2003 — hereinafter referred to as "Supply Agreement" —

between Bayer Schering Pharma AG
Muellerstrasse 178
D-13353 Berlin
Germany
- hereinafter referred to as "BAYER" -

and GW Pharma Limited
Porton Down Science Park
Salisbury, Wiltshire SP4 OJQ
- hereinafter referred to as "GW" -

WHEREAS, Bayer AG has transferred its Division Pharma to Bayer HealthCare AG following the execution of the Supply Agreement in 2003;

WHEREAS, Bayer HealthCare AG merged with BAYER effective as of December 30, 2008, with BAYER as the universal successor so that BAYER is the new contracting party to the Supply Agreement;

WHEREAS, BAYER and GW have entered into the Supply Agreement by which GW undertook to manufacture and supply all of BAYER's requirements for Products (as defined in the Supply Agreement) to BAYER;

WHEREAS, BAYER and GW intend to amend the Supply Agreement in respect of the Supply Prices for the first Commercial Year and the Net Sales forecast as it is relevant for the calculation of the Supply Price.

NOW, THEREFORE, the PARTIES agree to the following:

1. Unless otherwise defined in this Amendment # 3 all words written in capital letters shall bear the meaning as defined in the Supply Agreement.
2. The following sentence shall be added to APPENDIX 1 paragraph 1 as the second-last sentence:

"Such **five** percent (**5%**) shall not be added to the Supply Price in the first Commercial Year to the effect that the Supply Price shall be **forty** percent (**40%**) throughout the first Commercial Year."
3. The table in APPENDIX 1 Section "A. United Kingdom" shall be deleted and replaced by the following table:

Commercial Year	Net Sales £'000s	1 st 50% Net Sales	Supply Price	Supply Price for Net Sales above the 1 st 50%
1	6,090	3,045	40%	40%
2	13,824	6,912	40%	45%
3	16,492	8,246	40%	45%
4	18,101	9,050.5	40%	45%
5	18,705	9,352.5	40%	45%
6	19,079	9,539.5	40%	45%
7	19,365	9,682.5	40%	45%
8	19,616	9,808	40%	45%
9	19,832	9,916	40%	45%
10	20,031	10,015.5	40%	45%

4. This Amendment # 3 shall form an integral part of the Supply Agreement and shall be regarded as incorporated into the Supply Agreement in every respect. All other terms and conditions of the Supply Agreement shall remain in force unchanged.
5. This Amendment # 3 shall take effect upon its execution.
6. In all other respects, the terms of the Supply Agreement shall remain unchanged.

This Amendment # 3 has been made in duplicate and signed by the PARTIES hereto.

Bayer Schering Pharma AG

i.v. Hinzen 5.3.2010
Dr. Berthold Hinzen
 Head Global Licensing General Medicine

i.v. Deimel 1.3.2010
Klaus Deimel
 Head Business Development Region Europe

GW Pharma Limited

[Signature]
Name: Justin Gower
Title: Managing Director
Date: 10 March 2010

[Signature]
Name: David Kirk
Title: Finance Director
Date: 10 March 2010

[Handwritten initials]