

18-04916-E

June 22, 2018

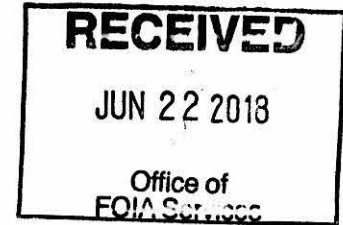
Dear SEC FOIA Office:

I am requesting a copy of  
Exhibit 10.3 Medicines Co/ Ma Form 10-Q dated 05/15/2002.  
I am willing to pay up to \$61.00.

Thank you,

Diane Martin

**AUS Consultants Inc.**  
155 Gaither Dr, Suite A  
Mt. Laurel  
NJ 08054  
856.234.9200





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

Office of FOIA Services

July 6, 2018

Ms. Diane Martin  
AUS Consultants, Inc.  
155 Gaither Dr., Suite A  
Mt. Laurel, NJ 08054

RE: Freedom of Information Act (FOIA), 5 U.S.C. § 552  
Request No. 18-04916-E

Dear Ms. Martin:

This letter is in response to your request, dated and received in this office on June 22, 2018, for Exhibit 10.3 Medicines Co. Ma Form 10-Q, dated May 15, 2002.

The search for responsive records has resulted in the retrieval of 43 pages of records that may be responsive to your request. They are being provided to you with this letter.

If you have any questions, please contact me at [fultonc@sec.gov](mailto:fultonc@sec.gov) or (202) 551-8186. You may also contact me at [foiapa@sec.gov](mailto:foiapa@sec.gov) or (202) 551-7900. You also have the right to seek assistance from 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](http://Archives.gov) or via e-mail at [ogis@nara.gov](mailto:ogis@nara.gov).

Sincerely,

A handwritten signature in cursive script that reads "Charlotte Fulton".

Charlotte Fulton  
FOIA Research Specialist

Enclosure

**The Medicines Company**  
requests that the marked portions of this agreement be granted confidential treatment  
pursuant to Rule 24b-2 under the Securities Exchange Act of 1934

## **SALES, MARKETING AND DISTRIBUTION AGREEMENT**

This Agreement is made 25<sup>th</sup> March 2002 (the "Effective Date") by and between THE MEDICINES COMPANY, INC., a Delaware corporation having offices at 5 Sylvan Way, Parsippany, New Jersey 07054 ("TMC") and NYCOMED DANMARK A/S, P.O. Box 88, Langebjerg 1 DK-4000 Roskilde, Denmark, a company duly organized and existing under the laws of the Kingdom of Denmark ("Nycomed").

The parties hereunder shall be referred to individually as a "Party" and collectively as the "Parties".

### **WITNESSETH**

Whereas, TMC is in the business of developing, manufacturing and marketing pharmaceutical products.

Whereas, TMC desires to appoint Nycomed as the exclusive distributor in the territory outlined in Exhibit A (the "Territory") for the Product and its Improvements manufactured by TMC described herein and as amended from time to time (the "Product"), and to sell the Product to Nycomed on the terms and subject to the conditions described in this Agreement.

Whereas, Nycomed is engaged in the marketing of pharmaceutical products and has represented to TMC that it has the facilities, personnel, and technical expertise to promote, market and distribute the Product in all countries of the Territory. Nycomed desires to accept such appointment as the exclusive distributor and to promote, market and distribute the Product in the Territory, and to purchase the Product from TMC on the terms and subject to the conditions described in this Agreement.

### **1. DEFINITIONS**

All capitalized terms used in this Agreement not otherwise defined shall have the meanings and definitions ascribed to them as listed below.

**1.1 "Adverse Event"** means any unintended, unfavorable clinical sign or symptom, any new illness or disease or deterioration of existing illness or disease or any clinically relevant

deterioration in laboratory variables (e.g., hematological, biochemical, hormonal) or other clinical tests (e.g., ECG, X-ray), whether or not considered treatment-related.

**1.2 “Affiliate”** means any corporation, company, joint venture, partnership or other entity which, directly or indirectly, controls, is controlled by, or is under common control with a Party to this Agreement. “Control” means the ownership of at least 50% of the issued share capital or business assets of another entity, the power to exercise at least 50% of the voting rights of another entity, or the power to appoint more than 50% of the Board of Directors of another entity. Notwithstanding this definition of control, Oy Leiras Finland Ab shall be deemed an Affiliate of Nycomed .

**1.3 “Angiomax”** means Angiomax<sup>TM</sup> or any other Trademark selected by TMC for the Product in the Territory.

**1.4 “Approvals”** means and includes all filings, approvals, registrations, permits, licenses and authorizations related to the Product which are necessary or which, in the reasonable opinion of TMC, are desirable, to be made with or obtained from any Governmental Authority for the importation, sale, marketing and promotion of the Products in the Territory or any part thereof, including primarily, but without limitation, authorizations of medicinal products for human use and approval of related labels and packaging, as well as pricing and social health system reimbursement approvals.

**1.5 “Average Net Unit Selling Price”** means the sum of Nycomed's calendar quarter Net Sales pursuant to this Agreement divided by such calendar quarter's number of units sold by Nycomed pursuant to this Agreement (but in respect of such units sold, excluding units which have been returned, rejected or reimbursed because of defects).

**1.6 “Chemilog”** means bivalirudin drug substance manufactured according to UCB Bioproducts SA process SF220, as defined in UCB bioproducts quality documents.

**1.7 “Combination Product”** means a product containing one or more active ingredients or components in addition to the Product.

**1.8 “Distributor”** means a person or entity in a country who (i) purchases Product from Nycomed or one of its Affiliates, and (ii) assumes responsibility for a portion of the promotion, marketing, sales and customer service effort related to Product in that country, and (iii) under an implied or express sublicense, sells Product in that country.

**1.9 “EEA”** means any current member countries of the European Union and Norway, Iceland, and Liechtenstein.

**1.10 “EMA”** means the European Agency for the Evaluation of Medicinal Products.



**1.11 "Firm Orders"** means orders received from Nycomed and accepted by TMC in writing for the purchase of Product.

**1.12 "First Approval Date"** means the first date on which the Product is eligible for sale in one or more countries of the Territory based on receipt of all necessary Approvals from Government Authorities of one or more countries of the Territory.

**1.13 "First Launch Date"** means the date of Launch of the Initial Indication(s) in any country of the Territory.

**1.14 "Governmental Authority"** means and includes all governmental and regulatory bodies, agencies, departments or entities, whether or not located in the Territory, which regulate, direct or control commerce in or with the Territory, including Approvals.

**1.15 "Gross Sales"** means gross invoices on sales of the Product by Nycomed and its Affiliates and Distributors to third parties.

**1.16 "Improvements"** means authorized, updated or modified manufacturing processes for the Product or its component substances, additional dosage unit sizes or other similar authorized modifications to the production and delivery of Product as part of an Approval for the Product.

**1.17 "Indication"** means a particular use for the Product which has received Approval from a Governmental Authority in one or more countries of the Territory.

**1.18 "Initial Indication"** means the Product's first Indication receiving Approval in one or more countries of the Territory.

**1.19 "Launch"** means the date of announcement to prescribers of pharmaceuticals, of the availability of Product upon prescription to treat an Initial Indication or a subsequent Indication in any country in Territory.

**1.20 "Minimum Transfer Price"**, means the minimum price for purchase of the Product by Nycomed, calculated in accordance with Exhibit B hereto.

**1.21 "Net Sales"** shall mean the gross amount invoiced (not dependent on whether such invoices have been actually paid) on sales of the Product by Nycomed and its Affiliates and Distributors to third parties, less the following items, as determined from the books and records of Nycomed or its Affiliates or Distributors, provided that such items do not exceed reasonable and customary amounts in the respective country(s) of the Territory in which such sale or other disposition occurred: (i) freight, insurance and other transportation charges, if billed separately; (ii) amounts repaid or credited by reason of returns, rejections, defects, recalls or because of retroactive price reductions; (iii) sales taxes, excise taxes, value-added taxes and other taxes (other than income taxes) levied on the invoiced amount; (iv) import and export duties; (v) cash,

trade and quantity discounts actually given or made; and (vi) rebates paid pursuant to government regulations. A sale of the Product by Nycomed to an Affiliate or Distributor for resale of the Product by such Affiliate or Distributor shall not be considered a sale for the purposes of this provision, but the resale of such Product by the Affiliate or Distributor to a third party who is not an Affiliate or Distributor of Nycomed shall be a sale for the purposes of this Agreement.

For the purposes of this Agreement, "sale" shall mean any transfer or other distribution or disposition, but shall not include transfers or other distributions or dispositions of Product, at no charge, for pre-clinical, clinical or regulatory purposes or to physicians or hospitals for promotional purposes, provided such transfer, distribution or disposition is not made in exchange for lower prices on other Nycomed products or for other non-cash consideration. In the event that consideration in addition to or in lieu of money is received for the sale of Product in an arms-length transaction, the fair market value of such consideration shall be included in the determination of Net Sales. To the extent that the Product is sold in other than an arms-length transaction, Net Sales for such sale shall be the average sales price of the Product if sold in an arms-length transaction during the applicable reporting calendar quarter in the country of the Territory in which the non-arms-length transaction occurred.

In the event that the Product is sold in the form of a Combination Product, Net Sales for the Combination Product shall be determined by multiplying actual Net Sales of the Combination Product (determined by reference to the definition of Net Sales set forth above) during the calendar quarter period by the fraction  $A/A+B$  where A is the average sale price of Product when sold separately in finished form, and B is the average sale price of the other active ingredients or components when sold separately in finished form in each case during the applicable reporting calendar quarter in the country in which the sale of the Combination Product was made, or if sales of both the Product and the other active ingredients or components did not occur in such period, then in the most recent calendar quarter in which sales of both occurred. In the event that such average sale price cannot be determined for both Product and all other active ingredients or components included in the Combination Product, Net Sales for purposes of determining payments under this Agreement shall be calculated by multiplying the Net Sales of the Combination Product by the fraction  $C/C+D$  where C is the standard fully-absorbed cost of the Product portion of the Combination and D is the sum of the standard fully-absorbed costs of all other active components or ingredients included in the Combination Product, in each case as determined by TMC using its standard accounting procedures consistently applied. In no event shall Net Sales of a Product included in a Combination Product be reduced to less than fifty percent (50%) of actual Net Sales of such Combination Product (determined by reference to the definition of Net Sales set forth above) by reason of any adjustment provision set forth in this paragraph.

**1.22 "Non-Required Trials"** means Product trials other than those trials required to secure Approval for an Indication.

**1.23 "Patents"** means patents and applications in any and all countries for patents (including provisional applications) and all reissues, divisions, renewals, extensions, continuations and continuations-in-part thereof and patent extensions with respect to the Product in the Territory, as further identified in Exhibit F hereto.

**1.24 "PCI"** means percutaneous coronary intervention.

**1.25 "Product"** means Bivalirudin, being a highly specific and reversible direct thrombin inhibitor, which operates by specific binding to both the catalytic site and to the anion-binding exosite of circulating and clot-bound thrombin. The active substance is a synthetic, twenty (20)-amino acid peptide, whose chemical name is D-phenylalanyl-L-prolyl-L-arginyl-L-prolyl-glycyl-glycyl-glycyl-L-asparagyl-glycyl-L-aspartyl-L-phenylalanyl-L-glutamyl-L-glutamyl-isoleucyl-L-prolyl-L-glutamyl-L-glutamyl-L-tyrosyl-L-leucine-trifluoroacetate (salt) hydrate. Its molecular weight is 218.19 daltons (anhydrous free base peptide).

**1.26 "Product Configuration"** means and includes any modifications to the package insert, labeling, or packaging of the Product required by Government Authority(s) of one or more countries of the Territory.

**1.27 "Production Volume Discount"** shall have the meaning ascribed to it in Exhibit B attached hereto.

**1.28 "PTCA"** means percutaneous coronary transluminal angioplasty.

**1.29 "Serious Adverse Event"** means (i) an Adverse Event that at any dose, results in death or is life-threatening, as well any Adverse Event that results in persistent or significant disability/incapacity or requires in-patient hospitalization or prolongs hospitalization, or (ii) any medically significant event that, based upon appropriate medical judgment, may jeopardize the patient and may require medical or surgical intervention.

**1.30 "Thrombin Inhibitor"** means any pharmaceutical with a mechanism of action involving the partial or complete inhibition of thrombin in the clotting cascade. Thrombin inhibitors shall include direct acting compounds including but not limited to lepirudin, desirudin and other members of the hirudin family as well as melagatran and small molecule direct thrombin inhibitors such as argatroban. Thrombin inhibitors shall also include indirect acting thrombin inhibitors which inhibit thrombin in conjunction with a co-factor such as AT-III. Such indirect thrombin inhibitors shall include but not be limited to unfractionated heparins and low molecular weight heparins such as enoxaparin sodium, dalteparin sodium, fondaparinux and reviparin sodium but shall exclude Warfarin.

**1.31 "TMC-UK"** means The Medicines Company of the United Kingdom, a limited liability corporation located at Buxton Court 3 West Way, Botley, Oxford, United Kingdom OX2 0SZ or such other EU incorporated entity of TMC which TMC may designate.

**1.32 "Trademarks"** means trademarks, trade names, service marks, and other proprietary symbols owned or controlled by TMC and as designated by TMC in Exhibit C hereto.

**1.33 "Unit"**, for the purpose of calculating the Average Net Unit Selling Price, the Transfer Price and the Minimum Transfer Price, shall mean the metric milligram (mg.).

**1.34 "WAC"** shall mean the U.S. Wholesale Acquisition Cost, as listed in the US Red Book for hospital injectables.

## **STATEMENT OF AGREEMENT**

In consideration of the mutual agreements set forth herein, TMC and Nycomed hereby agree as follows:

### **2. APPOINTMENT OF NYCOMED**

#### **2.1 Appointment, General Diligence.**

TMC hereby appoints Nycomed as the exclusive distributor of the Product and any Improvements in the Territory for any and all Indications (whether or not currently existing or planned) during the term of this Agreement and Nycomed hereby accepts such appointment subject to the terms and conditions described in this Agreement. In addition to the specific requirements of Articles 6 and 11 below, Nycomed shall promote and market the Product with no less effort than it customarily applies in promoting and marketing other products in the Territory. Nycomed shall have the right to appoint its Affiliates and other third parties as subdistributors of the Product in the Territory.

#### **2.2 Distribution Boundaries.**

Subject to the applicable regulations in the Territory and to the extent permitted by law Nycomed shall not (i) establish or maintain any distribution facility for the Product outside the Territory, or (ii) advertise or promote the Product to potential buyers located outside the Territory, or in any language, other than an official language of the Territory.

Particularly, Nycomed is cognizant of and recognizes the exclusive distribution rights granted by TMC to Grupo Ferrer Internacional S.A. for Spain, Portugal and Greece and for certain countries within Central and South America.

If Nycomed receives an order for, or inquiry concerning the Product from a potential customer located outside the Territory and outside the EEA, and unless such customer intends to resell the products within the EEA, Nycomed shall immediately refer such order or inquiry to TMC.

### 2.3 Non-Competition.

During the term of this Agreement, or any renewals, none of Nycomed, its Affiliates or its Distributors shall manufacture, distribute or sell any Thrombin Inhibitor in the Territory; provided, however, that with respect to countries in the Territory which are included in the EEA, this sentence shall only apply from the First Launch Date until the date which is five (5) years after the First Launch Date. During the term of this Agreement, or any renewals, Nycomed shall notify TMC regarding new pharmaceutical products (excluding line extensions and new formulations) Nycomed or its Affiliates intend to directly or indirectly sell, market or promote in the Territory. Notwithstanding the above, Nycomed shall be entitled to distribute any product for the same Indications as approved for the Product, other than abciximab, eptifibatide, or enoxaparin sodium, that may be used with the Product and/or which may be used in circumstances where the Product is not currently indicated or is contraindicated. Notwithstanding anything contained hererin to the contrary, Nycomed shall not be deemed to be in breach of this Section 2.3 if any of the customers of Nycomed, its Affiliates or its Distributors outside the Territory resell any Thrombin Inhibitor in the Territory which they purchased from Nycomed, its Affiliates or its Distributors.

## 3. MILESTONES

### 3.1. Distributor Fee

Upon execution of this Agreement, Nycomed shall (a) pay to TMC a non refundable, non creditable distributor fee of One Million Five Hundred Thousand United States Dollars (US\$1,500,000); and (b) purchase from TMC for an aggregate purchase price of US\$1,000,000 a number of shares of common stock of TMC determined by dividing US\$1,000,000 by the average closing sales price of TMC's common stock as reported on the Nasdaq National Market for the ten trading days ending on the date five trading days prior to the Effective Date. In connection with such purchase of shares, Nycomed will execute an investment representation letter in the form attached as Exhibit D.

### 3.2. Approval Milestones

- (a) Nycomed shall pay an additional non refundable, non creditable fee to TMC in the amount of Two Million Five Hundred Thousand United States Dollars (US\$2,500,000) upon approval of the PCI indication by any European Regulatory Agency. In the case of a centralized application in respect of the Product, approval shall include the receipt of a positive opinion from the Committee for Proprietary Medicinal Products ("CPMP").
- (b) If the fee described in Section 3.2 (a) above has not yet become payable to TMC, then upon approval of the PTCA indication by any European Regulatory Agency,



Nycomed shall pay an additional non refundable, non creditable fee (beyond the milestone described in Section 3.2(a) above) to TMC in the amount of One Million Five Hundred Thousand United States Dollars (US\$1,500,000). In the case of a centralised application in respect of the Product, approval shall include the receipt of a positive opinion from the CPMP. For the sake of clarification, Nycomed shall be required to pay one fee, as described in Sections 3.2(a) or (b) hereof, but shall not in any event be required to pay both of those fees.

- (c) If either of the Approvals described in Sections 3.2(a) or (b) above is delayed beyond June 30, 2004, the amount payable to TMC upon the occurrence of such Approval shall be reduced by ten percent (10%) for each six month (6) period which elapses between June 30, 2004 and such Approval. A reduction shall also be given, on a pro-rated basis, for periods of less than six months which elapse between June 30, 2004 and such Approval. By way of example, if the Approval for the PCI Indication by a European Regulatory Agency is delayed until March 31, 2005 (nine months after June 30, 2004), then the fee described in Section 3.2(a) above shall be reduced by \$375,000, calculated as follows: 10% for the first six months and 5% for the remaining portion of the delay (which is one-half of a second six (6) month period).

#### **4. PRODUCT OPTIMIZATION COMMITTEE**

##### **4.1 Role of Product Optimization Committee Generally.**

The Parties shall establish a Product Optimization Committee ("POC") no later than sixty (60) days following the Effective Date. The POC shall consist of four (4) voting members, comprising two (2) representatives of TMC and two (2) representatives of Nycomed. The POC shall have two co-chairs, one from each Party. TMC's appointees to the POC shall be determined by TMC. Nycomed's appointees to the POC shall be determined by Nycomed and shall include appropriate representation from its commercial organization. The POC shall meet at least three (3) months prior to the beginning of each calendar year at such time and place as mutually agreed upon by the Parties, and at such other dates as may be agreed upon by the Parties. Should the Parties mutually agree to do so, additional, non-voting members may be appointed to the POC and operating subcommittees and project teams may be appointed by and report to the POC.

The primary responsibility of the POC is to provide unified strategic and operating direction to the operating teams within TMC and Nycomed in a way that optimizes the value of the Product and maintains brand consistency for the Product in the Territory that is not in conflict with TMC's global commercialization strategy for the Product in accordance with Section 12. The POC shall also serve as a consensus-based decision-making unit of first resort with regard to the commercialization of the Product in the Territory. The POC shall be responsible for, among other things:

- a) Working with TMC to determine the optimal clinical strategy for the Product within the Territory, and where appropriate, how these efforts will be initiated and funded within the Territory
- b) Determining Product plans and establishing strategies for obtaining Approvals as well as marketing and selling the Product for new and approved Indications in Territory
- c) Managing and directing operating subcommittees and project teams appointed by the POC
- d) Working with TMC and Nycomed to ensure that TMC can take full advantage of and leverage the expertise and contacts that Nycomed has in the EEA and other European countries, in order to facilitate and expedite obtaining Approvals of the Product in the EEA and those other countries
- e) Monitoring TMC's compliance with rules, regulations and laws applicable to the manufacture of the Product, based on periodic information provided by TMC

In the event that a consensus decision cannot be reached by the POC, TMC shall have final authority for decisions with respect to the development of the Product for new Indications, Product trials, manufacturing and supply of the Product and Approvals, and Nycomed shall have final authority for decisions with respect to marketing and selling of the Product within the Territory, provided Nycomed's decisions (other than in respect of pricing, which shall be at Nycomed's entire discretion) are not in conflict with TMC's global commercialization strategy for the Product. For the sake of clarification, forecasts shall be provided by Nycomed, and shall not require any decision by the POC.

#### 4.2 Advisory Boards.

For the purpose of maximizing the medical community's knowledge and awareness of the Product, if TMC maintains a European advisory board for the Product, the members and meetings of such board shall be accessible to Nycomed's personnel, and if Nycomed develops national or regional advisory boards for the Product, the members and meetings of such boards shall be accessible to TMC's personnel. Each Party's participation in any such boards shall be subject to the confidentiality procedures imposed on other members of such boards.

#### 4.3 Clinical Development.

(a) The POC shall create a joint clinical plan for the Product in the Territory. For all Product trials included in that plan, the Parties shall share the cost of conducting such trials based on where each trial is conducted (e.g., Nycomed paying in full for trials conducted in the Territory and TMC paying in full for trials conducted outside the Territory); provided, however,

that (i) Nycomed shall not be required to pay for trials which are conducted without a consensus decision of the POC; and (ii) if any such trial for which Nycomed does not pay results in Approval of a new Indication, then within ninety (90) days after receiving notice of such Approval, Nycomed shall pay TMC an amount equal to (x) the amount which Nycomed would have paid for such trial if the POC had reached a consensus, multiplied by (y) 1.125.

(b) Trials currently under consideration are ACS, CABG off pump and HITS/CABG.

(c) Notwithstanding Section 4.3(a) above, TMC shall be fully responsible for funding the costs of conducting the current REPLACE II trial and any follow-up commitments which TMC undertakes as a condition to obtaining Approval from CPMP for the Initial Indication of the Product. Data generated from such trial may be used by Nycomed without charge in connection with obtaining Approvals for countries in the Territory which are not members of the EEA.

#### 4.4 Non-Required Trials.

Nycomed may from time to time propose Non-Required Trials to be conducted in the Territory. The POC shall discuss the structure of Non-Required Trials to be conducted in the Territory to expand approved Indications of the Product or to provide data supporting usage of the Product in the market. Prior to conducting any clinical evaluation of the Product, Nycomed shall furnish to all members of the POC the protocols for such evaluation written in the English language. TMC shall have final approval for Non-Required Trials. If approved by the POC, Non-Required Trials will be conducted at Nycomed's expense. Results from any such clinical evaluation shall not be publicly disclosed without TMC's prior written approval, such approval not to be unreasonably withheld.

### 5. REGULATORY AUTHORIZATIONS AND REGULATORY COMPLIANCE

#### 5.1. Approvals within the EEA

To the extent allowable by law, TMC-UK or its designated agent, at its own expense, will have primary responsibility for obtaining and maintaining all Approvals of the Product within the EEA. TMC-UK shall register the Product under TMC-UK's name or when required by law, the names of Nycomed, its agents and/or Distributors.

TMC-UK shall prepare applications, make submissions in the EEA, and conduct negotiations with Governmental Authority(s) regarding Approvals.

TMC-UK may require Nycomed to provide assistance to TMC-UK in the Approval process for one or more countries of the Territory within the EEA.



TMC-UK will determine whether a centralized filing through the EMEA or filings through the principle of mutual recognition of national authorizations is optimal for the Product.

5.2. Approvals outside the EEA.

Nycomed, at its own expense, will be responsible for obtaining and maintaining all Approvals of the Product within the Territory, but outside of the EEA.

The Parties will jointly determine, through the POC, the appropriate legal and regulatory approval plan to gain Approvals of the Product in such countries.

5.3 Compliance with Governmental Regulations.

TMC and Nycomed shall each comply with all laws, rules and regulations of every Governmental Authority having jurisdiction over its respective activities, as contemplated by this Agreement.

6. MINIMUM ANNUAL PURCHASES

6.1 The required minimum purchases Nycomed must make from TMC (the "Minimum Purchases") shall be defined as follows:

<u>By Specified Anniversary of First Approval Date</u>	<u>Minimum Purchases</u>
First	US\$ <u>1 million</u>
Second	US\$ <u>3 million</u>
Third	US\$ <u>5 million</u>

In the event that Nycomed from time to time exercises its option under Section 12 or 20.2(b) below to terminate this Agreement with respect to any of Germany, France, Italy or the United Kingdom, then the Minimum Purchases stated above shall be decreased by the following percentages, depending on which country or countries have been terminated: (a) Germany 40%; (b) France 27%; (c) Italy 7%; and (d) the United Kingdom 26%.

All purchases by Nycomed from TMC shall be counted towards these Minimum Purchase targets, regardless of the country in the Territory for which Nycomed makes those purchases.

For each year subsequent to the third anniversary of the First Approval Date, the POC shall set a new Minimum Purchase target. Such target shall be set no later than sixty (60) days prior to the beginning of each such year. If the POC does not set such target for any year (measured from the First Approval Date) by such date, then (i) the Minimum Purchase target shall be US\$7,500,000 for the fourth (4th) year; (ii) the Minimum Purchase target shall be

US\$11,250,000 for the fifth (5<sup>th</sup>) year; and (iii) thereafter, the Minimum Purchase target shall be equal to the greater of: (A) US\$11,250,000; or (B) seventy-five percent (75%) of the actual purchases of the Product by Nycomed from TMC during the immediately preceding year.

6.2. If Nycomed does not achieve the required Minimum Purchases for any one year period, then:

- (a) in the first instance, Nycomed shall, at its election, within sixty (60) days after the end of such year, either purchase or make a cash payment for a sufficient amount of Product at the then-current Minimum Transfer Price so as to satisfy such requirement. If Nycomed does not make such purchases or cash payment by the end of such sixty (60) day period, TMC shall have the option to terminate this Agreement with written notice to Nycomed, effective immediately;
- (b) in the second instance, Nycomed shall, at its election, within sixty (60) days after the end of such year, either purchase or make a cash payment for a sufficient amount of Product at the then-current Minimum Transfer Price so as to satisfy such requirement. If Nycomed does not make such purchases or cash payment by the end of such sixty (60) day period, TMC shall have the option to terminate this Agreement with written notice to Nycomed, effective immediately; and
- (c) in the third instance, Nycomed shall within sixty (60) days after the end of such year, purchase a sufficient amount of Product at the then-current Minimum Transfer Price so as to satisfy such requirement. If Nycomed does not make such purchases by the end of such sixty (60) day period, TMC shall have the option to terminate this Agreement with written notice to Nycomed, effective immediately. If Nycomed make such purchases by the end of such sixty (60) day period, TMC shall have the option to convert Nycomed's rights hereunder from exclusive to non-exclusive rights.

6.3 If after Nycomed's rights hereunder have been converted from exclusive to non-exclusive rights in accordance with Section 6.2(c) above, Nycomed does not achieve the required Minimum Purchases for any subsequent one year period, then TMC shall have the option to terminate this Agreement with written notice to Nycomed, effective immediately.

6.4. For the sake of clarification, Nycomed shall not be deemed to have failed to achieve the required Minimum Purchases for any one-year period, for the purposes of Section 6.2 above, if Firm Orders (as per Articles 7 and 8 hereunder) are sufficient for Nycomed to achieve the required Minimum Purchases but the required Minimum Purchases are not achieved as a result of Product supply limitations (including both non-delivery of ordered Product as well as delivery of non-conforming Product which must be replaced). In the event that TMC delivers less than 75% of the volumes of the Product covered by Firm Orders forecasted by Nycomed, then the one-year period in question shall be measured from the date on which those Product supply limitations are resolved and the required Minimum Purchases for such one-year period shall be

deemed to be reduced by a percentage of what the required Minimum Purchases would have been for such one-year period pursuant to Section 6.1 above and each subsequent one-year period pursuant to Section 6.1 above until Nycomed reestablishes the weighted (that is -- Germany 40%; France 27%; Italy 7%; and the United Kingdom 26%.) average of the market shares of the Product in Germany, France, Italy and the United Kingdom for the full calendar quarter immediately preceding the commencement of any such supply limitation. Such percentage reduction shall be equal to the weighted (that is -- Germany 40%; France 27%; Italy 7%; and the United Kingdom 26%.) average reduction in market share of the Product in Germany, France, Italy and the United Kingdom, if any. For purposes of determining market share, IMS data (or equivalent data where IMS data is not available) of the full calendar quarter immediately preceding the commencement of any such supply limitation shall be compared with IMS data (or equivalent data where IMS data is not available) for the first full calendar quarter immediately following the resolution of such supply limitation. By way of example, if the market share of the Product in Germany is reduced from 25% to 22.5% for the relevant quarters, it shall be deemed to be a 10% reduction in market share, for the purposes of computing the German portion of the above weighted average. Once Nycomed re-establishes the weighted average of the market shares of the Product in Germany, France, Italy and the United Kingdom as described above, the POC (or failing agreement, the Presidents of the Parties) shall meet and agree on revised required Minimum Purchases for subsequent years. Until the POC or the Parties reach such an agreement, the immediately preceding one-year period's Minimum Purchases (as adjusted pursuant to this Section 6.4) shall continue to apply.

## **7. FORECASTS**

Nycomed shall provide TMC with a twenty four (24) month Product forecast no later than six (6) months prior to the anticipated First Launch Date and shall thereafter update such forecast on a rolling quarterly basis. The rolling forecasts are to be broken down to single months. Nycomed shall use its reasonable commercial efforts to provide accurate forecasts to TMC.

The first six (6) months of each forecast (months 1 through 6) are Firm Orders and cannot be changed, by subsequent forecasts or otherwise.

The forecast for the remaining months (months 7 through 24) is not binding.

## **8. PLACING ORDERS AND SUPPLY**

### **8.1 Increases in Firm Orders.**

TMC shall use commercially reasonable efforts to deliver Product covered by Firm Orders. TMC shall make every reasonable effort to comply with unplanned increases in Firm Orders, but shall not be held liable for its inability to do so. In each Firm Order for any month,

Nycomed shall state, after consultation with TMC, a reasonable delivery schedule for Product to be delivered in that month.

#### 8.2 Quantities.

Product shall be provided to Nycomed by TMC and shall be ordered by Nycomed in 250 mg naked (unlabelled) vials. Naked vials shall be shipped to an agreed location in the European Union or Norway. TMC shall be responsible for the cost of filling the naked vials at Ben Venue Laboratories. Additionally, TMC may designate another qualified company in Europe or elsewhere that shall be responsible for filling the naked vials, and TMC shall provide all required technical know-how to the designated company for such purposes. TMC shall be responsible for the cost of filling, both at Ben Venue and at any such additional site. As marketing authorization holder, TMC shall be responsible for designating an authorized manufacturer and/or site of European batch release for the Product. Subsequent to further negotiations and approval, TMC may designate Nycomed to act in this capacity; provided, however, that TMC also reserves the right to designate other third parties as appropriate.

Nycomed shall be responsible for: (a) the shipping and insurance costs incurred in connection with transporting the Product from TMC's fill point to the agreed location in the European Union or Norway; and (b) the labeling and packaging costs of vials of Product, which shall be prepared by Nycomed in a manner consistent with the provisions of this Agreement, and applicable Territory laws and regulations.

#### 8.3 Product Packaging, Product Configuration and Destination Instructions

The Product will be supplied as a sterile lyophilized formulation in 10 ml glass vials containing material that, when reconstituted, will deliver 250mg of bivalirudin per 5ml. Each 250mg vial constitutes a single unit of Product. Nycomed will be responsible for the Product Configuration. TMC shall approve all labeling and package insert proofs prior to their use.

TMC shall not be obligated to fulfill any Product Configuration request for less than 1,000 vials.

#### 8.4 Cancellations, Cutbacks, No Liability.

The terms and conditions set forth in this Agreement shall apply to all purchases of Product by Nycomed, and to the extent such terms and conditions conflict with those set forth in any purchase order or invoice for Product, the terms and conditions set forth in this Agreement shall govern. Nycomed shall not change or cancel an order without the prior written consent of TMC.

If the Products are in limited supply or otherwise unavailable in the quantities requested by Nycomed, TMC will make its reasonable efforts to supply Nycomed. Specifically, TMC

shall allocate the available supply of Product among TMC, Nycomed and other TMC distributors in proportion to the relative shares of TMC's supply of Product resold by TMC itself or purchased by Nycomed and those other distributors during the immediately preceding twelve (12) month period. TMC shall not be liable to Nycomed for any losses or damages arising from TMC's inability to fill or accept any Firm Order as originally scheduled.

## **9. DELIVERY AND ACCEPTANCE**

### **9.1 Delivery.**

Except as set forth below, all Firm Orders shall be delivered **FCA (Incoterms 2000)** TMC's designated filling location(s). TMC shall only be required to deliver Product to Nycomed once in each month, with a 1,000 unit minimum delivery quantity. With respect to Firm Orders, lead time for the first delivery of the Product shall be three (3) months, and lead time for subsequent deliveries shall be one (1) month. TMC reserves the right to defer delivery of Product to Nycomed until Nycomed's cumulative Firm Orders for such Product Configuration exceed 1,000 units. Unless Nycomed requests otherwise, all Firm Orders shall be packed for shipment and storage in accordance with TMC's standard commercial practices. All Product delivered by TMC at the **FCA (Incoterms 2000)** point shall have a minimum expiry of eighty percent (80%) of its approved shelf life in the EEA, as measured from the date of delivery. The aforementioned term shall be proportionally increased from time to time in accordance with improved stability data. It is Nycomed's obligation to notify TMC of any special packaging requirements (which shall be at Nycomed's expense). TMC shall provide Certificates of Analysis for each lot of Product delivered to Nycomed to demonstrate that such lot was tested and released prior to delivery. Full batch documentation, including batch production records and manufacturing and analytical records, shall be available for review by Nycomed. TMC shall deliver Product into the possession of a common carrier designated by Nycomed, on the relevant Firm Order for such Product. If Nycomed does not designate a common carrier before the delivery date indicated on a Firm Order, then TMC may designate a common carrier on behalf of Nycomed. Title, risk of loss and damage to a Product shall pass to Nycomed upon such Product's removal from TMC's designated filling location.

The Parties shall enter into a separate technical agreement within thirty (30) days after the Effective Date.

TMC shall be entitled to withhold delivery of any unpaid Firm Order if either (i) payment is overdue for any Firm Order, or (ii) TMC has objective reasons for fearing that Nycomed might not be able to pay for the Products delivered or to be delivered.

### **9.2 Acceptance.**

Nycomed shall have thirty (30) days from receipt at the designated location in the European Union to examine such Product. Nycomed shall promptly notify TMC of short



shipments or any visually defective Product and shall return to or otherwise dispose of any defective shipments in accordance with TMC's instructions, at TMC's cost and expense. TMC shall provide for replacement delivery within one (1) month from existing production stock, if available, and if not available, within three (3) months therefrom. Such replacement shall be Nycomed's sole and exclusive remedy with respect to short shipments and visually defective Product delivered by TMC hereunder. Such limitations will not apply in case of latent defects.

## **10. FEES AND PAYMENT AMOUNTS**

### **10.1 Transfer Price.**

- a) For each quantity of Product sold by Nycomed, Nycomed shall pay TMC the transfer price for such quantity as calculated according to Exhibit B attached hereto.
- b) The Average Net Unit Selling Price and Net Sales for each calendar quarter shall be calculated by Nycomed at the end of such quarter and shall be reported by Nycomed to TMC within five (5) working days after the end of each such calendar quarter. If any Net Sales are stated in a currency other than United States Dollars during such quarter, then, for the purpose of calculating the Average Net Unit Selling Price for such quarter such Net Sales shall be converted into United States Dollars at the exchange rate between those two currencies most recently quoted in the European Central Bank in Frankfurt as of the last business day (that is – a day on which banks are open in Frankfurt) of such calendar quarter. If no such exchange rate has been quoted in the European Central Bank in Frankfurt at any time during the twelve (12) month period preceding the last business day of such quarter, such Net Sales shall be deemed to be equal to the Net Sales for the Product most recently charged by Nycomed in United States Dollars.
- c) Notwithstanding anything in this Agreement to the contrary, TMC's Transfer Price from the First Launch Date until the end of the then-current calendar quarter shall be at US\$125 per unit.
- d) Within forty-five (45) days after the end of each calendar year, TMC and Nycomed shall compute any Production Volume Discounts earned by Nycomed during such calendar year, in accordance with Exhibit B attached hereto. TMC will within forty-five (45) days after the end of such calendar year make a payment to Nycomed to reflect the amount of the Production Volume Discount earned by Nycomed during such calendar year.

### **10.2 Payment Form.**

All payments between the Parties shall be in US Dollars. Taxes now or hereafter imposed with respect to the transactions contemplated hereunder (with the exception of income taxes or other taxes imposed upon TMC and measured by the gross or net income of TMC) shall be the responsibility of Nycomed, and if paid or required to be paid by TMC, the amount thereof shall be added to and become a part of the amounts payable by Nycomed hereunder. Notwithstanding the foregoing, if Nycomed is required to withhold taxes from any amount payable by Nycomed to TMC, then Nycomed shall pay to TMC an additional amount as may be necessary so that TMC will receive, after deduction of such withholding tax, the amount which TMC would have received in the absence of such withholding tax. TMC will credit to Nycomed any withholding tax TMC recovers through a foreign tax credit that TMC actually uses to reduce its US tax liabilities, up to the additional amount as described above, that Nycomed has paid to TMC with respect to that recovered tax. TMC shall provide Nycomed with a certificate of residence and other documents which Nycomed may reasonably request in order to demonstrate that TMC is a tax resident of the United States.

#### 10.3 Payment Dates; Interest on Overdue Amounts.

Nycomed shall pay TMC's invoices for the Product as follows: (a) within sixty (60) days after receiving such invoice, the Minimum Transfer Price; and (b) within twenty (20) working days after the end of each calendar quarter, the amount, if any, by which the Transfer Price described in Exhibit B attached hereto exceeds such Minimum Transfer Price; provided, however, that with respect to the twelve (12) month period immediately following the First Launch Date, (i) US\$90.00 per unit shall be due within forty-five (45) days after Nycomed receives TMC's invoice; and (ii) the balance of the Transfer Price per unit (including without limitation the amount, if any, by which the Transfer Price described in Exhibit B attached hereto exceeds such Minimum Transfer Price) shall be due within ninety (90) days after Nycomed receives TMC's invoice. Additionally, all payments due under this Article 10 but not paid when due shall bear interest which is the lesser of: (i) the rate of Citibank N.A.'s prime rate plus 2% per annum or (ii) the maximum lawful interest rate permitted under applicable law. Such interest shall accrue on the balance of unpaid amounts from time to time outstanding from the date on which portions of such amounts become due and owing until payment thereof in full.

#### 10.4. Responsibilities for Expenses.

(a) TMC shall be responsible for: (i) the cost of bulk material; (ii) all license fees and royalties payable to third parties in connection with the manufacture, use or sale of the Product, in accordance with agreements between TMC and third parties; (iii) fill costs (excluding labeling and packaging costs); (iv) regulatory filing and maintenance costs within the EEA, including release testing required pursuant to the Approvals for the EEA (excluding country-specific local testing); and (v) its own incidental costs in assisting Nycomed in obtaining Approval outside the EEA.

(b) Nycomed shall be responsible for: (i) any third party payment obligations (including without limitation fees associated with obtaining Approval in countries in the Territory which are not members of the EEA, customs clearance and, if necessary, local release testing for Product) incurred by Nycomed in connection with distributing and marketing the Product in any country in the Territory; (ii) sales, marketing, labeling and packaging costs; (iii) its own incidental costs in assisting TMC in obtaining Approvals for countries which are members of the EEA; and (iv) regulatory filing and maintenance costs for countries in the Territory which are not members of the EEA.

## **11. MARKETING/PROMOTION RIGHTS AND RESPONSIBILITIES/REPORTING**

### **11.1 Pre-Launch.**

Nycomed shall assume all pre-launch marketing responsibility and expenditures with regard to the Product in the Territory. On or before an Approval is obtained from the EMEA for the Product with respect to any Indication, Nycomed shall have in place either an Affiliate or Distributor in Norway and in each member country of the European Union which is included in the Territory.

### **11.2 Cooperation**

Each Party shall cause its product manager for the Product to cooperate and share information (including without limitation Product-related market research) with the other Party during the development of Product-level planning, positioning and marketing strategies.

### **11.3 Promotional Materials**

- (a) Nycomed shall be responsible for creating all promotional materials for the Product, including, but not limited to sales materials. All such materials shall be in keeping with local laws and regulations and the Approval requirements regarding Product documentation and subject to TMC's prior written approval and shall be submitted to TMC in English and in the intended language for its review at least twenty (30) days prior to the proposed first use of such materials. Materials shall be deemed approved if no objection is received within ten (10) days after its submission by Nycomed to TMC.
- (b) TMC shall make its U.S. marketing materials available to Nycomed. Nycomed shall not use any adaptation of such marketing materials without TMC's prior written approval of such adaptations.

### **11.4 Press Releases.**



Any press release regarding the Product which Nycomed desires to release shall be submitted to TMC for review prior to the proposed release date. The release of such information is subject to the prior written consent of TMC, which consent shall not be unreasonably withheld. Press releases will be deemed approved if no objection is received within five (5) days after its submission by Nycomed to TMC.

11.5 INTENTIONALLY OMITTED.

11.6 INTENTIONALLY OMITTED

11.7. Business Reporting by Nycomed.

Nycomed agrees to submit a written report to TMC for each calendar quarter, within thirty (30) days after the end of such quarter (except that information on Net Sales and Average Net Unit Selling Price shall be provided on or before the fifth working day after the end of such quarter). Such quarterly reports shall begin no later than ninety (90) days from the First Launch Date.

Such reports shall include information, on a country-by-country basis, with respect to the units of the Product sold and Gross Sales, Net Sales and Average Net Unit Selling Price (and the calculation thereof) for such units, and in addition:

- (a) Market shares of the Product for the Territory, when and where available;
- (b) Nycomed developed and/or commissioned market research on the Product, if any, information on any markets Nycomed currently operates in or is considering operating in and plans concerning all publication and medical education activities; and
- (c) A breakdown of marketing and sales resources and costs expended by Nycomed for Germany, France, Italy, the United Kingdom and other countries designated by the POC vs. Nycomed's marketing plan as outlined in Article 12.

11.8. TMC Reporting Obligations.

TMC agrees to update Nycomed within thirty (30) days after the end of each calendar quarter with regard to:

- (a) Changes to planned publication activities;
- (b) Manufacturing ordering status for the Product, and any anticipated supply problems or delays;

- (c) Clinical trials' status;
- (d) Study reports;
- (e) Regulatory status in the EEA;
- (f) Product stability; and
- (g) Preclinical reports.

## **12. NYCOMED'S COMMERCIAL CAMPAIGN**

Subject to TMC's timely delivery of Product, Nycomed shall use its commercially reasonable efforts consistent with standard practices of an international pharmaceutical company to advertise, actively promote the sale of and sell the Product in each country in the Territory. Should Nycomed not Launch the Product in any member of the EEA within three (3) years after the First Launch Date for any reason (including without limitation lack of required Approvals in such country) or should Nycomed not file for Approval in any country in the Territory which is outside the EEA within one (1) year after the First Launch Date or, after obtaining such an Approval in a country, not Launch the Product in such country within one (1) year after receiving such Approval, then TMC shall have the option to terminate this Agreement, effective immediately, with all rights granted to Nycomed hereunder for such country reverting to TMC; provided, however, if a centralized application in respect of the Product is not filed with the EMEA, then the Parties shall in good faith agree upon an appropriate extension to the three (3) year period discussed above. Notwithstanding anything else in this Article 12 to the contrary, Nycomed shall not be obligated to continue to market or distribute the Product in any country of the Territory (and Nycomed shall have the option to terminate this Agreement with respect to such country, effective immediately, with all rights granted to Nycomed hereunder for such country reverting to TMC) in which Nycomed's actual realized gross profit from such marketing and distribution efforts is equal to or less than: (a) forty percent (40%), based on Net Sales in such country; or (b) US\$75 per 250mg vial. Nycomed, through the POC, shall furnish TMC with a detailed marketing plan with respect to the Product, six (6) months before the First Launch Date and three (3) months prior to the beginning of each calendar year thereafter.

TMC shall have the right to audit the books and records of Nycomed, its Distributors and its Affiliates that market the product, in order to confirm that Nycomed has made these required efforts.

## **13. COLLECTION OF INFORMATION ON ADVERSE AND SERIOUS ADVERSE EVENTS/REPORTING ON MEDICAL SAFETY/ RECALLS.**

### **13.1 Nycomed's Obligations regarding Regulatory Reporting ("Pharmacovigilance").**

To the extent permitted by Law, Nycomed shall have sole responsibility for Pharmacovigilance and for submitting Adverse Event/medical safety reports in the Territory, as may be required by the Government Authorities or regulations.

Nycomed shall not submit Adverse Event or safety reports to Government Authorities without first consulting TMC's designated drug surveillance and information contact.

The Parties shall enter into a separate Pharmacovigilance agreement within thirty (30) days after the Effective Date.

#### 13.2. Cooperation/Procedures.

TMC shall also be responsible for maintaining a central Adverse Event/medical safety database for the Product. The Parties shall cooperate towards establishing and maintaining such database. Reports based on this database will be made available to Nycomed during the term of the Agreement, as necessary, to meet the requirements of Government Authorities in the Territory. Without limiting the generality of the foregoing, Nycomed and TMC shall work together to develop standard operating procedures for exchange of information concerning Adverse Events and Product safety information derived from Product use in the Territory and each Party shall at all times comply with the procedures developed.

#### 13.3. Recalls.

In the event that either Party determines that an event, incident or circumstance has occurred which may result in the need for a recall or other removal of the Product; or any lot or lots thereof, from the market, such Party shall advise the other and the Parties shall consult with respect thereto in accordance with the technical agreement between the Parties. TMC shall have authority to decide whether a recall or other removal of such Product shall be made. The cost of recall and removing and destroying the Products recalled shall be borne by TMC. TMC shall, at Nycomed's discretion, reimburse or credit the Products recalled to Nycomed at the Transfer Price paid by Nycomed for such Products.

### 14. TRADEMARKS

#### 14.1 Right to Use

Nycomed shall use the Trademarks on an exclusive basis with respect to Exhibit C part a) and on a non-exclusive basis with respect to Exhibit C part b) during the term of this Agreement in the Territory solely for display, advertising, labeling and packaging purposes in connection with marketing, selling and distributing the Product in accordance with this Agreement. Nycomed shall not at any time do or permit any act to be done which may in any way impair the rights of TMC in the Trademarks. TMC shall at all times retain sole and exclusive ownership of the Trademarks. TMC agrees that, if required by the laws of any country

of the Territory, recordal of Nycomed's license with respect to the Trademarks or other recording of Nycomed's rights as a user of the Trademarks shall be permitted. Nycomed shall promptly inform TMC of any infringement or challenge of the Trademarks in the Territory. TMC shall have the sole and exclusive right to bring all actions or proceedings relating to the Trademarks, and Nycomed shall not take any legal action against a third party based on infringement of the Trademarks, unless so authorized by TMC. Furthermore, Nycomed shall provide all reasonable assistance to TMC towards defending the Trademarks from infringement or challenge by or against third parties. TMC shall be responsible for all application and registration procedures for the Trademarks in the Territory. Should such procedures be unsuccessful, TMC's obligation towards Nycomed shall only be limited to registering a new Trademark for the Product.

#### 14.2 Quality Control.

In order to comply with TMC's quality control standards, Nycomed shall: (i) use the Trademarks in compliance with all relevant laws and regulations; (ii) obtain TMC's prior written approval of each such use (and TMC hereby approves Nycomed's use of the Trademarks in correspondence with health care providers in its ordinary course of business pursuant to this Agreement); (iii) provide, at TMC's request, reasonable quantities of samples of advertisements and other promotional materials on which the Trademarks are affixed, in order to allow TMC to confirm that Nycomed's use of such Trademarks is in compliance with TMC's applicable standards and guidelines which are then in effect, and (iv) not modify any of the Trademarks in any way and not use any of the Trademarks on or in connection with any goods or services other than the Product.

#### 14.3 Promotion on Internet.

Nycomed shall not engage in active sales of the Product outside the Territory via the Internet and TMC shall not engage in active sales of the Product in the Territory. All Internet sales activities shall be in accordance with local laws and guidelines.

The Parties agree that at least the following behavior shall constitute breach of this Section 14.3:

- (a) the use on the Internet of a language other than any official language of the Territory;
- (b) the use on the Internet of banners or links specifically available to customers other than customers in the Territory;
- (c) the use on the Internet of any other symbol or denomination of any currency than those for the currencies of the Territory;
- (d) the use on the Internet of any other trademarks for the Product other than the Trademarks;

- (e) the use on the Internet of any other package of the Product than the packages of the Product for the Territory.

#### 14.4 Domain Names, Marks, Corporate Names and Meta-Tags.

In no event shall Nycomed: (i) establish, operate, sponsor, or contribute content to any site on the Internet which incorporates the word "Angiomax" or "The Medicines Company", any of TMC's trademarks, service marks or trade names identified in Exhibit E hereto (the "Marks") or any variation of such Marks as its URL address or any part of such address; (ii) register any domain name which incorporates any of the words "Angiomax" or "The Medicines Company" or the Marks (and Nycomed hereby agrees to transfer such domain name to TMC if it breaches this provision); (iii) register any of TMC's Marks or any Marks that are confusingly similar to any of the words "Angiomax" or "The Medicines Company" or TMC's Marks; (iv) form (or change the name of) any corporation or other entity under or to a name which incorporates any of the words "Angiomax" or "The Medicines Company" or any of TMC's Marks; or (v) at any time during or after the term of this Agreement, in order to attract visitors to any site on the Internet, (A) use "Angiomax" or "The Medicines Company", any of TMC's Marks or any variation thereof as a meta-tag or invisible text or on any unused frame or bridge page, (B) purchase "Angiomax" or "The Medicines Company", any of TMC's Marks or any variation thereof as a search term from any search engine; or (C) engage in any other practice designed to direct web browsers using search engines to different web pages or versions of web pages than the pages corresponding to search terms entered by the user (including without limitation "bridge pages", "cloaking" or "pagejacking").

#### 14.5 Equitable Relief.

Nycomed acknowledges and agrees that due to the unique nature of domain names, there can be no adequate remedy at law for any breach of its obligations under this Article 14, and that any breach may allow Nycomed or third parties to unfairly compete with TMC, and therefore, that upon any breach by Nycomed or threat thereof, TMC shall be entitled to appropriate equitable relief in addition to whatever remedies it might have at law. Nycomed shall notify TMC in writing immediately upon the occurrence of any such breach or any threat thereof of which it is aware.

### 15. PATENTS

TMC will defend and maintain at its cost the Patents in the Territory on the Product. At TMC's cost, TMC shall file patent extension applications and prosecute and maintain all such extensions for those countries in the Territory and in Spain, Portugal and Greece identified by Nycomed at least forty-five (45) days prior to the date that such extensions must be filed. If TMC does not take appropriate actions against any infringement or threatened infringement by a third party of the Patents, within ninety (90) days of Nycomed's request to do so, Nycomed will have the right to institute such proceedings at its own cost and expense. All damages, including

interest, profits and other recoveries awarded to the prosecuting party shall be retained by such party.

**16. NO RIGHTS BY IMPLICATION**

No rights or licenses with respect to the Product or the Trademarks are granted or deemed granted hereunder or in connection herewith, other than those rights expressly granted in this Agreement.

**17. CONFIDENTIAL INFORMATION**

**17.1 Obligations to Keep Confidential and Not Use.**

In connection with the ongoing business relationship between TMC and Nycomed, each Party (the "receiving Party") may gain access to proprietary information of the other Party (the "disclosing Party"), which may be considered confidential by the disclosing Party ("Confidential Information"). The receiving Party shall: (a) disclose Confidential Information of the disclosing Party only to the agents and employees of the Receiving Party, its Affiliates and its Distributors who have a reasonable need to know such information in order to perform their duties hereunder, and (b) shall not use such Confidential Information except in connection with performing its duties and exercising its rights hereunder. Such obligations of confidentiality and non-use shall terminate five (5) years after the term of this Agreement.

**17.2 Exceptions.**

Such obligations of confidentiality and non-use pursuant to Section 17.1 above shall not pertain to Confidential Information of the disclosing Party that:

- (a) Was known to the receiving Party, as shown by written evidence, at the time of receipt from the disclosing Party,
- (b) Was available to the public at the time of receipt from the disclosing Party,
- (c) Subsequently becomes available to the public without the receiving Party breaching this Agreement,
- (d) Is disclosed to the receiving Party by a third party who/which is under no confidentiality obligation to the disclosing Party,
- (e) Is independently developed by the receiving Party, or
- (f) Is disclosed pursuant to and only to the extent of court order or as otherwise compelled by law after giving the disclosing Party notice and reasonable



assistance in opposing or limiting such disclosure; provided, however, that information disclosed pursuant to this Section 17.2(e) shall remain Confidential Information for the purposes of this Agreement.

17.3 The Terms of the Agreement.

Either Party may provide to potential investors, lenders or acquirors who have a need to know the Confidential Information in order to assess the status of their investment in such Party or to determine whether to invest in such Party, provided that (i) the information is of a type customarily disclosed to investors, lenders or acquirors and (ii) the investors, lenders or acquirors to whom the information is disclosed are bound by obligations of confidentiality and non-use with respect to such information at least as stringent as those set forth within Section 17.1 above.

**18. *WARRANTY AND INDEMNIFICATION***

18.1 Product Warranty.

TMC hereby warrants that the Product is and shall be manufactured and delivered to Nycomed in conformity with (i) the specifications for the Product, (ii) the U.S. Federal Food, Drug and Cosmetic Act, as amended, (iii) the European Union Council Regulation No. 2309/93 of July 22, 1993 and any amendment thereof, (iv) the European Market Authorization granted to the Product and any extension thereof, and (v) any other regulations applicable to the Product in the EEA. In addition, upon Nycomed notifying TMC of additional requirements imposed by countries within the Territory but not members of the EEA which must be complied with for the Product to be manufactured and delivered to Nycomed in conformity with the regulations of such countries, (a) TMC shall use commercially reasonable efforts to comply with those requirements, and (b) Nycomed shall reimburse TMC for any additional costs which it may incur in connection with such efforts.

18.2 Disclaimer.

EXCEPT AS STATED IN SECTION 18.1 ABOVE, TMC DISCLAIMS ALL REPRESENTATIONS AND WARRANTIES, WHETHER EXPRESS OR IMPLIED, ORAL OR WRITTEN, WITH RESPECT TO THE PRODUCT, INCLUDING, WITHOUT LIMITATION, ALL IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR ANY PARTICULAR PURPOSE AND NON-INFRINGEMENT.

18.3 Indemnifications.

- (a) Nycomed hereby agrees to indemnify, defend and hold harmless TMC, all Affiliates of TMC and all officers, directors, employees and agents thereof from all liabilities, claims, damages, losses, costs, expenses, demands, suits and actions

(including without limitation attorneys' fees, expenses and settlement costs) (collectively, "Damages") arising out of: (i) Nycomed's breach of any of its obligations under this Agreement; or (ii) Nycomed's making representations or warranties which are not authorized by TMC hereunder.

- (b) TMC hereby agrees to indemnify, defend and hold harmless Nycomed, Affiliates of Nycomed and all officers, directors, employees and agents thereof from all Damages arising out of: (i) TMC's breach of any of its obligations under this Agreement; (ii) the Product infringing on the intellectual property rights of third parties or misappropriating any trade secrets of third parties; or (iii) personal injuries or damages suffered by third parties due to the Product not conforming to the warranty set forth in Section 18.1 above.
- (c) In the event a claim is based partially on an indemnified claim described in Sections 18.3(a) and/or 18.3(b) above and partially on a non-indemnified claim, or is based partially on a claim described in Section 18.3(a) above and partially on a claim described in Section 18.3(b) above, any payments and reasonable attorney fees incurred in connection with such claims are to be apportioned between the Parties in accordance with the degree of cause attributable to each Party.
- (d) The indemnified Party under this Section 18.3 hereby agrees that (i) it will give written notice to the indemnifying Party of each claim for which it seeks indemnification hereunder and that the indemnifying Party shall have sole control and authority with respect to the defense and settlement of any such claim; and (ii) the indemnified Party shall cooperate fully with the indemnifying Party, at the indemnifying Party's sole cost and expense, in the defense of any such claim. The indemnifying Party shall not accept any settlement which imposes liability not covered by this indemnification or restrictions on the indemnified Party without the indemnified Party's prior written consent, which consent shall not be unreasonably withheld or delayed..
- (e) In the event that the Product is held in a suit or proceeding to infringe any intellectual property rights or misappropriate any trade secrets of a third party and the use of such Product is enjoined, or TMC reasonably believes that it is likely to be found to infringe or constitute a misappropriation or likely to be enjoined, then TMC shall, at its sole cost and expense, either (i) procure for Nycomed the right to continue distributing the Product; or (ii) modify the Product so that it becomes non-infringing. If TMC determines, in its reasonable discretion, that neither (i) nor (ii) are commercially practicable, then TMC may terminate this Agreement upon giving Nycomed ninety (90) days prior written notice; provided, however, that before resuming the marketing and distribution of the Product in the Territory, (A) Nycomed shall have a ninety (90) days right of first refusal



with respect to such rights, without the payment of any up-front or additional milestone payments; and (B) if Nycomed does not exercise such right of first refusal, then TMC shall not offer terms more favorable to a third party without first offering those more favorable terms to Nycomed in accordance with (A) above.

- (f) TMC shall have no obligation for any claim of infringement or misappropriation arising from: (i) any combination by Nycomed of the Product with products not supplied or approved in writing by TMC, where such infringement would not have occurred but for such combination; (ii) the adaptation or modification of the Product not performed by TMC, where such infringement would not have occurred but for such adaptation or modification; (iii) the use of the Product for an Indication for which it was not approved, where such infringement would not have occurred but for such use; or (iv) a claim based on intellectual property rights owned by Nycomed or any of its Affiliates.
- (g) This Section 18.3 states Nycomed's sole remedy and TMC's exclusive liability in the event that a Product infringes on the intellectual property rights of, or misappropriates the trade secrets of, any third party.

#### 18.4 Insurance.

Each Party shall: (a) maintain public liability insurance including but not limited to premises/operations, contractual (for contracts made in the ordinary course of business), personal injury, and independent contractor liability coverages with a combined single limit of liability of at least US \$6,000,000 per occurrence and an aggregate amount of US \$7,000,000 and written on the so-called "occurrence" form (except that Nycomed's insurance may be written on the so-called "claims made" form) and products/completed operations liability with a combined single limit of liability of at least US \$20,000,000 per occurrence and an aggregate amount of US \$20,000,000 and written on the so-called "claims made" form, such insurance to be provided by insurer(s) licensed and in good standing in the Territory for Nycomed and in the United States for TMC; (b) provide the other Party with a properly executed certificate of insurance evidencing this coverage; and (c) notify the other Party in writing at least ten (10) days in advance of any cancellation, non-renewal, modification of coverage or exhaustion of limits of liability for the above required coverages.

### 19. LIMITATIONS ON LIABILITY

#### 19.1 Limitation on Direct Damages.

EXCEPT AS STATED IN SECTION 18.3 (b) (ii) and (iii), TMC'S LIABILITY FOR DAMAGES TO NYCOMED FOR ANY CAUSE WHATSOEVER, REGARDLESS OF THE

FORM OF ANY CLAIM OR ACTION, SHALL NOT EXCEED (a) PRIOR TO THE FIRST ANNIVERSARY OF THE FIRST LAUNCH DATE, US\$1,000,000; AND (b) THEREAFTER, THE AGGREGATE PRICE PAID FOR PRODUCT UNDER THIS AGREEMENT DURING THE PRECEDING TWELVE (12) MONTHS.

19.2 No Indirect Damages.

EXCEPT AS STATED IN SECTION 18.3 (b) (ii) and (iii), TMC SHALL IN NO EVENT BE LIABLE FOR ANY LOSS OF PROFITS OR USE OF THE PRODUCT, OR FOR ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL, EXEMPLARY, MULTIPLE OR OTHER INDIRECT DAMAGES ARISING OUT OF OR IN CONNECTION WITH THE USE OR PERFORMANCE OF THE PRODUCT OR PERFORMANCE OR TERMINATION OF THIS AGREEMENT OR TMC'S FAILURE OR DELAY IN SUPPLYING THE PRODUCT, EVEN IF TMC HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES OR LOSSES.

19.3 FOR PERSONAL INJURIES RESULTING FROM THE PRODUCT NOT CONFORMING TO THE SPECIFICATIONS FOR THE PRODUCT, SECTIONS 19.1 AND 19.2 SHALL NOT APPLY AND TMC'S LIABILITY SHALL BE IN ACCORDANCE WITH APPLICABLE LAWS AND REGULATIONS.

20. TERM AND TERMINATION

20.1 Term.

Without prejudice to TMC's termination rights under Article 6 above or Sections 20.3 or 20.4 below or Nycomed's termination rights under Section 20.2, 20.3 or 20.4 below, this Agreement shall begin on the Effective Date and shall continue on a country by country basis until the later of:

- a) the expiration of the last to expire Patent (and any extensions thereof) covering the Product or processes relating to the Product, or
- b) 10 years after Launch of the Product in such country.

The term of this Agreement may be extended upon further mutual written agreement of the Parties.

20.2 Nycomed's Additional Termination Rights.

(a) Should Nycomed decide to terminate this Agreement, other than pursuant to Section 20.3 or 20.4 below, Nycomed must provide TMC at least twelve (12) months prior written notice, except as provided in Section 20.2(b) below.

(b) Nycomed shall have the right to terminate this Agreement, for a specific country in the Territory, without indemnifying TMC, with six (6) months written notice if Approval for the Product in such country is not obtained in such country within thirty-six (36) months following the filing of a complete Approval application for the Product for such country.

(c) Upon Nycomed's giving of notice pursuant to either Section 20.2(a) or (b) above, all of Nycomed's rights under this Agreement shall immediately become non-exclusive for the Territory for a termination under Section 20.2(a), or non-exclusive for the terminated country for a termination under Section 20.2(b), as the case may be. Nycomed agrees to, during such notice period, cooperate with TMC to transition all Product-related responsibilities in an orderly fashion, to TMC or a third party designated by TMC. At the end of such notice period, Nycomed shall be discharged from all further payment obligations under this Agreement beyond those amounts owed to TMC in accordance with Section 20.5 below.

#### 20.3 Termination for Breach.

In the event of a breach of this Agreement by either Party and such Party's failure to remedy such breach within thirty (30) days after receiving notice thereof from the non-breaching Party which specifies the circumstances that constitute the breach, then the non-breaching Party may terminate this Agreement with immediate effect upon written notice to the breaching Party; provided, however, that such thirty (30) day period shall be reduced to twenty (20) days with respect to any failure by Nycomed to pay amounts due under this Agreement on the date when such amounts become due.

#### 20.4 Termination upon Bankruptcy.

This Agreement may be terminated by either Party with immediate effect upon the filing of a petition in bankruptcy, insolvency or reorganization against or by the other Party, or such other Party becoming subject to a composition for creditors, whether by law or agreement, or such other Party going into receivership or otherwise becoming insolvent.

#### 20.5 Payment Obligations Continue.

Termination or expiration of this Agreement shall not result in the reimbursement of non refundable, non creditable payments or affect the obligation of either Party to pay the other all amounts owing or to become owing as a result of the Product delivered by TMC on or before the date of such termination or expiration or to pay reimbursements for expenses as required by this Agreement, as well as interest thereon at the rate specified in Section 10.3 above to the extent any such amounts are paid after the date they became or will become due pursuant to this Agreement. TMC will have the option but not the obligation to repurchase, within thirty (30) days after such termination or expiration, saleable inventory at the Transfer Price paid by Nycomed for such inventory.

**20.6 No Post-Termination Compensation for Loss of Good Will.**

In the event of a termination pursuant to any of these provisions or upon expiration of this Agreement, TMC shall not have any obligation to Nycomed, or to any employee, agent, representative or sub-distributor of Nycomed, for compensation or for damages of any kind, whether on account of the loss by Nycomed or such employee, agent, representative or sub-distributor of present or prospective sales, investments, compensation or goodwill as a result of termination or expiration in accordance with the terms of this Agreement. Nycomed, for itself and on behalf of each of its employees, agents, representatives or Distributors, hereby waives any rights that may be granted to it or them under the laws and regulations of the Territory or otherwise which are not granted to it or them by this Agreement. Nycomed hereby indemnifies and holds TMC harmless from and against any and all claims, costs, damages and liabilities whatsoever asserted by any employee, agent, representative or Distributor of Nycomed under any applicable termination, labor, social security or other laws or regulations other than those for which TMC is obligated to indemnify Nycomed under Section 18.3(b) above.

**20.7 Survival of Terms.**

Notwithstanding anything else in this Agreement to the contrary, the Parties agree that Sections 5.3, 11.4, 14.3, 14.4, 14.5, 20.5, 20.6 and 20.7 and Articles 13, 17, 18, 19, 21, 22, 23, 24, 25, 26, 27, 28 and 31 shall survive the termination and expiration of this Agreement. In addition, ownership of any filings and Approvals for the Product obtained by Nycomed in Nycomed or TMC's name for a particular country or countries of the Territory shall be transferred at no charge or expense to TMC upon this Agreement expiring or being terminated with respect to such country or countries.

**21. COMPLIANCE WITH LAWS**

Each of Nycomed and TMC covenants that all of its activities under or pursuant to this Agreement shall comply with all applicable laws, rules and regulations.

**22. DISPUTE RESOLUTION**

Prior to submission to arbitration, the Parties shall negotiate in good faith within the POC any disagreements or controversies arising out of or relating to this Agreement. Should the POC be unable to resolve an issue, the President of TMC and the President of Nycomed Holding A/S shall meet, either by telephone or in person, to discuss and attempt resolution of the issue.

If the representative of the Parties cannot, within ten (10) days of their initial discussion, reach a resolution through informal channels of the issue in dispute, then such dispute, controversy or claim arising out of or relating to this Agreement, or the breach, termination or invalidity thereof, shall be finally settled by binding arbitration conducted in the English

language in Cambridge, Massachusetts, U.S.A. under the commercial arbitration rules of the United Nations Commission on International Trade Law. Each Party shall appoint an arbitrator and the two arbitrators so appointed shall jointly appoint a third arbitrator; provided, however, that if they cannot agree (or if one Party refuses to appoint an arbitrator) within thirty (30) days after the initiation of the arbitration, then this third arbitrator shall be appointed by the Presiding Judge of the London Court of International Arbitration. Disputes about arbitration procedure shall be resolved by the arbitrators or failing agreement, by the Presiding Judge of the London Court of International Arbitration in London, England. The arbitrators may proceed to an award notwithstanding the failure of a Party to participate in the proceedings. Discovery shall be limited to mutual exchange of documents relevant to the dispute, controversy or claim; depositions shall not be permitted unless agreed to by both Parties. The arbitrators shall be authorized to grant interim relief, including to prevent the destruction of goods or documents involved in the dispute, protect trade secrets and provide for security for a prospective monetary award. In no event shall punitive or multiple damages be assessed against either Party. The prevailing Party shall be entitled to an award of reasonable attorney fees incurred in connection with the arbitration in such amount as may be determined by the arbitrators. The award of the arbitrators shall be the sole and exclusive remedy of the Parties and shall be enforceable in any court of competent jurisdiction, subject only to revocation on grounds of fraud or clear bias on the part of the arbitrators. Notwithstanding anything contained in this Section 22 to the contrary, TMC shall have the right to institute judicial proceedings against Nycomed or against or anyone acting by, through or under Nycomed, in order to enforce TMC's rights hereunder through specific performance, injunction or similar equitable relief.

### **23. AUDIT AND INSPECTION**

During the term of this Agreement, upon reasonable prior notice and during normal business hours and no more frequently than once a year, TMC shall be entitled to audit and inspect at its cost those relevant records and facilities which are maintained by Nycomed in direct connection with its performance under this Agreement.

For a period of three (3) years next following each calendar year, Nycomed shall keep, and shall cause each of its Affiliates involved with distribution of the Product and each Distributor to keep, full, true, and accurate books and records containing all particulars relevant to sales of the Product during such year in sufficient detail to enable TMC to verify the amounts payable by Nycomed to TMC hereunder. TMC and its licensors shall have the right, not more than once during any calendar year, to have the books and records of Nycomed related to the sales of Product audited by a qualified nationally-recognized, independent accounting firm of TMC's choosing, during normal business hours upon reasonable notice, for the sole purpose of verifying the accuracy of the amounts paid by Nycomed to TMC hereunder. In the event that an audit shows that Nycomed has underpaid TMC by five percent (5%) or more, then Nycomed shall pay for all costs of such audit, otherwise the costs of such audit shall be borne by TMC. In all cases, Nycomed shall pay to TMC any underpaid compensation promptly and with interest annualized at the prime rate then in effect at Citibank N.A., plus two percent (2%), and TMC



shall promptly pay to Nycomed any overpaid compensation. All information and data reviewed in any audit conducted under this Article 23 shall be used only for the purpose of verifying the amounts due to TMC under this Agreement and shall be treated as Confidential Information of Nycomed subject to the terms of this Agreement.

**24. RELATIONSHIP OF THE PARTIES**

The relationship among the Parties is and shall be that of independent contractors. This Agreement does not establish or create a partnership or joint venture among the Parties, and neither Party shall hold itself out as an agent or employee of the other Party. Neither Party shall have authority to make any statements, representations, warranties or commitments of any kind, or to take any action, which shall be binding on the other Party.

**25. NOTICES**

Any notice or other communication required or desired to be given to any Party under the Agreement shall be in writing and shall be directed to the attention of the Chief Financial Officer if sent to TMC (with a copy to Ken Slade of Hale and Dorr LLP, 60 State Street, Boston, MA 02109 via e-mail at [kenneth.slade@haledorr.com](mailto:kenneth.slade@haledorr.com) or via facsimile at +1-617-526-5000) or to the attention of the President if sent to Nycomed (with a copy to the General Counsel of Nycomed, Hagalokkvn. 13, NO-1372 Asker, Norway via e-mail at [thc@nycomed.com](mailto:thc@nycomed.com) or via facsimile at +47 66 76 35 13). Such notice or communication shall be deemed given (a) seven (7) days after it is mailed registered, return receipt, first-class postage prepaid, and addressed to such Party at the address for such Party set forth at the beginning of this Agreement, (b) two (2) days after it is delivered to Federal Express, Airborne, or any other similar express delivery service for delivery to such Party at such address, or (c) on the day sent if sent via electronic mail to the electronic mail address provided for such Party at the end of this Agreement, accompanied by facsimile copy sent to the facsimile number provided for such Party at the end of this Agreement. Any Party may change its address, electronic mail address, facsimile number or contact person for notices and communications under this Agreement by giving the other Party notice of such change.

**26. GOVERNING LAW**

All questions concerning the validity or meaning of this Agreement or relating to the rights and obligations of the Parties with respect to performance under this Agreement shall be construed and resolved under, and any arbitration or court action hereunder shall apply, the laws of the Commonwealth of Massachusetts, excluding (i) its conflicts of law principles; and (ii) the United Nations Convention on Contracts for the International Sale of Goods.

**27. SEVERABILITY**

The intention of the Parties is to comply fully with all laws and public policies, and this Agreement shall be construed consistently with all laws and public policies to the extent possible. If and to the extent that any arbitration panel or any court of competent jurisdiction determines that it is impossible to construe any provision of this Agreement consistently with any law or public policy and consequently holds that provision to be invalid, inoperative, unenforceable, or to render other, material, provisions of this agreement invalid, inoperative or unenforceable, such provision shall be set aside, without, however, in any way affecting the validity of the other provisions of this Agreement, which shall remain in full force and effect.

**28. FORCE MAJEURE**

A Party shall be excused from performing its obligations under this Agreement (other than payment obligations) if its performance is prevented by any cause beyond its control, including but not limited to, Acts of God, fire, explosion, weather, war, insurrection, riots, or government action. Performances shall be excused only to the extent of and during the reasonable continuance of such disability. All obligations of both Parties shall return to being in full force and effect upon the termination of such cause.

**29. COMPLETE AGREEMENT**

This Agreement contains the entire agreement between the Parties and supersedes all prior or contemporaneous discussion, negotiations, representations, warranties, or agreements relating to the subject matter of this Agreement. No changes to this Agreement will be made or be binding on either Party unless made in writing and signed by each Party.

**30. ASSIGNMENT**

Nycomed shall not assign, transfer or otherwise dispose of this Agreement in whole or in part to any third party without the prior written consent of TMC; provided, however, that such consent shall not be required with respect to assignments, transfers or other dispositions by Nycomed to (i) an Affiliate of Nycomed; or (ii) an acquiror of all or substantially all of the capital stock or assets of Nycomed related to the Product, through purchase, merger, consolidation, or otherwise, unless such acquiror is a competitor of TMC, in which case TMC's consent shall still be required. TMC shall not assign, transfer or otherwise dispose of this Agreement in whole or in part to any third party without the prior written consent of Nycomed; provided, however, that such consent shall not be required with respect to assignments, transfers or other dispositions by TMC to (i) an Affiliate of TMC; or (ii) an acquiror of all or substantially all of the capital stock or assets of TMC related to the Product, through purchase, merger, consolidation, or otherwise. This Agreement shall inure to the benefit of the permitted successors and assigns of each Party.

**31. MISCELLANEOUS**

(a) Waiver. None of the conditions or provisions of this Agreement shall be held to have been waived by any act or knowledge on the part of either Party, except by an instrument in writing signed by a duly authorized officer or representative of such Party. Further, the waiver by either Party of any right hereunder or the failure to enforce at any time any of the provisions of this Agreement, or any rights with respect thereto, shall not be deemed to be a waiver of any other rights hereunder or any breach or failure of performance of the other Party.

(b) Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

(c) Headings. Headings and captions are included in this Agreement for reference purposes only, and shall not be used in order to interpret or construe this Agreement.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed under seal by their respective duly authorized representative as of the date set forth above.

THE MEDICINES COMPANY, INC

NYCOMED DANMARK A/S

By: Clive Meanwell  
Clive Meanwell  
Executive Chairman

By: Bent Kjærsgaard  
Bent Kjærsgaard  
President

(Clive.Meanwell@themedco.com)

(bkj@nycomed.com)

1 (617) 225-9099

(+ 45 46 75 69 68)

NYCOMED HOLDING A/S

By: Håkan Björklund  
Håkan Björklund  
CEO

(hbjo@nycomed.com)

(+45 46 75 42 72)



## **EXHIBIT A**

### **Countries Included in Territory**

- The following countries of the European Union : Austria, Belgium, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, the Netherlands, the United Kingdom and Sweden; but not Greece, Portugal and Spain.
- Iceland.
- Liechtenstein.
- Malta.
- Norway.
- Poland.
- The Russian Federation and all other former Soviet Republics (excluding the Baltic States)
- Baltic States (i.e., Latvia, Lithuania and Estonia)
- Switzerland.
- Turkey
- Hungary

## EXHIBIT B

### Transfer Price

1. Upon Product delivery, Nycomed shall pay to TMC, pursuant to the terms and conditions of the Agreement, the greater of:

- (a) 50% of the Average Net Unit Selling Price of the Product x the Number of Product units sold by Nycomed (in US dollars based on the applicable exchange rate(s)); and
- (b) A Minimum Transfer Price of \$112.50 per unit of Product until the third (3rd) anniversary of the First Launch Date, with the Minimum Transfer Price increased annually thereafter by the annual percentage increase in TMC's manufacturing costs (excluding royalties on sale payable to Biogen or its successor) for the Product, if any, after such third (3<sup>rd</sup>) anniversary date, such increase not to exceed 2% per annum.

2. Nycomed (a) may be entitled to the following discount (a "Production Volume Discount") in a particular calendar year:

<u>Annual Global Chemilog Production by TMC for all Purchasers</u>	<u>% discount off Average Net Unit Selling Price</u>
<u>0 to 50</u> kilos	<u>0%</u>
More than <u>50</u> kilos - <u>100</u> kilos	<u>1%</u>
More than <u>100</u> kilos - <u>200</u> kilos	<u>2%</u>
More than <u>200</u> kilos	<u>3%</u>

(b) so long as Nycomed 's total purchases of the Product (in kilos) from TMC during such calendar year equals or exceeds the following minimum percentage of TMC's total annual global Chemilog production (in kilos) of the Product during such calendar year:

<u>Calendar Year</u>	<u>Minimum Percentage</u>
Calendar year during which First Launch Date occurs	<u>5%</u>

All calendar years thereafter                      10%

For the sake of clarification, (i) if Nycomed does not equal or exceed such minimum percentage in a calendar year, then Nycomed shall not be entitled to a Production Volume Discount during such calendar year; and (ii) by way of example, if TMC's annual global Chemilog Production for Nycomed and all of its other purchasers is greater than 200 kilos during a calendar year (and assuming that Nycomed has equaled or exceeded the minimum percentage for such year), then for such year Nycomed shall have earned a 3% discount off of the Average Net Unit Selling Price for Product which Nycomed sells during such calendar year, reducing the reference in Paragraph 1(a) above from 50% of the Average Net Unit Selling Price to 47% of the Average Net Unit Selling Price for Product sold by Nycomed during such year; provided, however, that notwithstanding any Production Volume Discount earned hereunder, in no event shall Nycomed pay less than the Minimum Transfer Price on any unit of Product.

3. For the purposes of computing the Production Volume Discount, the Annual Global Chemilog Production levels under Paragraph 2(a) above and the minimum percentage under Paragraph 2(b) above for the calendar year during which the First Launch Date occurs shall be pro rated to reflect a partial year. By way of example, if the First Launch Date occurs on July 1 of a calendar year, then for the purposes of that calendar year only, (a) Annual Global Chemilog Production levels in the chart above shall be adjusted to 0-25, 25-50, 50-100 and over 100 kilos to determine which percentage discount shall apply; and (b) the minimum percentage shall be reduced to 2.5% to determine whether Nycomed is entitled to such percentage discount.

4. For the purposes of computing the minimum percentage under Paragraph 2(b) above for a calendar year, all units of Product delivered to Nycomed during such calendar year will be counted towards Nycomed's total purchases of Product during such calendar year.

## **EXHIBIT C**

### **Trademarks**

- (a) TMC trademarks subject to exclusive use by Nycomed in the Territory:  
Angiomax® or any other trademark selected by TMC for the Product in the Territory
- (b) TMC trademarks subject to non-exclusive use by Nycomed in the Territory:  
The Medicines Company™ (and its logo)  
REPLACE HEPARIN, IMPROVE OUTCOMES™

## **EXHIBIT D**

### **Investment Representation Letter**

The Medicines Company

Dear Sirs:

In order to induce The Medicines Company, a Delaware corporation (the "Company"), to issue and sell to [Nycomed] the number of shares of Common Stock of the Company set forth below (the "Shares"), pursuant to the \_\_\_\_\_ Agreement dated as of \_\_\_\_\_, [Nycomed] represents, warrants and covenants as follows:

(a) It is purchasing the Shares for its own account for investment only, and not with a view to, or for sale in connection with, any distribution of the Shares in violation of the Securities Act of 1933 (the "Securities Act"), or any rule or regulation under the Securities Act.

(b) It has had such opportunity as it has deemed adequate to obtain from representatives of the Company such information as is necessary to permit it to evaluate the merits and risks of its investment in the Company.

(c) It has sufficient experience in business, financial and investment matters to be able to evaluate the risks involved in the purchase of the Shares and to make an informed investment decision with respect to such purchase.

(d) It can afford a complete loss of the value of the Shares and is able to bear the economic risk of holding such Shares for an indefinite period.

(e) It understands that (i) the Shares have not been registered under the Securities Act and are "restricted securities" within the meaning of Rule 144 under the Securities Act, (ii) the Shares cannot be sold, transferred or otherwise disposed of unless they are subsequently registered under the Securities Act or an exemption from registration is then available; (iii) in any event, the exemption from registration under Rule 144 or otherwise may not be available for at least one year and even then will not be available unless a public market then exists for the Common Stock, adequate information concerning the Company is then available to the public, and other terms and conditions of Rule 144 are complied with; and (iv) there is now no registration statement on file with the Securities and Exchange Commission with respect to any

stock of the Company and the Company has no obligation or current intention to register the Shares under the Securities Act.

(f) A legend substantially in the following form will be placed on the certificate representing the Shares:

“The shares represented by this certificate have not been registered under the Securities Act of 1933, as amended, and may not be sold, transferred or otherwise disposed of in the absence of an effective registration statement under such Act or an opinion of counsel satisfactory to the corporation to the effect that such registration is not required.”

Very truly yours,

NYCOMED DANMARK A/S

Number of Shares: \_\_\_\_\_

Date \_\_\_\_\_

\_\_\_\_\_  
(Signature)

\_\_\_\_\_  
Bent Kjærsgaard

\_\_\_\_\_  
President

NYCOMED HOLDING A/S

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

Håkan Björklund  
CEO



**EXHIBIT E**

**TMC Marks**

each of the Trademarks identified in Exhibit C

Hirulog

## EXHIBIT F

### Patents

Status of Patents Relating to Hirulog® (B135)

#### "HIRUDIN ANALOGS"

Country	Patent/Appln. No.	Status (Expiration Date)
Austria	90912754.0 E137246	Granted (17-AUG-2010)
Belgium	90/912754 489070	Granted (17-AUG-2010)
Denmark	90912754.0 489070	Granted (17-AUG-2010)
EPO	90912754.0 489070	Granted (17-AUG-2010)
Finland	920672 102183	Granted (17-AUG-2010)
France	90912754.0 489070	Granted (17-AUG-2010)
Great Britain	90912754.0 489070	Granted (17-AUG-2010)
Germany	90912754.0 69026715.0-08	Granted (17-AUG-2010)
Hungary	P/P00684 211158	Granted (17-AUG-2010)
Italy	90912754.0 489070	Granted (17-AUG-2010)
Luxembourg	90912754.0 489070	Granted (17-AUG-2010)
Netherlands	90912754.0 489070	Granted (17-AUG-2010)
Norway	19920616 310.294	Granted (17-AUG-2010)
Sweden	90912754.0 489070	Granted (17-AUG-2010)
Switzerland	90912754.0 489070	Granted (17-AUG-2010)

**Status of Patents Relating to Improved Thrombin Inhibitors (B159)**

<b>Country</b>	<b>Appl. No./ Date</b>	<b>Pat. No./ Date</b>	<b>Exp. Date</b>
EPO*		529031 5/28/2000	2/3/2012
Finland	924503		
Hungary	P9203500	218 831	2/3/2012

\* EPO application is designating the countries: Austria, Belgium, Denmark, France, Germany, Great Britain, Italy, Luxembourg, Netherlands, Sweden and Switzerland.