PUBLIC VERSION

CT – 2010-007

COMPETITION TRIBUNAL

IN THE MATTER of the *Competition Act*, R.S.C. 1985, c. C-34, and the *Competition Tribunal Rules*, SOR/2008-141;

AND IN THE MATTER of the proposed acquisition by Teva Pharmaceutical Industries Ltd. of Merckle GmbH, CT Arzneimittel GmbH and AbZ-Pharma Holding GmbH;

AND IN THE MATTER of the filing and registration of a consent agreement pursuant to section 105 of the *Competition Act*.

BETWEEN:

THE COMMISSIONER OF COMPETITION

Applicant

– and –

TEVA PHARMACEUTICAL INDUSTRIES LTD., MERCKLE GMBH, CT ARZNEIMITTEL GMBH AND ABZ-PHARMA HOLDING GMBH

Respondents

CONSENT AGREEMENT IN RELATION TO THE PROPOSED ACQUISITION BY TEVA PHARMACEUTICAL INDUSTRIES LTD. OF MERCKLE GMBH, CT ARZNEIMITTEL GMBH AND ABZ-PHARMA HOLDING GMBH

WHEREAS pursuant to a Share Purchase Agreement, dated March 18, 2010, as amended, Teva Pharmaceutical Industries Ltd. ("**Teva**") will, indirectly through Teva Health GmbH, acquire the shares of Merckle GmbH ("**Merckle**"), CT Arzneimittel GmbH ("**CT**") and AbZ-Pharma Holding GmbH ("**ABZ**"), which together directly or indirectly control all operational entities of the Merckle/ratiopharm Group, and NRx Pharma Canada Inc., a wholly-owned subsidiary of Teva, will acquire the shares of ratiopharm Canada Inc. (the "**Acquisition**");

AND WHEREAS the Commissioner of Competition (the "**Commissioner**") has concluded that the Acquisition is likely to result in a substantial lessening of competition in Canada for the supply of each of Acetaminophen Oxycodone tablets and Morphine Sulfate SR tablets, and that the Divestiture of the Divestiture Assets (as defined herein) is necessary to ensure that such substantial lessening of competition will not result from the completion of the Acquisition;

AND WHEREAS the Respondents do not admit but will not for the purposes of the enforcement of any provision of this Agreement, or in any subsequent proceeding relating to the Acquisition, including in any proceedings under section 106 of the *Competition Act* (the "**Act**"), contest: (i) the Commissioner's conclusion that the Acquisition is likely to result in a substantial lessening of competition in the supply of Acetaminophen Oxycodone tablets and Morphine Sulfate SR tablets in Canada; and (ii) the Commissioner's conclusion that the implementation of this Agreement is necessary to ensure that any substantial lessening of competition will not result from the Acquisition;

AND WHEREAS the Respondents consensually attorn to the jurisdiction of the Competition Tribunal ("**Tribunal**") for purposes of this Agreement and any proceeding initiated by the Commissioner relating to this Agreement;

AND WHEREAS the Respondents agree to the immediate filing by the Commissioner of this Agreement for registration with the Tribunal;

NOW THEREFORE the Respondents and the Commissioner agree as follows:

I. DEFINITIONS

[1] For the purposes of this Agreement, unless something in the subject matter or context is inconsistent therewith, the following capitalized terms have the following meanings:

(a) "**ABZ**" means AbZ-Pharma Holding GmbH, its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and Affiliates in each case controlled by ABZ and the respective directors, officers, employees, agents, representatives, successors, and assigns of each;

(b) "**Act**" means the *Competition Act*, R.S.C., 1985, c. C-34, as amended;

(c) "**Acquisition**" means the acquisition contemplated by the Share Purchase Agreement between Teva and VEM Vermogensverwaltung GmbH and others dated March 18, 2010, as amended (the "**Acquisition Agreement**");

(d) "**Affiliate**" means an affiliated corporation, partnership or sole proprietorship within the meaning of subsection 2(2) of the Act;

(e) "**Agency**" means any government regulatory authority in Canada responsible for granting approvals, clearances, qualifications, licences, or permits for any aspect of the research, Development, manufacture, marketing, distribution, or sale of a Product;

(f) "**Agreement**" means this Consent Agreement entered into by Teva, Merckle, CT, ABZ and the Commissioner pursuant to section 105 of the Act, including the schedules hereto;

(g) "**Business Day**" means a day other than a Saturday, Sunday or statutory holiday in the Province of Ontario;

(h) "**cGMP**" means current Good Manufacturing Practice, as set forth in the *Food and Drugs Act*, R.S.C. 1985, c. F-27, as amended, and all rules and regulations promulgated thereunder;

(i) "**Closing Date**" means the date upon which the Acquisition is completed;

(j) "**Commissioner**" means the Commissioner of Competition appointed pursuant to section 7 of the Act and any Person designated by the Commissioner to act on her behalf;

(k) "**Confidential Business Information**" means all information owned by, or in the possession or control of, a Respondent that is not in the public domain and that is directly related to the Divestiture Products, provided, however, that the restrictions contained in this Agreement regarding the Respondents' use, conveyance, provision, or disclosure of "Confidential Business Information" shall not apply to the following:

(i) information that subsequently falls within the public domain through no violation of this Agreement or breach of a confidentiality or non-disclosure agreement with respect to such information by the Respondent(s);

(ii) information related to the Divestiture Products that the MR Group can demonstrate it obtained without the assistance of Teva prior to the Acquisition;

(iii) information related to the Divestiture Products that Teva can demonstrate it obtained without the assistance of MR Group prior to the Acquisition;

(iv) information that is required by law to be publicly disclosed;

(v) information relating to the Respondents' general business strategies or practices regarding research, Development, manufacture, storage,

marketing, or sales of Products that does not discuss with particularity the Divestiture Products;

(vi) information specifically excluded from the Divestiture Assets;

(vii) all intellectual property licensed to the Purchaser on a non-exclusive basis; and

(viii) information prepared in connection with the Acquisition that is protected by legal privilege;

(l) "**CT**" means CT Arzneimittel GmbH, its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and Affiliates in each case controlled by CT and the respective directors, officers, employees, agents, representatives, successors, and assigns of each;

(m) "**Development**" means all drug development activities, including test method development and stability testing, toxicology, formulation, process development, manufacturing scale-up, development-stage manufacturing, quality assurance and quality control development, statistical analysis, report writing and bioequivalence studies and preparatory work for the purpose of obtaining any and all Product Approvals, and regulatory affairs related to the foregoing. "**Develop**" means to engage in Development;

(n) "**Divestiture**" means the sale, conveyance, transfer, auction, public tender, public offering, assignment, licensing or other disposal of the Divestiture Assets, such that the Respondents will have no direct or indirect interest in such assets, except as permitted herein; "**Divest**" means to implement and complete the Divestiture;

(o) "**Divestiture Assets**" means all of the applicable Respondent's assets related to the Divestiture Products in Canada, and all such Respondent's rights, title and interest in and to all such assets to the extent legally transferable, including the research, Development, manufacture, distribution, marketing, and sale of the Divestiture Products, including, without limitation, the following:

(i) all Divestiture Product Intellectual Property;

(ii) all Product Approvals;

(iii) all Divestiture Product Manufacturing Technology that is tangible and exclusive to the Divestiture Products;

(iv) all Divestiture Product Marketing Materials;

(v) a list of all customers and targeted customers for such Divestiture Products and the net sales (in either units or dollars) of such Divestiture Products to such customers on either an annual, quarterly or monthly basis;

(vi) all applications for all Product Approvals granted by any Agency, and all supplements, amendments, and revisions thereto, any preparatory work, drafts and data necessary for the preparation thereof, and all correspondence between the Respondents and the applicable Agency related thereto;

(vii) a list of all drug identification numbers ("**DINs**"), and rights, to the extent permitted by law, to require the Respondents to discontinue use of those DINs in respect of any Divestiture Product, other than with respect to returns, rebates, allowances, and adjustments for Divestiture Products sold prior to the applicable Divestiture Date;

(viii) all Divestiture Product Development Reports;

(ix) at the Purchaser's option, subject to any rights of the customer, all unfilled customer purchase orders for the Divestiture Products;

(x) at the Purchaser's option, all Divestiture Product Assumed Contracts;

(xi) all strategic safety programs submitted to Health Canada related to the Divestiture Products that are designed to decrease product risk by using one or more interventions or tools beyond the package insert;

(xii) all patient registries related to the Divestiture Products, and any other systematic active post-marketing surveillance program to collect patient data, laboratory data and identification information required to be maintained by Health Canada to facilitate the investigation of adverse effects related to the Divestiture Products;

(xiii) at the Purchaser's option and to the extent approved by the Commissioner in the relevant Remedial Agreement, all inventory (except such inventory that is subject to retention requirements imposed on the Respondent by applicable law) in existence as of the Divestiture Date including, but not limited to, raw materials, packaging materials, work-in-process and finished goods related to the Divestiture Products; and

(xiv) all of the applicable Respondent's books, records, and files directly related to the foregoing or to the Divestiture Product(s),

provided, however, that "Divestiture Assets" shall not include: (1) documents relating to either the Respondent's general business strategies or practices relating to research, Development, manufacture, marketing or sales of pharmaceutical Products, where such documents do not discuss with particularity the Divestiture Products; (2) administrative, financial, and accounting records that do not discuss with particularity the Divestiture Products; (3) quality control records that are determined by the Monitor or the Purchaser to not be material to the manufacture of the Divestiture Products; (4) any real estate and the buildings and other permanent structures located on such real estate; and (5) assets licensed to the

Purchaser pursuant to the Divestiture Product Licences; provided further, however, that in cases in which documents or other materials included in the relevant assets to be divested contain information: (A) that relates both to the Divestiture Products and to other Products or businesses of the Respondent and cannot be segregated in a manner that preserves the usefulness of the information as it relates to the Divestiture Products; or (B) for which the Respondent has a legal obligation to retain the original copies, the Respondent shall be required to provide only copies or relevant excerpts of the documents and materials containing this information. In instances where such copies are provided to the Purchaser, the Respondent(s) shall provide such Purchaser access to original documents under circumstances where copies of documents are insufficient for evidentiary or regulatory purposes;

(p) "**Divestiture Date**" means, in respect of each Divestiture Product, the date on which the Divestiture Assets are Divested to a Purchaser pursuant to this Agreement by the Respondents or a Divestiture Trustee;

(q) "**Divestiture Product**" means:

(i) Acetaminophen Oxycodone tablets, 325 mg/5mg strength (at the option of the Respondents or, as applicable, the Divestiture Trustee, either Teva DIN 02307898 or ratiopharm DIN 00608165); and

(ii) Morphine Sulfate SR tablets, 15 mg, 30 mg and 60 mg strengths (at the option of the Respondents or, as applicable, the Divestiture Trustee, either Teva DINs 02302764, 02302772 and 02302780 or ratiopharm DINs 02244790, 02244791, 02244792);

(r) "**Divestiture Product Assumed Contracts**" means contracts or agreements (copies of each such contract or agreement to be provided to the Purchaser on or before the Divestiture Date and segregated in a manner that clearly identifies the purpose(s) of each such contract):

(i) that make specific reference to a Divestiture Product and pursuant to which any Third Party is obligated to purchase, or has the option to purchase without further negotiation of terms, the Divestiture Product from a Respondent unless such contract applies generally to the Respondent's sales of Products to that Third Party;

(ii) pursuant to which the applicable Respondent purchases the active pharmaceutical ingredient or other necessary ingredient or had planned to purchase the active pharmaceutical ingredient or other necessary ingredient from any Third Party for use in connection with the manufacture of a Divestiture Product;

(iii) relating to any bioequivalence studies, tests or trials involving a Divestiture Product;

(iv) with universities or other research institutions for the use of a Divestiture Product in scientific research;

(v) relating to the particularized marketing of a Divestiture Product or educational matters relating solely to a Divestiture Product;

(vi) pursuant to which a Third Party manufactures or packages a Divestiture Product on behalf of a Respondent;

(vii) pursuant to which a Third Party provides Divestiture Product Manufacturing Technology to a Respondent;

(viii) pursuant to which a Third Party is licensed by a Respondent to use Divestiture Product Manufacturing Technology;

(ix) constituting confidentiality agreements involving a Divestiture Product;

(x) involving royalty, licensing, or similar arrangements with a Third Party involving a Divestiture Product;

(xi) pursuant to which a Third Party provides any specialized services necessary to the research, Development, manufacture or distribution of a Divestiture Product to the applicable Respondent including, but not limited to, consultation arrangements; and

(xii) pursuant to which any Third Party collaborates with the applicable Respondent in the performance of research, Development, marketing, distribution or selling of a Divestiture Product,

provided, however, that where any such contract or agreement also relates to a Retained Product, the Respondent shall assign the Purchaser all such rights under the contract or agreement as are related to the Divestiture Products, but concurrently may retain similar rights for the purposes of the Retained Product;

(s) "**Divestiture Product Copyrights**" means rights to all original works of authorship of any kind directly related to a Divestiture Product, and any registrations and applications for registrations thereof, within Canada;

(t) "**Divestiture Product Development Reports**" means, in relation to a Divestiture Product:

(i) pharmacokinetic, bioavailability, and bioequivalence study reports (including any applicable reference listed drug information);

(ii) annual and periodic reports related to any application to any Agency for Product Approvals, including any safety update reports;

(iii) Health Canada-approved Product labelling;

(iv) currently used Product package inserts (including historical change of controls summaries);

(v) Health Canada-approved patient circulars and information related to a Divestiture Product;

(vi) adverse event/serious adverse event summaries;

(vii) summary of Product complaints from physicians;

(viii) summary of Product complaints from customers; and

(ix) Product recall reports filed with Health Canada;

(u) "**Divestiture Product Intellectual Property**" means all of the following related to a Divestiture Product (other than Divestiture Product Licensed Intellectual Property):

(i) Patents;

(ii) Divestiture Product Copyrights;

(iii) Divestiture Product Trade-marks, industrial designs, distinguishing guises, trade secrets, Divestiture Product Know-How, techniques, data, inventions, practices, methods, and other confidential or proprietary technical, business, research, Development and other information; and

(iv) rights to obtain and file for Patents and copyrights and registrations thereof in Canada,

provided, however, "Divestiture Product Intellectual Property" does not include the corporate names of "Teva" or "ratiopharm", or abbreviations thereof, or the corporate names of any other corporations or companies owned or controlled by the Respondents or the related logos thereof;

(v) "**Divestiture Product Know-How**" means all the know-how that is used for the Divestiture Products, including all specifications, processes, designs, plans, trade secrets, ideas, concepts, inventions, manufacturing, engineering and other manuals and drawings, standard operating procedures, formulae, flow diagrams, toxicological, biological, physical, analytical, safety, stability, supply, selection, constitution, or use of any raw material, quality assurance, quality control and clinical data, technical information, and research records;

(w) "**Divestiture Product Licence**" means all of the following related to the Divestiture Products:

(i) a perpetual, non-exclusive, fully paid-up, royalty-free, irrevocable, transferable licence, with rights to sublicense, to all Divestiture Product

Licensed Intellectual Property and all Divestiture Product Manufacturing Technology related to general manufacturing and research and Development know-how solely:

A. to research and Develop the Divestiture Products for marketing, distribution or sale within Canada;

B. to use, make, have made, distribute, offer for sale, promote, advertise, or sell the Divestiture Products within Canada;

C. to import or export the Divestiture Products to or from Canada to the extent related to the marketing, distribution or sale of the Divestiture Products in Canada; and

D. to have the Divestiture Products made anywhere in the world for distribution or sale within, or import into Canada; and

(ii) a perpetual, exclusive (even as to the Respondents), fully paid-up, royalty-free, irrevocable, transferable, licence, with rights to sublicense, to all Divestiture Product Know-How,

provided, however, that for any Divestiture Product Licensed Intellectual Property that is the subject of a licence from a Third Party to the Respondents, the scope of the rights granted hereunder shall only be required to be equal to the scope of the rights granted by the Third Party to the Respondents;

(x) "**Divestiture Product Licensed Intellectual Property**" means the following intellectual property owned, controlled, or licensed by a Respondent existing prior to the Closing Date:

(i) Patents that are related to a Divestiture Product that the Respondent can demonstrate have been used, prior to the Closing Date, for a Retained Product; and

(ii) trade secrets, know-how, techniques, data, inventions, practices, methods, and other confidential or proprietary technical, business, research, Development, and other information, and all rights in Canada to limit the use or disclosure thereof, that are related but not exclusive to a Divestiture Product and that the Respondent can demonstrate have been used, prior to the Closing Date, for a Retained Product, and shall include tangible and intangible Divestiture Product Manufacturing Technology not exclusive to the Divestiture Products;

(y) "**Divestiture Product Manufacturing Technology**" means:

(i) all technology, trade secrets, Divestiture Product Know-How, and proprietary information (whether patented, patentable or otherwise) related to the manufacture of a Divestiture Product that is owned, controlled or

licensed by a Respondent prior to the Closing Date, including, but not limited to: all product specifications, processes, product designs, plans, trade secrets, ideas, concepts, manufacturing, engineering, and other manuals and drawings, standard operating procedures, flow diagrams, chemical, safety, quality assurance, quality control, research records, clinical data, compositions, annual product reviews, regulatory communications, control history, current and historical information associated with Product Approval application conformance and cGMP compliance, labeling and all other information related to the manufacturing process, and supplier lists;

(ii) all active pharmaceutical ingredients related to a Divestiture Product that are owned, controlled or licensed by the Respondent(s) prior to the Closing Date; and

(iii) for those instances in which the manufacturing equipment is not readily available from a Third Party, at the Purchaser's option, all such equipment used to manufacture the Divestiture Products that is owned, controlled or licensed by the Respondents prior to the Closing Date, the price for which will be set at a reasonable price, not to exceed the applicable Respondent's depreciated value of such equipment;

(z) "**Divestiture Product Marketing Materials**" means all marketing materials used specifically in the marketing or sale of a Divestiture Product in Canada as of the Divestiture Date;

(aa) "**Divestiture Product Trade-marks**" means all proprietary names or designations, trade-marks, service marks, trade names, and brand names, including registrations and applications for registration therefor (and all renewals, modifications, and extensions thereof) and all common law rights, and the goodwill symbolized thereby and associated therewith, all in Canada, for the Divestiture Products;

(bb) "**Divestiture Trustee**" means a Person appointed by the Commissioner pursuant to the relevant provisions of this Agreement and any employees, agents or other Persons acting for or on behalf of the Divestiture Trustee;

(cc) "**Divestiture Trustee Sale Period**" shall have the meaning ascribed thereto in Confidential Schedule "A";

(dd) "**Initial Sale Period**" shall have the meaning ascribed thereto in Confidential Schedule "A";

(ee) "**Merckle**" means Merckle GmbH, its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and Affiliates in each case controlled by Merckle and the respective directors, officers, employees, agents, representatives, successors, and assigns of each;

(ff) "**MR Group**" means Merckle, CT and ABZ;

(gg) "**Monitor**" means a Person appointed pursuant to Part IV of this Agreement and any employees, agents or other Persons acting for or on behalf of the Monitor;

(hh) "**Patent**" means any Canadian patent or patent application, including provisional patent applications, invention disclosures, certificates of invention and applications for certificates of invention and statutory invention registrations, in each case existing as of the Closing Date (except where this Agreement specifies a different time), and includes, without limitation, all inventions disclosed therein, and all rights therein provided by international treaties and conventions, related to any Divestiture Product in Canada of or owned by the Respondent(s) as of the Closing Date (except where this Agreement specifies a different time);

(ii) "**Person**" means any individual, partnership, joint venture, firm, corporation, association, trust, unincorporated organization, joint venture, or other business or government entity, and any subsidiaries, divisions, groups or Affiliates thereof;

(jj) "**Product**" means any pharmaceutical, biological, or genetic composition containing any formulation or dosage of a compound referenced as its pharmaceutically, biologically, or genetically active ingredient and in any stage of Development, including commercialized Products;

(kk) "**Product Approvals**" means any approvals, registrations, permits, licences, consents, authorizations, and other approvals, and pending applications and requests therefor, required by any Agency related to the research, Development, manufacture, use, distribution, finishing, packaging, promotion, marketing, sale, storage, transport, import or export of a Product within Canada;

(ll) "**Proposed Purchaser**" means a Person proposed by the Respondents (or a Divestiture Trustee) to the Commissioner and submitted for the approval of the Commissioner as the Purchaser for particular Divestiture Assets pursuant to this Agreement;

(mm) "**Purchaser**" means a Person approved by the Commissioner to acquire particular Divestiture Assets, and includes any Person (other than a Respondent) that has been designated by a Purchaser to manufacture a Divestiture Product for that Purchaser;

(nn) "**Remedial Agreement(s)**" means any agreement between the Respondent(s) and a Purchaser, or between a Divestiture Trustee (on behalf of the Respondent(s)) and a Purchaser or a Third Party (to effect the assignment of assets or rights of the Respondent(s) related to the Divestiture Products to the benefit of a Purchaser), that has been approved by the Commissioner and that is specifically referenced in this Agreement as constituting a Remedial Agreement;

(oo) "**Respondent**" means Teva, Merckle, CT, and ABZ, individually and collectively;

(pp) "**Retained Product**" means any Product of the Respondents other than the Divestiture Products;

(qq) "**Supply Cost**" means a cost not to exceed the manufacturer's average direct per unit cost of manufacturing the Divestiture Product for the twenty-four (24) month period immediately preceding the Closing Date; provided, however, that in each instance where an agreement to contract manufacture becomes a Remedial Agreement for a Divestiture Product, "Supply Cost" means the cost as specified in such Remedial Agreement for that Divestiture Product;

(rr) "**Technology Transfer Standards**" means requirements and standards sufficient to ensure that the information and assets required to be delivered pursuant to this Agreement are delivered in an organized, comprehensive, complete, useful, timely (*e.g.*, ensuring no unreasonable delays in transmission), and meaningful manner. Such standards and requirements shall include, among other things:

(i) designating employees knowledgeable about the Divestiture Product Manufacturing Technology (and all related intellectual property) related to each of the Divestiture Products who will be responsible for communicating directly with the Purchaser and the Monitor, for the purpose of effecting such delivery;

(ii) preparing technology transfer protocols and transfer acceptance criteria for both the processes and analytical methods related to the Divestiture Products that are acceptable to the Purchaser;

(iii) preparing and implementing a detailed technological transfer plan, as approved by the Monitor, that contains, *inter alia*, the transfer of all relevant information, all appropriate documentation, all other materials, and projected time lines for the delivery of all such Divestiture Product Manufacturing Technology to the Purchaser; and

(iv) providing, in a timely manner, assistance and advice to enable the Purchaser to:

A. manufacture the specified Divestiture Product(s) in the quality and quantities achieved by the Respondent(s), or the manufacturer and/or developer of such Divestiture Product;

B. obtain any Product Approvals necessary for the Purchaser to manufacture, distribute, market and sell the specified Divestiture Product(s) in commercial quantities and to meet all Agency-approved specifications for Divestiture Product(s); and

C. receive, integrate and use all such Divestiture Product Manufacturing Technology;

(ss) "**Teva**" means Teva Pharmaceutical Industries Ltd., its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and Affiliates in each case controlled by Teva and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. Following the Acquisition, Teva shall include the MR Group;

(tt) "**Third Party**" means any non-governmental Person other than the Respondents, or a Purchaser; and

(uu) "**Tribunal**" means the Competition Tribunal established by the *Competition Tribunal Act*, R.S.C. 1985, c.19 (2nd Supp.), as amended;

All other terms defined in this Agreement have the meanings established elsewhere in this Agreement.

II. APPLICATION

[2] The provisions of this Agreement shall apply to:

(a) Teva;

(b) MR Group;

(c) each officer, director, employee, agent or other Person acting for or on behalf of the Respondents with respect to any of the matters referred to in this Agreement;

(d) all other Persons acting in concert or participating with one or more of those listed in (a) or (b), with respect to the matters referred to in this Agreement, who shall have received actual notice of this Agreement;

(e) the Commissioner;

(f) the Monitor;

(g) the Divestiture Trustee; and

(h) each Purchaser and the Purchaser's heirs, successors, legal representatives and assigns.

III. NO REACQUISITION OF THE DIVESTITURE ASSETS

[3] The Respondents shall not, for a period of ten (10) years from the date of this Agreement, directly or indirectly acquire any interest in the Divestiture Assets, without the prior written approval of the Commissioner.

IV. MONITOR

[4] The Commissioner may appoint a Monitor, as selected in her sole discretion, responsible for monitoring the compliance of the Respondents with this Agreement.

[5] The Monitor's obligations and powers shall not expire under this Agreement until the Respondents have complied with all of their obligations under Parts IV-X of this Agreement or further order of the Tribunal.

[6] Within seven (7) days of the appointment of the Monitor, the Respondents and the Monitor shall execute an agreement, subject to the approval of the Commissioner, agreeing to be bound by the terms and conditions of this Agreement and that confers on the Monitor all of the rights and powers necessary to permit the Monitor to monitor the Respondents' compliance with this Agreement. If the Respondents and the Monitor fail to agree on terms within seven (7) days from the date of appointment of the Monitor, the Commissioner shall establish the terms of the Monitor's service.

[7] The Respondents shall be responsible for all reasonable fees and expenses properly charged or incurred by the Monitor in the course of carrying out the Monitor's duties under this Agreement, and those of any substitute Monitor appointed pursuant to this Agreement. The Monitor shall serve without bond or security, and shall account for all fees and expenses incurred and such account shall be subject to the approval of the Commissioner only.

[8] The Respondents shall pay within sixty (60) days of receipt all reasonable invoices submitted by the Monitor. Any outstanding monies owed to the Monitor by the Respondents shall be paid out of the proceeds of the Divestiture.

[9] If the Monitor ceases to act or fails to act diligently or otherwise in accordance with this Agreement, the Commissioner shall appoint a substitute Monitor as selected in her sole discretion.

[10] The Monitor shall have, subject to a legally recognized privilege, full and complete access to all personnel, books, records, documents and facilities related to the Divestiture Assets or to any other information relevant to the performance of his responsibilities as Monitor, including Confidential Business Information, as the Monitor may reasonably request from the Respondents. The Respondents shall cooperate with any request of the Monitor. The Respondents shall not take any action to interfere with or impede the Monitor's compliance with this Agreement or the Monitor's ability to oversee the performance of this Agreement by the Respondents.

[11] The Monitor shall have the authority to engage, at the cost and expense of the Respondents, such consultants, accountants, attorneys, and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties and responsibilities under this Agreement.

[12] The Respondents shall indemnify the Monitor and hold the Monitor harmless against any losses, claims, damages, liabilities or expenses arising out of, or in connection with, the performance of their duties under this Agreement. This includes all reasonable fees of counsel and other expenses incurred in connection with the preparation or defence of any claim, whether or not such claim results in any liability, except to the extent that such

liabilities, losses, damages, claims or expenses result from malfeasance, gross negligence or bad faith by the Monitor.

[13] The Monitor shall report in writing to the Commissioner concerning compliance with this Agreement by the Respondents: (i) no later than thirty (30) days after the Closing Date and every thirty (30) days thereafter until the completion of the Divestiture; (ii) no later than thirty (30) days from the date upon which the Divestiture is completed in accordance with this Agreement; and (iii) within five (5) Business Days following a request by the Commissioner for supplemental information.

[14] The Respondents shall not exert or attempt to exert any influence, direction or control over the Monitor.

[15] The Monitor is not the agent of the Respondents and this Agreement shall not be construed as providing the Monitor with ownership, management, possession, charge or control of the Divestiture Assets.

[16] The Monitor shall execute a confidentiality agreement in a form determined by the Commissioner, pursuant to which the Monitor will undertake to the Respondents not to disclose any Confidential Business Information acquired in the performance of the Monitor's duties to any Person, except as permitted by such confidentiality agreement or by this Agreement.

[17] If the Monitor believes that a Respondent is in breach of any of the terms of this Agreement, the Monitor shall immediately notify the Commissioner and the Respondents of the breach, setting out the particulars of such breach.

V. PRESERVATION OF THE DIVESTITURE ASSETS

[18] In order to preserve the Divestiture Assets pending completion of the Divestiture, the Respondents shall:

a) ensure that the management and operation of the Divestiture Assets continues in the ordinary course of business and in a manner that is reasonably consistent in nature, scope and magnitude with past practices;

b) take all commercially reasonable efforts to maintain the full viability and saleability of the Divestiture Assets;

c) operate the Divestiture Assets in compliance with all applicable laws;

d) minimize any risk of loss of the competitive potential of the Divestiture Assets;

e) maintain all Product Approvals necessary for the operation of the Divestiture Assets;

f) maintain and hold the Divestiture Assets in an operating condition and state of repair at least equal to the current level for such assets, normal wear and tear excepted, and to standards at least equal to those that existed at the date of this Agreement;

g) prevent the destruction, removal, wasting, deterioration, or impairment of any of the Divestiture Assets, except for ordinary wear and tear;

h) subject to all applicable laws, maintain all fees, deductions, discounts, credits or allowances with respect to the services provided in connection with the Divestiture Assets;

i) honour all customer contracts and maintain quality and service standards for customers of the business related to the Divestiture Assets at least equal to the standards that existed prior to the date of this Agreement;

j) not enter into, withdraw from, amend or otherwise take steps to alter any obligations in material contracts relating to the Divestiture Assets, except as necessary to comply with this Agreement;

k) not sell, transfer, encumber or otherwise impair the Divestiture Assets (other than in the manner prescribed in this Agreement) nor take any action that lessens the full economic viability, marketability, or competitiveness of the Divestiture Assets;

l) ensure that the Divestiture Assets are not engaged in any type of business other than the type of business conducted as of the date of this Agreement, except with the prior approval of the Monitor and the Commissioner;

m) not communicate any Confidential Business Information related to the Divestiture Assets to anyone other than the Monitor, the Commissioner, or as otherwise permitted herein;

n) not take or allow to be taken any action that materially and adversely affects the competitiveness, operations, financial status or value of the Divestiture Assets;

o) not materially curtail marketing, sales, promotional or other activities in relation to the Divestiture Assets in connection with the solicitation of existing or prospective customers, except with the prior approval of the Monitor and the Commissioner;

p) not alter to any material extent, or cause to be altered, the management of the Divestiture Assets as it existed prior to the date of this Agreement, except: (i) as may be necessary to comply with the terms of this Agreement; (ii) to replace employees who may resign; or (iii) with the prior approval of the Monitor;

q) not terminate or alter any employment, salary or benefit agreements, as they existed at the date of this Agreement, for Persons employed in connection with the Divestiture Assets, without the prior approval of the Monitor; and

r) ensure that all financial information with respect to the Divestiture Products is maintained including, without limitation, volumes, pricing, discounts and cost of goods sold.

VI. DIVESTITURE PROCESS (INITIAL SALE PERIOD)

[19] The Initial Sale Period commences on the Closing Date and ends at the time prescribed in Confidential Schedule "A" to this Agreement.

[20] During the Initial Sale Period, the Respondents shall promptly use all commercially reasonable efforts to:

(a) complete the Divestiture in accordance with this Agreement, such that the Respondents will have no direct or indirect interest in the Divestiture Assets, except as permitted herein;

(b) complete the Divestiture to a Purchaser that is:

(i) approved in writing by the Commissioner and on terms approved in writing by the Commissioner, each as determined in her sole discretion;

(ii) at arm's length from the Respondents; and

(iii) able to satisfy the Commissioner, in her sole discretion, that such Purchaser:

A. is committed to carrying on the business of the Divestiture Assets in Canada;

B. has the managerial, operational and financial capability to compete effectively in the production, marketing, distribution and sale of generic drugs in Canada; and

C. will complete the Divestiture prior to the expiry of the Initial Sale Period.

The determination of whether the above conditions are satisfied is at the sole discretion of the Commissioner. In exercising her discretion to approve a Divestiture to a Proposed Purchaser, the Commissioner may take into account, *inter alia*, the likely impact of the Divestiture on competition.

[21] The Respondents shall Divest of all of the Divestiture Assets to the same Purchaser, unless otherwise agreed in writing by the Commissioner.

[22] The Respondents shall promptly notify the Commissioner of their intention to enter into a Divestiture Agreement with respect to any proposed Divestiture.

[23] Within five (5) Business Days of receipt of the notice described in paragraph 22 above, the Commissioner may request additional information concerning the proposed Divestiture and the Proposed Purchaser. The Commissioner may request further additional information within three (3) Business Days of all of the information received from the prior request.

[24] The Commissioner shall notify the Respondents of her approval of, or objection to, the proposed Divestiture or the Proposed Purchaser as soon as possible, and in any event within five (5) Business Days of receipt of all information requested pursuant to paragraph 23 above, or, if no additional information was requested, within ten (10) Business Days of the receipt of notice described in paragraph 22 above. In the event that the Commissioner approves a Divestiture, any agreement entered into by any Respondent and the Proposed Purchaser shall constitute a Remedial Agreement.

[25] The Respondents shall provide reasonable and customary commercial covenants, representations, warranties and indemnities to the Purchaser, consistent with those typically included in sales of assets similar to the Divestiture Assets.

[26] Any Person making a *bona fide* inquiry of the Respondents shall be notified by the Respondents that the Divestiture is being made pursuant to this Agreement and shall be provided with a copy of this Agreement, with the exception of the provisions hereof which are confidential.

[27] Subject to paragraphs 28 and 29 below, any prospective Purchaser who has demonstrated a *bona fide* interest and who has the financial capability to complete a purchase of the Divestiture Assets shall:

(a) be furnished with all pertinent information regarding the Divestiture Assets within fourteen (14) days of a request therefor;

(b) be permitted to make reasonable inspection of the Divestiture Assets and of all financial, operational or other non-privileged documents and information, including Confidential Business Information, which may be relevant to the Divestiture, except for any documents which, at the time of the request for inspection of such documents, the Commissioner has agreed need not be disclosed; and

(c) be given such full and complete access as is reasonable in the circumstances to the management personnel relating to the Divestiture Assets.

[28] If the Monitor is concerned as to the *bona fides* or the financial capability of any Person making an inquiry, or as to the Respondents' compliance with the requirements of subparagraphs 27(a)-(c) above, the Monitor shall advise the Commissioner of such concern and the final determination of *bona fides*, financial capability, or requirements shall be made by the Commissioner alone.

[29] Access by a prospective Purchaser to the information identified in paragraph 27 above shall be conditional on the approval of the Commissioner and on the prospective Purchaser demonstrating its financial capability to complete a purchase of the Divestiture Assets and executing a standard confidentiality agreement in a form determined by the Commissioner.

[30] Prior to the Divestiture Date, the Respondents shall obtain all consents and waivers from all Third Parties that are necessary to permit the Respondents to Divest the Divestiture Assets and grant the Divestiture Product Licences to the Purchaser, and/or to permit the Purchaser to continue the research, Development, manufacture, sale, marketing or distribution of the Divestiture Products, provided, however, the Respondents may satisfy this requirement by certifying that the Purchaser has executed all such agreements directly with each of the relevant Third Parties.

[31] The Respondents shall transfer and deliver, or cause to be transferred and delivered, to the Purchaser all Divestiture Product Manufacturing Technology related to the Divestiture Products and shall transfer and deliver, or cause to be transferred and delivered, all rights to all Product Manufacturing Technology that is owned by a Third Party and licensed by the Respondents to the Purchaser in a manner consistent with the Technology Transfer Standards. The Respondents shall obtain any consents from Third Parties required to comply with this provision. The Respondents shall continue for one (1) additional year from the Divestiture Date to make personnel available, in a reasonable time and manner, to respond to inquiries from the Purchaser related to the Divestiture Assets and Divestiture Product Licences.

[32] The Respondents shall:

(a) deliver to the Purchaser, at the Respondents' expense, all Confidential Business Information:

(i) in good faith;

(ii) in a timely manner, *i.e.*, as soon as practicable, avoiding any delays in transmission of the respective information; and

(iii) in a manner that ensures its completeness and accuracy and that fully preserves its usefulness;

(b) pending complete delivery of all such Confidential Business Information to the Purchaser, provide the Purchaser and the Monitor with access to all such Confidential Business Information and employees who possess or are able to locate such information for the purposes of identifying the books, records, and files directly related to the Divestiture Products that contain such Confidential Business Information and facilitating the delivery in a manner consistent with this Agreement;

(c) not use, directly or indirectly, any Confidential Business Information other than as necessary to comply with the following:

(i) the requirements of this Agreement;

(ii) the Respondents' obligations to the Purchaser under the terms of any Remedial Agreement; or

(iii) applicable law; and

(d) not disclose or convey any such Confidential Business Information, directly or indirectly, to any Person except the Purchaser or other Persons specifically authorized by the Purchaser to receive such information.

[33] The Respondents shall not enforce any agreement against a Third Party or the Purchaser to the extent that such agreement may limit or otherwise impair the ability of such Purchaser to acquire or use the Divestiture Product Manufacturing Technology from the Third Party. Such agreements include, but are not limited to, agreements with respect to the disclosure of Confidential Business Information related to such Divestiture Product Manufacturing Technology.

[34] Not later than ten (10) days after the Divestiture Date, the Respondents shall grant a release to each Third Party that is subject to an agreement as described in paragraph 33 that allows the Third Party to provide the relevant Divestiture Product Manufacturing Technology to the Purchaser. Forthwith upon the execution of each such release, the Respondents shall provide a copy of the release to the Purchaser.

[35] On the Divestiture Date, the Respondents shall provide written notification of the restrictions on the use of the Confidential Business Information by Respondents' personnel to all of the Respondents' employees who:

(a) are or were directly involved in the research, Development, manufacturing, distribution, sale or marketing of any of the Divestiture Products; or

(b) may have Confidential Business Information.

The Respondents shall give such notification by e-mail with return receipt requested or similar transmission, and keep a file of such receipts for one (1) year after the Divestiture Date. The Respondents shall provide a copy of such notification to the Purchaser. The Respondents shall maintain complete records of all such correspondence at the Respondents' applicable registered office and shall provide an officer's certification to the Commissioner stating that such acknowledgment program has been implemented and is being complied with. The Respondents shall provide the Purchaser with copies of all certifications, notifications and reminders sent to the Respondents' personnel.

VII. CONTRACT MANUFACTURE

[36] The Respondents shall:

(a) upon reasonable written notice and request from a Purchaser to the Respondents, contract manufacture (which contract shall constitute a Remedial Agreement) and

deliver to the Purchaser, in a timely manner and under reasonable terms and conditions (as approved by the Commissioner in her sole discretion), a supply of each of the Divestiture Products at the Respondents' Supply Cost, for a period of time sufficient to allow such Purchaser to obtain all of the relevant Product Approvals necessary to manufacture in commercial quantities, and in a manner consistent with cGMP, the finished Divestiture Product independently of the Respondents and to secure sources of supply of the active pharmaceutical ingredients, excipients, other ingredients, and/or necessary components for the Divestiture Products from Persons other than the Respondents;

(b) make representations and warranties to the Purchaser that the Product(s) supplied pursuant to the Remedial Agreement meet the relevant Agency-approved specifications for the Divestiture Product(s) to be marketed or sold in Canada. The Respondents shall agree to indemnify, defend and hold the Purchaser harmless from any and all suits, claims, actions, demands, liabilities, expenses or losses alleged to result from the failure of the Product(s) supplied to the Purchaser pursuant to the Remedial Agreement by the Respondents to meet cGMP. This obligation may be made contingent upon the Purchaser giving the Respondents prompt written notice of such claim and cooperating fully in the defense of such claim. The Remedial Agreement shall be consistent with the obligations assumed by the Respondents under this Agreement; provided, however, that the Respondents may reserve the right to control the defense of any such litigation, including the right to settle the litigation, so long as such settlement is consistent with the Respondents' responsibilities to supply the ingredients and/or components in the manner required by this Agreement; provided further that this obligation shall not require the Respondents to be liable for any negligent act or omission of the Purchaser or for any representations and warranties, express or implied, made by the Purchaser that exceed the representations and warranties made by the Respondents to the Purchaser;

(c) give priority to supplying contract manufacture Divestiture Products to the Purchaser over manufacturing and supplying of Product(s) for the Respondents' own use or sale;

(d) make representations and warranties to the Purchaser that the Respondents shall hold harmless and indemnify the Purchaser for any liabilities or loss of profits resulting from the failure by the Respondents to deliver the contract manufactured Divestiture Products in a timely manner as required by the Remedial Agreement(s) unless the Respondents can demonstrate that any failure was entirely beyond the control of the Respondents and in no part the result of negligence or willful misconduct by the Respondents; provided, however, that in each instance where an agreement to divest relevant assets becomes a Remedial Agreement for a Divestiture Product, each such agreement may contain limits on the Respondents' aggregate liability for such a breach;

(e) during the term of any contract manufacture between the Respondents and a Purchaser, upon written request of such Purchaser or the Monitor, make available

to the Purchaser and the Monitor all records that relate to the manufacture of the relevant contract manufacture Divestiture Products that are generated or created after the Closing Date;

(f) during the term of any contract manufacture between the Respondents and a Purchaser, maintain manufacturing facilities necessary to manufacture each of the relevant contract manufacture Divestiture Products in finished form, *i.e.*, suitable for sale to the ultimate consumer/patient; and

(g) during the term of any contract manufacture between the Respondents and a Purchaser, provide consultation with knowledgeable employees of the Respondents and training, at the written request of the Purchaser and at a facility chosen by the Purchaser, for the purposes of enabling such Purchaser to obtain all Product Approvals to manufacture the Divestiture Products in the same quality achieved by, or on behalf of, the Respondents and in commercial quantities, and in a manner consistent with cGMP independently of the Respondents, and sufficient to satisfy the Monitor and management of the Purchaser that the Purchaser's personnel are adequately trained in the manufacture of the Divestiture Products.

[37] The foregoing subparagraphs 36(a) – (g) shall remain in effect with respect to each Divestiture Product until the earliest of: (1) the date the Purchaser of the applicable Divestiture Product is approved to manufacture such Divestiture Product and able to manufacture such Divestiture Product in commercial quantities, in a manner consistent with cGMP, independently of the Respondents; (2) the date the Purchaser of the applicable Divestiture Product notifies the Commissioner and the Respondents of its intention to abandon its efforts to manufacture such Divestiture Product; (3) the date of written notification from the Commissioner that the Monitor, in consultation with the Commissioner, has determined that the Purchaser of the applicable Divestiture Product has abandoned its efforts to manufacture such Divestiture Product; or one (1) year from the Closing Date.

VIII. DIVESTITURE TRUSTEE PROCESS

[38] In the event that the Respondents fail to complete the Divestiture during the Initial Sale Period, the Commissioner may appoint a Divestiture Trustee to, within the Divestiture Trustee Sale Period, complete the Divestiture in accordance with this Agreement, including Confidential Schedule "B", to a Purchaser approved by the Commissioner and on terms approved by the Commissioner, in her sole discretion. The Divestiture Trustee shall use whatever procedure he believes is suitable, as determined by the Divestiture Trustee in his sole discretion, subject to oversight and approval by the Commissioner only.

[39] The Commissioner may appoint the Divestiture Trustee ten (10) days before the expiry of the Initial Sale Period or on such later date as determined by the Commissioner. Immediately following the appointment of the Divestiture Trustee, and prior to the expiry of the Initial Sale Period, the Respondents shall provide the Divestiture Trustee with

complete access to all information relating to the Divestiture Assets, including Confidential Business Information, to facilitate the Divestiture by the Divestiture Trustee. At that time, the Respondents shall notify the Divestiture Trustee of any negotiations that were held with any prospective Purchasers and shall forward to the Divestiture Trustee copies of any agreement with a prospective Purchaser, including non-binding expressions of interest.

[40] The Divestiture Trustee shall have full and exclusive authority during the Divestiture Trustee Sale Period to complete the Divestiture and enter into a legally binding agreement with a Purchaser that will be binding on the Respondents. The Respondents shall be bound by any agreement entered into by the Divestiture Trustee on behalf of the Respondents to complete the Divestiture in accordance with this Part. The Respondents agree that they will do all such acts and execute all such further documents, and will cause the doing of all such acts and the execution of all such further documents as are within their power to cause the doing or execution of, as may be reasonably necessary to ensure that the Divestiture Assets are Divested in the Divestiture Trustee Sale Period and that agreements entered into by the Divestiture Trustee are binding upon and enforceable against the Respondents.

[41] Any Person making a *bona fide* inquiry of the Respondents shall be notified that the Divestiture is being made pursuant to this Agreement and shall be provided with a copy of this Agreement, with the exception of Confidential Schedule "B", which sets out certain terms in accordance with which the Divestiture Trustee is to complete the Divestiture.

[42] The Respondents consent to the following terms and conditions regarding the Divestiture Trustee's powers, duties, authority, and responsibilities:

(a) Subject to oversight and approval by the Commissioner only, the Divestiture Trustee shall have the exclusive authority to control the Divestiture by whatever procedure the Divestiture Trustee believes in its sole discretion is suitable.

(b) The Respondents will not be included in the Divestiture process, including negotiations, nor will the Respondents have contact with the prospective Purchasers, except with the prior approval of the Commissioner; provided, however, the Divestiture Trustee may consult with the Respondents in the presence of a representative of the Commissioner when the Divestiture Trustee considers such consultation to be appropriate and the Commissioner consents.

(c) Notwithstanding any term of this Agreement, the Divestiture Trustee's obligations and powers under this Agreement shall not expire until the Divestiture is completed.

(d) The Divestiture Trustee shall execute a confidentiality agreement in a form determined by the Commissioner and shall refrain from communicating any Confidential Business Information to anyone except to the extent reasonably required to effect the Divestiture.

(e) The Respondents shall grant the Divestiture Trustee full and complete access to all personnel, books, records and facilities related to the Divestiture Assets and to any other information, including Confidential Business Information, deemed relevant by the Divestiture Trustee to effect the Divestiture. The Respondents shall take no action to interfere with or impede the Divestiture Trustee's efforts to complete the Divestiture.

(f) The Respondents shall fully and promptly respond to all requests from the Divestiture Trustee and shall provide all information the Divestiture Trustee may request. The Respondents shall identify an individual who shall have primary responsibility for responding to such requests from the Divestiture Trustee on behalf of the Respondents.

(g) The Divestiture Trustee shall have the sole authority to determine, and the Respondents shall provide, all reasonable and customary commercial covenants, representations, warranties and indemnities for the purpose of completing the Divestiture.

(h) The Divestiture Trustee shall serve, without bond or other security, at the cost and expense of the Respondents, and on such reasonable terms and conditions as the Commissioner may set.

(i) The Respondents shall pay within thirty (30) days of receipt all reasonable invoices submitted by the Divestiture Trustee. Any outstanding monies owed to the Divestiture Trustee by the Respondents shall be paid out of the proceeds of the Divestiture.

(j) The Divestiture Trustee shall have the authority to employ, at the expense of the Respondents, such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are necessary to carry out the Divestiture Trustee's duties and responsibilities. The Divestiture Trustee shall account for all fees and expenses incurred and such account shall be subject to the approval of the Commissioner only.

(k) The Respondents shall indemnify the Divestiture Trustee and hold the Divestiture Trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Divestiture Trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation or defence of any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from malfeasance, gross negligence or bad faith by the Divestiture Trustee.

(l) If the Divestiture Trustee ceases to act or fails to act diligently or otherwise in accordance with this Agreement or any agreement between the Commissioner and the Divestiture Trustee, the Commissioner may appoint a substitute Divestiture

Trustee in the same manner as provided in this Part for the initial Divestiture Trustee.

(m) The Divestiture Trustee shall have no obligation or authority to operate or maintain the Divestiture Assets.

(n) The Divestiture Trustee shall report in writing to the Commissioner every thirty (30) days following the date of the Divestiture Trustee's Appointment, and upon the Commissioner's request within three (3) days, concerning the Divestiture Trustee's efforts to complete the Divestiture. Such reports shall contain reasonable detail on the steps being taken by the Divestiture Trustee to complete the Divestiture, including but not limited to: the identity of the prospective Purchasers; the status of negotiations with the prospective Purchasers; and any additional information requested by the Commissioner.

(o) The Divestiture Trustee shall promptly notify the Commissioner of any proposed agreement to effect the Divestiture. Such notice shall include: the identity of the Proposed Purchaser; the details of the proposed Divestiture; information concerning whether, in the view of the Divestiture Trustee, the Proposed Purchaser would likely satisfy the terms of this Agreement; and any additional information requested by the Commissioner.

(p) The Divestiture Trustee shall complete the Divestiture to a Purchaser that is:

(i) approved in writing by the Commissioner and on terms approved in writing by the Commissioner, each as determined in her sole discretion;

(ii) at arm's length from the Respondents; and

(iii) able to satisfy the Commissioner, in her sole discretion, that such a Purchaser:

(a) is committed to carrying on business in Canada using the Divestiture Assets;

(b) has the managerial, operational and financial capability to compete effectively in the production, marketing, distribution and sale of generic drugs in Canada; and

(c) will complete the Divestiture prior to the expiry of the Divestiture Trustee Sale Period.

The determination of whether the above conditions are satisfied is at the sole discretion of the Commissioner. In exercising her discretion to approve a Divestiture to a Proposed Purchaser, the Commissioner may take into account, *inter alia*, the likely impact of the Divestiture on competition. The decision of the Commissioner as to whether to approve the proposed Divestiture shall be in writing. In the event that the Commissioner approves a Divestiture, any

agreement entered into by the Divestiture Trustee and a Proposed Purchaser shall constitute a Remedial Agreement.

(q) The Respondents may not object to or challenge the performance of the Divestiture Trustee's duties under this Agreement or a Divestiture by the Divestiture Trustee on any grounds other than the Divestiture Trustee's malfeasance, gross negligence or bad faith in executing its obligations hereunder. If the Respondents object to the terms and conditions of a Divestiture that has been proposed by the Divestiture Trustee on the grounds of malfeasance, gross negligence or bad faith by the Divestiture Trustee, the Respondents or the Commissioner may apply to the Tribunal for directions, but in no event shall any such dispute serve to suspend the Divestiture Trustee Sale Period.

IX. FAILURE OF DIVESTITURE TRUSTEE SALE

[43] If, by the end of the Divestiture Trustee Sale Period, the Divestiture has not been completed, or if the Commissioner is of the opinion that the Divestiture likely will not be completed prior to the end of the Divestiture Trustee Sale Period, the Commissioner may apply to the Tribunal for such order as is necessary to complete the Divestiture, or for such order as is necessary to ensure that the Acquisition is not likely to lessen competition substantially. The Respondents agree that they shall not, in any such application, contest the Commissioner's conclusions that: (i) the Acquisition is likely to result in a substantial lessening of competition in the supply of Acetaminophen Oxycodone tablets and Morphine Sulfate SR tablets in Canada; and (ii) the implementation of this Agreement is necessary to ensure that any substantial lessening of competition will not result from the Acquisition.

[44] The Respondents agree that the Tribunal has jurisdiction to grant such relief as contemplated in paragraph 43, and as is required to give effect to this Agreement and complete the Divestiture.

X. REMEDIAL AGREEMENTS

[45] Any Remedial Agreement shall be deemed incorporated into this Agreement.

[46] The Respondents shall include in each Remedial Agreement related to each of the Divestiture Products a specific reference to this Agreement and provisions to reflect the full scope and breadth of each of the Respondents' obligations to the Purchaser pursuant to this Agreement.

[47] The Respondents shall also include in each Remedial Agreement a representation from the Purchaser that such Purchaser shall use commercially reasonable efforts to secure the Health Canada approval(s) necessary to manufacture, or to have manufactured by a Third Party, in commercial quantities, each such Divestiture Product and to have any such manufacture be independent of the Respondents, all as soon as reasonably practicable.

[48] Any failure by a Respondent to comply with any term of such Remedial Agreement shall constitute a failure to comply with this Agreement.

[49] The Respondents shall not modify or amend any of the terms of any Remedial Agreement without the prior approval of the Commissioner.

[50] The Respondents shall not seek, directly or indirectly, pursuant to any dispute resolution mechanism incorporated in any Remedial Agreement, or in any agreement related to any of the Divestiture Products, a decision the result of which would be inconsistent with the terms of this Agreement.

XI. COMPLIANCE

[51] Within five (5) days of the Closing Date, the Respondents shall submit to the Commissioner a letter certifying the date on which the Acquisition occurred.

[52] The Respondents shall: (i) thirty (30) days from the Closing Date, and every thirty (30) days thereafter until the completion of the Divestiture, and every ninety (90) days thereafter until the Respondents have fully complied with Parts IV-X of this Agreement, provide to the Commissioner a declaration of compliance with this Agreement; and (ii) provide to the Commissioner information requested by the Commissioner to confirm compliance with this Agreement no later than ten (10) Business Days after receiving a request for such information from the Commissioner.

[53] In the event of a material breach of any of the terms of this Agreement, the Respondents shall, upon becoming aware of such breach, promptly notify the Commissioner thereof, and shall provide details sufficient to describe the nature, date and effect (actual or anticipated) of the breach.

[54] For purposes of determining or securing compliance with this Agreement, subject to any legally recognized privilege, and upon written request and two (2) days notice to any Respondent, such Respondent shall, without restraint or interference, permit any representative of the Commissioner:

(a) access, during business office hours of such Respondent, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda and all other records and documents in the possession or under the control of such Respondent related to compliance with this Agreement, which copying services shall be provided by such Respondent at their expense; and

(b) to interview officers, directors, or employees of such Respondent regarding compliance with this Agreement,

it being understood that this paragraph 54 shall not be construed so as to derogate from any protections afforded by section 29 of the Act.

XII. NOTIFICATION

[55] Notices, reports and other communications required or permitted pursuant to this Agreement shall be in writing and shall be considered to be given if dispatched by personal delivery, registered mail or facsimile transmission to the parties as follows:

(a) If to the Commissioner:

Competition Bureau
Place du Portage, 21st Floor
50 Victoria Street, Phase I
Gatineau, Quebec K1A 0C9
Attention: Commissioner of Competition
Fax: (819) 953-5013

With a copy to:

Executive Director and Senior General Counsel
Competition Bureau Legal Services
Justice Canada
Place du Portage, Phase I
50 Victoria Street
Gatineau, Quebec K1A 0C9

(b) If to the Respondents:

Teva Canada Limited
30 Novopharm Court
Toronto, Ontario
M1B 2K9
Attention: Ildiko Mehes
Fax: (416) 335-4472

With a copy to:

Bennett Jones LLP
3400 One First Canadian Place
P.O. Box 130
Toronto, Ontario
M5X 1A4
Attention: Adam Kalbfleisch
Fax: (416) 863-1716

or to such other street address, individual or electronic communication number or address as may be designated by notice given by any party to the other parties. Any demand, notice or other communication given by personal delivery will be conclusively deemed to have been given on the day of actual delivery and, if given by registered mail, on the fifth day following the deposit thereof in the mail and, if given by electronic communication, on the day of transmittal thereof if given during the normal business hours of the recipient and on the day during which such normal business hours next occur if not given during such hours on any day. If the party giving any demand, notice or other communication knows or ought reasonably to know of any difficulties with the postal system that might affect the delivery of mail, any such demand, notice or other

communication may not be mailed but must be given by personal delivery or by electronic communication.

XIII. DURATION

[56] The Respondents shall be bound by the terms of this Agreement:

(a) in respect of the obligations set forth in Part III of this Agreement, for a period of ten (10) years from the date of this Agreement; and

(b) in respect of the remainder of this Agreement, until the Respondents have fully complied with Parts IV-X of this Agreement or further order of the Tribunal.

XIV. GENERAL

[57] The Respondents agree to the immediate filing by the Commissioner of this Agreement for registration with the Tribunal.

[58] Information in Confidential Schedule "A" shall be made public upon the expiry of the Initial Sale Period. Information in Confidential Schedule "B" shall be made public upon the completion of the Divestiture.

[59] The Commissioner may, in her sole discretion, extend any of the time periods contemplated by this Agreement. The Respondents and the Commissioner may mutually agree to amend this Agreement in any manner pursuant to subsection 106(1) of the Act.

[60] Nothing in this Agreement (including the recitals hereto) precludes the Respondents from bringing an application under section 106 of the Act (or a successor or equivalent provision under the Act) to vary or rescind this Agreement. The Respondents agree that they shall not, in any such application, contest the Commissioner's conclusions that: (i) the Acquisition is likely to result in a substantial lessening of competition in the supply of Acetaminophen Oxycodone tablets and Morphine Sulfate SR tablets in Canada; and (ii) the implementation of this Agreement is necessary to ensure that any substantial lessening of competition will not result from the Acquisition.

[61] This Agreement constitutes the entire agreement between the Commissioner and the Respondents and supersedes all prior agreements, understandings, negotiations and discussions, whether written or oral, with respect to the subject matter hereof.

[62] This Agreement shall be governed by and interpreted in accordance with the laws of Ontario and the laws of Canada applicable therein.

[63] Computation of time periods contemplated by this Agreement shall be in accordance with the *Interpretation Act*, R.S.C. 1985, c. I-21. For the purpose of this Agreement, the definition of "holiday" in the *Interpretation Act* shall be deemed to include Saturday.

[64] Nothing in this Agreement abrogates the notification obligations set out in Part IX of the Act.

[65] In the event of a dispute regarding the interpretation, implementation or application of this Agreement, any of the Commissioner, the Monitor or the Respondents may apply to the Tribunal for directions or an order. In the event of any discrepancy between the English language version of this Agreement and the French language version of this Agreement, the English language version of this Agreement shall prevail. In no event shall any dispute serve to suspend the Initial Sale Period or the Divestiture Trustee Sale Period.

[66] Words used in this Agreement in the singular shall include the plural and words used in the plural shall include the singular.

[67] This Agreement may be executed in two or more counterparts, each of which shall be an original instrument, but all of which shall constitute one and the same Agreement.

[INTENTIONALLY LEFT BLANK]

The undersigned hereby agree to the immediate filing for registration of this Agreement.

DATED this 30th day of July, 2010.

"Melanie L. Aitken"

Name: Melanie L. Aitken

Title: Commissioner of Competition

TEVA PHARMACEUTICALS INDUSTRIES LTD.

By: *"Bill Marth"*

Name: Bill Marth

Title: President and CEO, Teva North America

By: *"Ildiko Mehes"*

Name: Ildiko Mehes

Title: General Counsel, Teva Canada

MERCKLE GMBH

By: *"Oliver Windholz"* *"Dr. Matthias Eschricht"*

Name: Oliver Windholz Dr. Matthias Eschricht

Title: Managing Director General Counsel

CT ARZNEIMITTEL GMBH

By: *"Ludwig Merckle"*

Name: Ludwig Merckle

Title: Managing Director

ABZ-PHARMA HOLDING GMBH

By: *"Ludwig Merckle"*

Name: Ludwig Merckle

Title: Managing Director

CONFIDENTIAL SCHEDULE "A"

[CONFIDENTIAL]

CONFIDENTIAL SCHEDULE "B"

[CONFIDENTIAL]