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UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

COMMISSIONERS: **William E. Kovacic, Chairman**
Pamela Jones Harbour
Jon Leibowitz
J. Thomas Rosch

In the Matter of	)	
INVERNESS MEDICAL INNOVATIONS, INC., a corporation.	)	**Docket No. C-**

DECISION AND ORDER
[Public Record Version]

The Federal Trade Commission ("Commission"), having initiated an investigation of certain acts and practices of Respondent Inverness Medical Innovations, Inc., hereinafter referred to as "Respondent," and Respondent having been furnished thereafter with a copy of a draft of Complaint which the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondent with violations of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondent, its attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Order ("Consent Agreement"), containing an admission by Respondent of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondent that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondent has violated the said Act, and that a Complaint should issue stating its charges in that respect, and having thereupon issued its Complaint, and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby makes the following jurisdictional findings and issues the following Decision and Order ("Order"):

1. Respondent Inverness Medical Innovations, Inc. is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its headquarters address at 51 Sawyer Road, Suite 200, Waltham, Massachusetts 02453.

2. The Commission has jurisdiction of the subject matter of this proceeding and of Respondent, and the proceeding is in the public interest.

ORDER

I.

IT IS ORDERED that, as used in the Order, the following definitions shall apply:

A. "Inverness" or "Respondent" means Inverness Medical Innovations, Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Inverness Medical Innovations, Inc., and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.

B. "Commission" means the Federal Trade Commission.

C. "ACON" means ACON Laboratories, Inc., a corporation organized, existing and doing business under and by virtue of the laws of the State of California, with its headquarters address located at 4108 Sorrento Valley Boulevard, San Diego, California 92121. The term "ACON" includes ACON Laboratories, Inc., its parent, directors, officers, employees, agents, representatives, successors and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by ACON Laboratories, Inc., and the respective directors, officers, employees, agents, representatives, predecessors, successors, and assigns of each.

D. "Acquisition" means Respondent Inverness's acquisition of certain assets and rights of ACON pursuant to an Acquisition Agreement by and among Inverness Medical Innovations, Inc., ACON Laboratories, Inc., Azure Institute, Inc., LBI, Inc., Oakville Hong Kong Co., Ltd., ACON Biotech (Hangzhou) Co., Ltd., and Karsson Overseas, Ltd., dated as of February 24, 2006, and includes certain "Noncompetition Agreements" attached as exhibits thereto.

E. "Aemoh" means Aemoh Products, LLC, a limited liability company, organized, existing, and doing business under and by virtue of the laws of the State of Massachusetts, with its headquarters address at 12 Hopewell Farm Road, South Natick, MA 01760.

F. "Agency(ies)" means any government regulatory authority or authorities in the world responsible for granting approval(s), clearance(s), qualification(s), license(s), or permit(s) for any aspect of the research, Development, manufacture, marketing, distribution, or sale of

a product. The term "Agency" includes, without limitation, the United States Food and Drug Administration ("FDA").

G. "Assays" means any qualitative or quantitative analysis of a substance to determine its components or characteristics, the results of such analysis, and all information necessary to replicate such analysis, including without limitation, the following: all data, observations, and records relating to the analysis, the methodologies and procedures used in such analysis, all experiments performed, all information related to the development and qualification of such an analysis, and the identities of the person or persons responsible for such development and qualification of such an analysis.

H. "Bayer" means Bayer Healthcare LLC, a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware, with its headquarters address at 511 Benedict Avenue, Tarrytown, New York 10591-5097. The term "Bayer" includes Bayer Healthcare LLC, its parent, directors, officers, employees, agents, representatives, successors and assigns; and its joint ventures, subsidiaries (including Metrika, Inc.), divisions, groups and affiliates in each case controlled by Bayer Healthcare LLC, and the respective directors, officers, employees, agents, representatives, predecessors, successors, and assigns of each.

I. "Church & Dwight" means Church & Dwight Co., Inc., a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware, with its headquarters address at 469 N. Harrison Street, Princeton, New Jersey 08543-5297.

J. "Church & Dwight/ACON R&D Agreement" shall mean the "Research and Development Agreement" between ACON and Church & Dwight (dated April 27, 2005), as amended.

K. "Church & Dwight/ACON Supply Agreement" shall mean the "Supply Agreement" between ACON and Church & Dwight (dated June 23, 2006), as amended.

L. "Confidential Business Information" means all information owned by, or in the possession or control of, Respondent that is not in the public domain and that is directly related to the research, Development, manufacture, marketing, commercialization, importation, exportation, cost, supply, sales, sales support or use of the Digital Consumer Pregnancy Test Products and was created, generated, or Developed by either ACON or Church & Dwight under the Church & Dwight/ACON R&D Agreement or the Church & Dwight/ACON Supply Agreement; *provided, however*, that the restrictions contained in this Order regarding the use, conveyance, provision or disclosure of "Confidential Business Information" shall not apply to the following:

1. information that subsequently falls within the public domain through no violation of this Order or breach of confidentiality or non-disclosure agreement with respect to such information by Respondent;

2. information related to the Digital Consumer Pregnancy Test Products that Respondent can demonstrate it obtained without the assistance of ACON prior to the Acquisition; and

3. information that is required by Law to be publicly disclosed.

M. "Consumer Pregnancy Test(s)" means any product marketed, or designed to be marketed, to an end user in the over-the-counter market that uses a lateral flow strip to detect the presence or absence of a pregnancy-indicating hormone in a urine sample.

N. "Contract Manufacture" means the testing and manufacture of a Digital Consumer Pregnancy Test Product to be supplied by Respondent, ACON, or a Designee to Church & Dwight.

O. "Designee" means any entity other than Respondent or ACON that will manufacture a Digital Consumer Pregnancy Test Product on behalf of Church & Dwight.

P. "Development" means all product development activities, including: test method development and stability testing; toxicology; formulation; process development; manufacturing scale-up; development-stage manufacturing; quality assurance/quality control development; statistical analysis and report writing; conducting tests or trials for any and all approvals, licenses, registrations or authorizations from any Agency necessary for the manufacture, use, storage, import, export, transport, promotion, marketing, and sale of a product (including any government price or reimbursement approvals); and regulatory affairs related to the foregoing. "Develop" means to engage in Development.

Q. "Digital Consumer Pregnancy Test Product(s)" means the Consumer Pregnancy Test products that are the subject of Appendix 1 of Church & Dwight/ACON R&D Agreement and/or Attachment A-1 of the Church & Dwight/ACON Supply Agreement.

R. "Digital Consumer Pregnancy Test Product Assets" means all rights, title and interest in and to the following assets:

1. all Digital Consumer Pregnancy Test Product Intellectual Property;

2. all Product Approvals directly related to the Digital Consumer Pregnancy Test Products;

3. all Product Manufacturing Technology that was created, generated, or Developed by ACON and/or Church & Dwight under the Church & Dwight/ACON R&D Agreement or the Church & Dwight/ACON Supply Agreement;

4. all Product Development Reports directly related to the Digital Consumer Pregnancy Test Products;

5. all Trademarks used prior to, up to, and including, the Order Date by Church and Dwight and/or ACON to market or sell the Digital Consumer Pregnancy Test Products;

6. all options acquired by Respondent from ACON to acquire or exercise rights in the Digital Consumer Pregnancy Test Products;

7. all contingent interests or claims acquired by Respondent from ACON in the Digital Consumer Pregnancy Test Products; and

8. all of ACON's books, records, and files directly related to the foregoing;

9. *Provided, however*, that the Digital Consumer Pregnancy Test Product Assets:

    a. shall not include any and all technology, intellectual property or intellectual property right that was not created, generated, or Developed by ACON and/or Church & Dwight under the Church & Dwight/ACON R&D Agreement or the Church & Dwight/ACON Supply Agreement including the Reserved Patent Rights or the Metrika Patents;

    b. shall not include administrative, financial, and accounting records;

    c. shall include copies or relevant excerpts of documents and materials containing information relating to the Digital Consumer Pregnancy Test Product Assets in cases in which the documents or other materials included in the relevant assets to be provided to Church & Dwight contain information: (1) that relates both to any Digital Consumer Pregnancy Test Product and to other products or businesses of ACON or Respondent and cannot be segregated in a manner that preserves the usefulness of the information as it relates to such Digital Consumer Pregnancy Test Product; or (2) for which ACON or Respondent has a legal obligation to retain the original copies; and

    d. shall include access to original documents under circumstances where copies of documents are insufficient for evidentiary or regulatory purposes.

S. "Digital Consumer Pregnancy Test Product Core Employees" means the employees listed on Appendix A attached hereto.

T. "Digital Consumer Pregnancy Test Product Intellectual Property" means all of the following intellectual property to the extent owned, controlled, held, or otherwise possessed by Respondent:

1. any and all Patents that were or are filed by either Church & Dwight or ACON, after April 27, 2005, do not claim priority to a patent application filed before April 27, 2005 and claim an invention conceived, created, generated, or Developed under the Church & Dwight/ACON R&D Agreement;

2. any and all Other Intellectual Property, including the rights to obtain, file, and prosecute applications for patents and copyrights and registrations thereof, that was, or the subject matter of which was, created, generated, or Developed, by Church & Dwight and/or ACON under the Church & Dwight/ACON R&D Agreement or Church & Dwight/ACON Supply Agreement; and

3. rights to sue and recover damages or obtain injunctive relief for infringement, dilution, misappropriation, violation, or breach of any of the foregoing.

U. "Government Entity" means any Federal, state, local or non-U.S. government, or any court, legislature, government agency, or government commission, or any judicial or regulatory authority of any government.

V. "Interim Monitor" means any monitor appointed pursuant to Paragraph V of this Order.

W. "Law" means all laws, statutes, rules, regulations, ordinances, and other pronouncements by any Government Entity having the effect of law.

X. "May-Davis Patents" means any United States Patent claiming priority from British patent application numbers GB 8725457 and GB 8709873 (May), or GB 8903627 (Davis).

Y. "Metrika Patents" means the following United States Patents:

1. US Patent No. 5,580,794; and

2. US Patent No. 5,837,546.

Z. "Order Date" means the date on which this Order becomes final.

AA. "Other Intellectual Property" means trade secrets, copyrights (and right to obtain, file and prosecute copyrights and registrations thereof), know-how, techniques, data, inventions, practices, methods, and other confidential or proprietary technical, business, research, Development and other information.

BB. "Ownership Interest" means any and all rights, present or contingent, of Respondent to hold any voting or nonvoting stock, share capital, assets, equity or other interests or beneficial ownership in a Person.

CC. "Patents" means all patents, patent applications, including provisional patent applications, statutory invention registrations, and inventor's certificates, and rights to obtain, file and prosecute applications for patents, in each case existing as of the Order Date (*except* where this Order specifies a different date or time), and includes all reissues, divisions, continuations, continuations-in-part, supplementary protection certificates, extensions and reexaminations thereof, all inventions disclosed therein, and all rights therein provided by international treaties and conventions.

DD. "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.

EE. "Premarket Approval(s)" means the applications for a product filed or to be filed with the FDA pursuant to 21 C.F.R. § 814, and all supplements, amendments, and revisions thereto, any preparatory work, drafts and data necessary for the preparation thereof, all information submitted with or incorporated by reference, and all correspondence between Respondent and the FDA related thereto. The term "Premarket Approval(s)" includes all orders of approval and all reports and documents submitted to the FDA under postapproval requirements.

FF. "Premarket Notification(s)" means a premarketing submission for a product filed or to be filed with the FDA pursuant to 21 C.F.R. § 807, and all supplements, amendments, and revisions thereto, any preparatory work, drafts and data necessary for the preparation thereof, all information submitted with or incorporated by reference, and all correspondence between Respondent and the FDA related thereto, to demonstrate that a device to be marketed is as safe and effective as, or substantially equivalent to, a legally marketed device that is not subject to Premarket Approval. The term "Premarket Notification(s)" includes all notices of registration and all reports and documents required to be submitted to the FDA related to the marketing of such product.

GG. "Product Approval(s)" means any approvals, registrations, permits, licenses, consents, authorizations, and other approvals, and pending applications and requests therefor, required by applicable Agencies related to the research, Development, manufacture, distribution, finishing, packaging, marketing, sale, storage or transport of the product within the United States of America, and includes, without limitation, all approvals, registrations, licenses or authorizations granted in connection with any Premarket Approval and/or Premarket Notification.

HH. "Product Development Reports" means all of the following documents to the extent directly related to the Digital Consumer Pregnancy Test Products and Water Soluble Consumer Pregnancy Test Products:

1. inventory of research and development records, research history, research efforts, research notebooks, research reports, technical service reports, testing methods, invention disclosures, and know how;

2. all correspondence to or from the FDA related to such product(s);

3. annual and periodic reports;

4. approved product labeling;

5. currently used product package inserts;

6. customer circulars and information;

7. summary of product complaints from customers; and

8. product recall reports.

II. "Product Manufacturing Technology" means, to the extent owned, controlled, held, or otherwise possessed by Respondent, any and all of the following:

1. all technology, trade secrets, know-how, and proprietary information (whether patented, patentable or otherwise) directly related to the manufacture of the specified products including, without limitation, the following: all techniques and specifications, quality control processes, analytical methods for process controls, 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 the Product Approvals, and labeling and all other information related to the manufacturing process;

2. the identity of all suppliers and subcontractors;

3. all Assays; and

4. all Product Development Reports.

JJ. "Reserved Patent Rights" means, collectively, any and all Respondent's rights in, to or under any and all patents and patent applications claiming the benefit of or priority to (i) U.S. Patent Application Serial No. 07/211,582, including, without limitation, U.S. Patent Nos. 5,714,389; 5,989,921; and 6,485,982; (ii) one or more of GB Patent Application Serial Nos. 8709873 and 8725457, including, without limitation, U.S. Patent Nos. 5,602,040; 5,622,871; 5,656,503; 6,187,598; 6,228,660; 6,818,455; and 7,109,042; (iii) GB Patent Application Serial No. 8903627, and including, without limitation, U.S. Patent Nos. 6,352,862; 7,238,537; 7,384,796; and 7,407,813; (iv) U.S. Patent Application Serial No. 07/072,459, including, without limitation, U.S. Patent Nos. 5,120,643; 5,578,577; and 6,534,320; and (v) any and all continuations, divisionals, reissues, reexaminations, and foreign counterparts or equivalents of any and all of the foregoing.

KK. "Technology Transfer Standards" means requirements and standards sufficient to ensure that the information and assets required to be delivered pursuant to this Order are delivered in an organized, comprehensive, complete, useful, timely (*i.e.*, ensuring no unreasonable delays in transmission), and meaningful manner. Such standards and requirements may include, *inter alia*,

a. designating employees knowledgeable about the Product Manufacturing Technology and intellectual property included in either the Digital Consumer Pregnancy Test Assets or the Water Soluble Consumer Pregnancy Test Assets, as applicable, who will be responsible for communicating directly with any Person designated to receive such information and assets, including the Interim Monitor (if one has been appointed), for the purpose of effecting such delivery;

b. preparing technology transfer protocols and transfer acceptance criteria for both the processes and analytical methods related to the specified product(s) that are acceptable to any Person designated to receive such information and assets;

c. preparing and implementing a detailed technological transfer plan 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 Product Manufacturing Technology and all such intellectual property to any Person designated to receive such information and assets; and

d. providing, in a timely manner, assistance and advice to enable any Person designated to receive such information and assets (or its Designee) to:

(1) manufacture the specified product(s) in the quality and quantities achieved by ACON;

(2) obtain any Product Approvals necessary for any Person designated to receive such information and assets to manufacture, distribute, market, and sell the specified product(s) in commercial quantities; and

(3) receive, integrate, and use all such Product Manufacturing Technology and all such intellectual property related to the specified product(s).

LL. "Third Party(ies)" means any private entity other than the following: (1) Respondent; (2) ACON; (3) Church & Dwight or (4) Aemoh.

MM. "Trademark(s)" means all United States proprietary names or designations, trademarks, tradenames, 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.

NN. "Water Soluble Consumer Pregnancy Test Product(s)" means the lateral flow immunoassay Consumer Pregnancy Tests based on the use of water-soluble dyes Developed or under Development by ACON prior to February 24, 2006 for sale in the United States and any improvement to such tests. The term "Water Soluble Consumer Pregnancy Test Product(s)" shall not include lateral flow immunoassay pregnancy tests that use particulate labels, *e.g.*, colloidal gold or latex particles.

OO. "Water Soluble Consumer Pregnancy Test Product ACON Patents" means the following United States Patents:

1. US Patent No. 6627460; and

2. US Patent No. 5543332.

PP. "Water Soluble Consumer Pregnancy Test Product Assets" means all Respondent's rights, title in and interest in and to the following assets related directly to the Water Soluble Consumer Pregnancy Test Products:

1. The sublicense described in Paragraph III.A.1 of this Order;

2. all Product Approvals directly related to the Water Soluble Consumer Pregnancy Test Products;

3. all Product Manufacturing Technology that was created, generated, or Developed by ACON for the Water Soluble Consumer Pregnancy Test Products;

4. copies of all Product Development Reports directly related to the Water Soluble Consumer Pregnancy Test Products; and

5. copies of all of Respondent books, records, and files directly related to the foregoing;

6. *Provided, however*, that the Water Soluble Consumer Pregnancy Test Product Assets:

    a. shall not include the administrative, financial, and accounting records;

    b. shall include copies or relevant excerpts of documents and materials containing information relating to the Water Soluble Consumer Pregnancy Test Product Assets in cases in which the documents or other materials included in the relevant assets to be provided to Aemoh contain information: (1) that relates both to any Water Soluble Consumer Pregnancy Test Product and to other products or businesses of Respondent or ACON and cannot be segregated in a manner that preserves the usefulness of the information as it relates to such Water Soluble Consumer Pregnancy Test Product; or (2) for which Respondent or ACON has a legal obligation to retain the original copies; and

    c. shall include access to original documents under circumstances where copies of documents are insufficient for evidentiary or regulatory purposes.

QQ. "Water Soluble Consumer Pregnancy Test Product Core Employees" means the employees listed in Appendix B attached hereto.

RR. "Water Soluble Consumer Pregnancy Test Product Intellectual Property" means all of the following intellectual property to the extent owned, controlled, held, or otherwise possessed by Respondent:

1. any and all Water Soluble Consumer Pregnancy Test Product ACON Patents and Patents that ACON filed that contain subject matter that relates directly to the Water Soluble Consumer Pregnancy Test Product(s);

2. any and all Other Intellectual Property, including the rights to obtain, file, and prosecute applications for patents and copyrights and registrations thereof, that was, or the subject matter of which was, created, generated, or Developed, by ACON for the Water Soluble Consumer Pregnancy Test Product(s); and

3. rights to sue and recover damages or obtain injunctive relief for infringement, dilution, misappropriation, violation, or breach of any of the foregoing.

SS. "Water Soluble Consumer Pregnancy Test Product Releasee(s)" means Aemoh or any entity controlled by or under common control with Aemoh ("affiliated entities"), or any licensees, sublicensees, manufacturers, suppliers, distributors, or customers of Aemoh or its affiliated entities.

II.

IT IS FURTHER ORDERED that:

A. Not later than ten (10) days after the Order Date, Respondent shall:

1. disclaim in writing any and all rights, title and interest in or to the Digital Consumer Pregnancy Test Product Assets in favor of Church & Dwight;

2. to the extent owned or controlled, directly or indirectly, by or otherwise in the possession of Respondent, and at the expense of Respondent, transfer and deliver all Digital Consumer Pregnancy Test Product Assets to Church & Dwight;

3. amend, or provide written clarification of, any contract(s) or agreement(s) between the Respondent and ACON, and enter into such other contract(s) or agreement(s) as may be necessary with ACON, in order to:

    a. permit ACON fully to transfer and deliver all of the Digital Consumer Pregnancy Test Product Assets to Church & Dwight to the extent such assets are owned or controlled, directly or indirectly, by ACON, or are otherwise in the possession of ACON, in a manner consistent with the Technology Transfer Standards;

b. remove any prohibitions or impediments that would prevent ACON from transferring and delivering such Digital Consumer Pregnancy Test Product Assets to Church & Dwight;

c. permit, and provide all rights within Respondent's control necessary to allow, ACON to perform the Contract Manufacture of Digital Consumer Pregnancy Test Products on behalf of Church & Dwight on an uninterrupted basis for a period of time continuing at least until December 22, 2010;

d. remove any prohibitions or impediments that would prevent ACON from performing the Contract Manufacture of Digital Consumer Pregnancy Test Products on behalf of Church & Dwight for a period of time continuing at least until December 22, 2010;

e. remove any financial disincentives to the extent that such financial disincentives would prevent ACON from making and retaining a profit on any Contract Manufacture of Digital Consumer Pregnancy Test Products on behalf of Church & Dwight for a period continuing at least until December 22, 2010;

f. permit, and provide all rights within Respondent's control necessary to allow, ACON to maintain the manufacturing and related testing, storage, and shipping facilities necessary to manufacture the Digital Consumer Pregnancy Test Products in finished form suitable for commercial sale for a period of time continuing at least until December 22, 2010; *provided however*, this requirement shall end if Church & Dwight exercises any rights it may have or otherwise determines to discontinue purchasing Digital Consumer Pregnancy Test Products from ACON at an earlier date;

g. to the extent the foregoing ACON manufacturing and related testing, storage, and shipping facilities are subject to any rights held by the Respondent, permit Church & Dwight to continue purchasing Digital Consumer Pregnancy Test Products for a period of time continuing at least until December 22, 2010, or to discontinue purchasing Digital Consumer Product Pregnancy Test Products, from such facilities, without penalty, upon Church & Dwight providing agreed-to or otherwise reasonable notification to ACON or Respondent; and

h. permit, and provide all rights within Respondent's control necessary to allow, ACON to provide all records that relate to the manufacture of the Digital Consumer Pregnancy Test Products by ACON on behalf of Church & Dwight that are generated or created after the Order Date, as such records are requested by Church & Dwight or the Interim Monitor (if one has been appointed);

provided, however, Paragraph II shall not require Respondent to transfer, disclaim, license, grant, or not assert, any technology, intellectual property or intellectual property right that was not created, generated, or Developed by ACON and/or Church & Dwight

under the Church & Dwight/ACON R&D Agreement or the Church & Dwight/ACON Supply Agreement, including the Reserved Patent Rights.

B. Respondent shall:

1. cooperate with, and take no action that interferes with or impedes:

   a. ACON's transfer and delivery of such Digital Consumer Pregnancy Test Product Assets to Church & Dwight in a manner consistent with the Technology Transfer Standards; or

   b. ACON's performance of the Contract Manufacture of Digital Consumer Pregnancy Test Products on behalf of Church & Dwight during the period of time continuing until December 22, 2010; and

2. not seek to enforce, directly or indirectly, any of Respondent's rights under any contract or agreement with ACON that would interfere with or impede ACON's ability to transfer and deliver such Digital Consumer Pregnancy Test Product Assets to Church & Dwight, or that would interfere with or impede ACON's ability to Contract Manufacture Digital Consumer Pregnancy Test Products on behalf of Church & Dwight for a period of time continuing at least until December 22, 2010;

3. not enforce any agreement between Respondent and ACON, a Third Party, or Church & Dwight against the applicable counterparty to the extent that such agreement may limit or otherwise impair the ability of Church & Dwight to acquire the Digital Consumer Pregnancy Test Product Intellectual Property or the Product Manufacturing Technology included in the Digital Consumer Pregnancy Test Product Assets from any Third Party. Such agreements include, but are not limited to, agreements with respect to the disclosure of Confidential Business Information directly related to such Product Manufacturing Technology; and

4. not later than ten (10) days after the Order Date, grant a release to each Third Party that is subject to any agreement described in Paragraph II.B.3 allowing such Third Party to provide all such Digital Consumer Pregnancy Test Product Intellectual Property and/or, all such Product Manufacturing Technology included in the Digital Consumer Pregnancy Test Product Assets to Church & Dwight. Within five (5) days of the execution of each such release, Respondent shall provide a copy of the release to Church & Dwight.

C. For a period of up to twelve (12) months from the Order Date, Respondent shall not interfere with the hiring or employing by Church & Dwight of the Digital Consumer Pregnancy Test Product Core Employees, and shall remove any impediments within the control of Respondent that may deter these employees from accepting employment with Church & Dwight, including, but not limited to, any noncompete or nondisclosure provision of employment or other contracts with Respondent that would affect the ability or incentive

of those individuals to be employed by Church & Dwight. In addition, Respondent shall not make any counteroffer to such a Digital Consumer Pregnancy Test Product Core Employee who has received a written offer of employment from Church & Dwight of which Respondent is aware.

D. Respondent shall take no action that would interfere with or prohibit knowledgeable employees of ACON from assisting Church & Dwight to defend against, respond to, or otherwise participate in any litigation directly related to the Digital Consumer Pregnancy Test Product Intellectual Property.

E. Respondent shall:

1. submit to Church & Dwight all Confidential Business Information;

2. deliver such Confidential Business Information:

   a. in good faith;

   b. as soon as practicable, avoiding any delays in transmission of the respective information; and

   c. in a manner that ensures its completeness and accuracy and that fully preserves its usefulness;

3. pending complete delivery of all Confidential Business Information to Church & Dwight, provide Church & Dwight and the Interim Monitor (if one has been appointed) with access to all such Confidential Business Information, and to employees who possess or are able to locate such information, for the purpose of identifying the books, records and files related to the Digital Consumer Pregnancy Test Products that contain such Confidential Business Information and facilitating the delivery of such information in a manner consistent with this Order.

F. Respondent shall not:

1. use, directly or indirectly, any such Confidential Business Information directly related to the research, Development, manufacturing, marketing, or sale of the Digital Consumer Pregnancy Test Products other than as necessary to comply with the following:

   a. the requirements of this Order;

   b. obligations to Church & Dwight under the terms of any pre-existing agreement between ACON and Church & Dwight; or

   c. applicable Law;

2. disclose or convey any Confidential Business Information, directly or indirectly, to any private-entity Person (including the Respondent) except Church & Dwight; and

3. provide, disclose or otherwise make available, directly or indirectly, any such Confidential Business Information to the employees of the Respondent associated with its business(es) related to rapid detection pregnancy tests.

G. Respondent shall require that each Digital Consumer Pregnancy Test Product Core Employee hired or retained by Respondent, the direct supervisor(s) of any such employee, and any other employee hired or retained by Respondent and designated by the Interim Monitor (if one has been appointed) sign a confidentiality agreement pursuant to which such employee shall be required to maintain all Confidential Business Information directly related to the Digital Consumer Pregnancy Test Products as strictly confidential, including the nondisclosure of such information to all other employees, executives or other personnel of Respondent (other than as necessary to comply with the requirements of this Order).

H. Respondent shall assure, in any instance wherein its counsel (including in-house counsel under appropriate confidentiality arrangements) either retains unredacted copies of documents or other materials provided to Church & Dwight, or accesses original documents (under circumstances where copies of documents are insufficient or otherwise unavailable) provided to Church & Dwight, that Respondent's counsel does so only for the following purposes:

1. to assure Respondent's compliance with this Order, any Law (including, without limitation, any requirement to obtain regulatory licenses or approvals), any agreement with Church & Dwight, any data retention requirement of any applicable Government Entity, or any taxation requirements; or

2. to defend against, respond to, or otherwise participate in any litigation, investigation, audit, process, subpoena or other proceeding relating to the transfer of the Product Manufacturing Technology directly related to the research, Development, or manufacture of the Digital Consumer Pregnancy Test Products or the Digital Consumer Pregnancy Test Product Intellectual Property or businesses associated with the Digital Consumer Pregnancy Test Products; *provided*, *however*, that Respondent may disclose such information as necessary for the purposes set forth in this Paragraph pursuant to an appropriate confidentiality order, agreement or arrangement;

provided further, *however,* that pursuant to this Paragraph, Respondent shall: (1) require those who view such unredacted documents or other materials to enter into confidentiality agreements with Church & Dwight (but shall not be deemed to have violated this requirement if Church & Dwight withholds such agreement unreasonably); and (2) use its best efforts to obtain a protective order to protect the confidentiality of such information during any adjudication.

I. Not later than ten (10) days after the Order Date, Respondent shall amend any contract(s) or agreement(s) between the Respondent and Bayer (including, without limitation such contract(s) or agreement(s) with Metrika, Inc.), and enter such other contract(s) or agreement(s) as may be necessary with Bayer, in order to authorize Bayer to sell a co-exclusive license to the Metrika Patents, in the United States, to Church & Dwight (*i.e.*, a license to the Metrika Patents under which license the Respondent and Church & Dwight would be co-exclusive licensees); *provided however*, that Respondent may condition the authorization granted to Bayer upon payment to Respondent of an amount not to exceed the lesser of: (1) one-half of Respondent's original purchase price for Respondent's exclusive license to the Metrika Patents, or (2) one half of the license fee paid to Metrika by Church & Dwight.

J. Respondent shall not enforce any agreement between Respondent and Bayer, a Third Party, or Church & Dwight against the applicable counterparty to the extent that such agreement may limit or otherwise impair the ability of Church & Dwight to acquire the above-described co-exclusive license to the Metrika Patents, and shall not interfere with, or take any action that might delay, such licensing of these patents to Church & Dwight.

K. The purpose of Paragraph II of this Order is to ensure the continued use of the Digital Consumer Pregnancy Test Product Assets in the research, Development, and manufacture of the Digital Consumer Pregnancy Test Products, including variations and improvements thereto, fully independent of the Respondent, and to remedy the lessening of competition resulting from the acts and practices of the Respondent as alleged in the Commission's Complaint.

III.

IT IS FURTHER ORDERED that:

A. Not later than ten (10) days after the Order Date, Respondent shall:

1. grant to Aemoh an exclusive, perpetual, fully paid-up and royalty-free sub-license in the United States, with rights to sub-license of all of Respondent's rights to the Water Soluble Consumer Pregnancy Test Product Intellectual Property to the full extent of the fields of use for which Respondent is licensed to use such Water Soluble Consumer Pregnancy Test Product Intellectual Property including, without limitation, the right and sub-license:

   a. to use, make, distribute, offer for sale, promote, advertise, sell, import, or export the Water Soluble Consumer Pregnancy Test Products; and

   b. to have used, made, distributed, offered for sale, promoted, advertised, sold, imported, or exported the Water Soluble Consumer Pregnancy Test Products;

2. deliver all Water Soluble Consumer Pregnancy Test Product Assets, or copies thereof, in the possession of or under the control of Respondent to Aemoh in a manner consistent with the Technology Transfer Standards;

3. amend, and/or provide written clarification of, any contract(s) or agreement(s) between the Respondent and ACON, and enter such other contract(s) or agreement(s) as may be necessary with ACON, in order to permit ACON fully to deliver any and all Water Soluble Consumer Pregnancy Test Product Assets to Aemoh to the extent such assets are owned or controlled, directly or indirectly, by ACON, or otherwise in the possession of ACON, in a manner consistent with the Technology Transfer Standards.

B. Respondent shall take all actions within its control to secure all consents and waivers from Third Party(ies) to the extent such consents are necessary to permit Respondent and/or ACON to grant, transfer or deliver such Water Soluble Consumer Pregnancy Test Product Assets to Aemoh, in a timely manner, and/or to permit Aemoh to research, Develop, manufacture, sale, market or distribute Water Soluble Consumer Pregnancy Test Products;

provided, however, Respondent may satisfy this requirement by certifying that Aemoh has executed all such agreements directly with each of the relevant Third Parties.

C. Respondent shall:

1. not enforce any agreement between Respondent and ACON, a Third Party, or Aemoh against the applicable counterparty to the extent that such agreement may limit or otherwise impair the ability of Aemoh to acquire the Water Soluble Consumer Pregnancy Test Product Intellectual Property or the Product Manufacturing Technology included in the Water Soluble Consumer Pregnancy Test Product Assets from any Third Party; and

2. not later than ten (10) days after the Order Date, grant a release to each Third Party that is subject to any agreement described in Paragraph III.C.1 allowing such Third Party to provide all such Water Soluble Consumer Pregnancy Test Product Intellectual Property and/or all such Product Manufacturing Technology included in the Water Soluble Consumer Pregnancy Test Product Assets to Aemoh. Within five (5) days of the execution of each such release, Respondent shall provide a copy of the release to Aemoh.

D. For a period of up to twelve (12) months from the Order Date, Respondent shall not interfere with the hiring or employing by Aemoh of the Water Soluble Consumer Pregnancy Test Product Core Employees, and shall remove any impediments within the control of Respondent that may deter these employees from accepting employment with Aemoh, including, but not limited to, any noncompete or nondisclosure provision of employment or other contracts with Respondent that would affect the ability or incentive of those individuals to be employed by Aemoh. In addition, Respondent shall not make any counteroffer to such a Water Soluble Consumer Pregnancy Test Product Core Employee

who has received a written offer of employment from Aemoh of which Respondent is aware.

E. Respondent shall take no action which would interfere with or prohibit knowledgeable employees of ACON from assisting Aemoh to defend against, respond to, or otherwise participate in any litigation directly related to the Water Soluble Consumer Pregnancy Test Product Intellectual Property.

F. Respondent shall not join, file, prosecute or maintain any suit, in law or equity, against Aemoh or the Water Soluble Consumer Pregnancy Test Product Releasee(s) for the research, Development, manufacture, use, import, export, distribution, or sale of the Water Soluble Consumer Pregnancy Test Product(s) under the following:

1. any Patent owned or licensed by Respondent as of the Order Date that claims a method of making, using, or administering, or a composition of matter, relating to lateral flow immunoassay technology, or that claims a device relating to the use thereof, including, without limitation, the Reserved Patent Rights; or

2. any Patent owned or licensed by Respondent at any time after the Order Date that claims any aspect of the research, Development, manufacture, use, import, export, distribution, or sale of the relevant lateral flow immunoassay technology, including, without limitation, the Reserved Patent Rights, other than Patents that claim inventions conceived by and reduced to practice after the Order Date;

if such suit would have the potential to interfere with Aemoh's freedom to practice the following: (1) the research, Development, or manufacture of the relevant Water Soluble Consumer Pregnancy Test Product(s); or (2) the use, import, export, supply, distribution, sale, or offer for sale of the relevant Water Soluble Consumer Pregnancy Test Product(s) within the United States. Respondent shall also covenant to Aemoh that as a condition of any assignment, transfer, or exclusive license to a Third Party of the above-described Patents, the Third Party shall agree to provide a covenant to Aemoh whereby the Third Party covenants not to sue Aemoh or the related Water Soluble Consumer Pregnancy Test Product Releasee(s) under such Patents, if the suit would have the potential to interfere with Aemoh's freedom to practice the following: (1) the research, Development, or manufacture of the relevant Water Soluble Consumer Pregnancy Test Product(s); or (2) the use, import, export, supply, distribution, sale, or offer for sale of the relevant Water Soluble Consumer Pregnancy Test Product(s) within the United States;

provided however, this Paragraph III.F shall have no force or effect with respect to any product that uses particulate labels, *e.g.*, colloidal gold or latex particles, whether or not such product uses (i) conjugates claimed or described in the Water Soluble Consumer Pregnancy Test Product Intellectual Property and/or (ii) Water Soluble Consumer Pregnancy Test Product Intellectual Property created, generated, or Developed by ACON for the Water Soluble Consumer Pregnancy Test Products.

G. The purpose of Paragraph III of this Order is to provide for the future use of the Water Soluble Consumer Pregnancy Test Product Assets in the research, Development, manufacture, distribution, sale and marketing of Consumer Pregnancy Tests, and to remedy the lessening of competition resulting from the acts and practices of the Respondent as alleged in the Commission's Complaint.

IV.

IT IS FURTHER ORDERED that for a period commencing on the Order Date and continuing for the term of this Order, Respondent shall not, without providing advance written notification to the Commission, acquire, through subsidiaries or otherwise, directly or indirectly (including, without limitation, acquisitions by any joint venture in which Inverness is a partner from any other partner(s) of such joint venture), the following:

A. any Ownership Interest in any Person that is not already included within the definition of Respondent and that engages in manufacture, distribution, marketing of Consumer Pregnancy Tests for sale in the United States; *provided, however,* that this provision shall not apply to an acquisition of assets that are not used in the manufacture, distribution, or marketing of Consumer Pregnancy Tests for sale in the United States;

B. any right, title, or interest under exclusive license or assignment from any Person that is not already included within the definition of Respondent under a United States Patent that: (1) includes the term "hCG" or "chorionic gonadotropin," and (2) contains a claim directed to a lateral flow immunoassay technology for the detection of human chorionic gonadotropin (hCG); or

C. any right, title, or interest under exclusive license or assignment from any Person that is not already included within the definition of Respondent under a United States Trademark that has been used to market, sell or distribute a Consumer Pregnancy Test of such Person in the United States at any time since February 24, 2006.

Said notifications shall be given on the Notification and Report Form set forth in the Appendix to Part 803 of Title 16 of the Code of Federal Regulations as amended (hereinafter referred to as "the Notification"), and shall be prepared and transmitted in accordance with the requirements of that part, except that no filing fee will be required for any such Notification, Notification shall be filed with the Secretary of the Commission with a copy to the Assistant Director, Bureau of Competition, Division of Compliance. Notification need not be made to the United States Department of Justice, and Notification is required only of the Respondent and not of any other party to the transaction. Respondent shall provide three (3) complete copies (with all attachments and exhibits) of the Notification at least thirty (30) days prior to consummating any such transaction (hereinafter referred to as the "first waiting period"), as follows: one (1) such copy to the Assistant Director of the Bureau of Competition, Division of Compliance, and two (2) such copies to the Secretary of the Commission. If, within the first waiting period, representatives of the

Commission make a written request for additional information or documentary material (within the meaning of 16 C.F.R. § 803.20), Respondent shall not consummate the transaction until thirty (30) days after substantially complying with such request. Early termination of the waiting periods in this Paragraph may be requested and, where appropriate, granted by letter from the Bureau of Competition; *provided, however*, that prior notification shall not be required by this Paragraph for a transaction for which notification is required to be made, and has been made, pursuant to Section 7A of the Clayton Act, 15 U.S.C. § 18a; *provided however*, that the notification requirements of this Paragraph IV shall not apply to the acquisition by Respondent of any of the assets and rights of ACON that are or were the subject of the Acquisition.

V.

IT IS FURTHER ORDERED that:

A. At any time after Respondent signs the Consent Agreement in this matter, the Commission may appoint a monitor ("Interim Monitor") to assure that Respondent expeditiously complies with all of its obligations and performs all of its responsibilities as required by this Order.

B. The Commission shall select the Interim Monitor, subject to the consent of Respondent, which consent shall not be unreasonably withheld. If Respondent has not opposed, in writing, including the reasons for opposing, the selection of a proposed Interim Monitor within ten (10) days after notice by the staff of the Commission to Respondent of the identity of any proposed Interim Monitor, Respondent shall be deemed to have consented to the selection of the proposed Interim Monitor.

C. Not later than ten (10) days after the appointment of the Interim Monitor, Respondent shall execute an agreement that, subject to the prior approval of the Commission, confers on the Interim Monitor all the rights and powers necessary to permit the Interim Monitor to monitor Respondent's compliance with the relevant requirements of the Order in a manner consistent with the purposes of the Order.

D. If an Interim Monitor is appointed, Respondent shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Interim Monitor:

    1. The Interim Monitor shall have the power and authority to monitor Respondent's compliance with the transfer of the Product Manufacturing Technology and the related intellectual property, and with the asset maintenance obligations and related requirements of the Order, and shall exercise such power and authority and carry out the duties and responsibilities of the Interim Monitor in a manner consistent with the purposes of the Order and in consultation with the Commission.

    2. The Interim Monitor shall act in a fiduciary capacity for the benefit of the Commission.

3. The Interim Monitor shall serve until the later of:

    a. the completion of Respondent's obligations regarding the transfer of the Product Manufacturing Technology included in the Digital Consumer Pregnancy Test Assets and the Digital Consumer Pregnancy Test Product Intellectual Property to Church & Dwight (or the Designee(s) of Church & Dwight) in a manner that fully satisfies the requirements of the Order; or

    b. the completion of Respondent's obligations regarding the transfer of the Product Manufacturing Technology included in the Water Soluble Consumer Pregnancy Test Assets and the Water Soluble Consumer Pregnancy Test Product Intellectual Property to Aemoh (or the Designee(s) of Aemoh) in a manner that fully satisfies the requirements of the Order;

   provided, however, that the Commission may shorten or extend this period as may be necessary or appropriate to accomplish the purposes of the Order.

4. Subject to any demonstrated legally recognized privilege, the Interim Monitor shall have full and complete access to Respondent's personnel, books, documents, records kept in the ordinary course of business, facilities and technical information, and such other relevant information as the Interim Monitor may reasonably request, related to Respondent's compliance with its obligations under the Order, including, but not limited to, its obligations related to the relevant assets. Respondent shall cooperate with any reasonable request of the Interim Monitor and shall take no action to interfere with or impede the Interim Monitor's ability to monitor Respondent's compliance with the Order.

5. The Interim Monitor shall serve, without bond or other security, at the expense of Respondent, on such reasonable and customary terms and conditions as the Commission may set. The Interim Monitor shall have authority to employ, at the expense of Respondent, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Interim Monitor's duties and responsibilities.

6. Respondent shall indemnify the Interim Monitor and hold the Interim Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Interim Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Interim Monitor.

7. Respondent shall report to the Interim Monitor in accordance with the requirements of this Order and/or as otherwise provided in any agreement approved by the Commission. The Interim Monitor shall evaluate the reports submitted to the Interim Monitor by

Respondent, and any reports submitted by Church & Dwight with respect to the performance of Respondent's obligations under the Order. Within thirty (30) days from the date the Interim Monitor receives these reports, the Interim Monitor shall report in writing to the Commission concerning performance by Respondent of its obligations under the Order.

8. Respondent may require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement; *provided, however,* that such agreement shall not restrict the Interim Monitor from providing any information to the Commission.

E. The Commission may, among other things, require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Interim Monitor's duties.

F. If the Commission determines that the Interim Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Interim Monitor in the same manner as provided in this Paragraph.

G. The Commission may on its own initiative, or at the request of the Interim Monitor, issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Order.

VI.

IT IS FURTHER ORDERED that:

A. Within thirty (30) days after the Order Date, and every sixty (60) days thereafter until Respondent has fully complied with Paragraphs II.A., II.E., II.I. and III.A of this Order, Respondent shall submit to the Commission a verified written report setting forth in detail the manner and form in which it intends to comply, is complying, and has complied with this Order. Respondent shall submit at the same time a copy of its report concerning compliance with this Order to the Interim Monitor, if an Interim Monitor has been appointed. Respondent shall include in its reports, among other things that are required from time to time, a full description of the efforts being made to comply with the relevant Paragraphs of the Order.

B. One (1) year after the Order Date, annually for the next nine (9) years on the anniversary of the Order Date, and at such other times as the Commission may require, Respondent shall file a verified written report with the Commission setting forth in detail the manner and form in which it is complying and has complied with this Order.

VII.

IT IS FURTHER ORDERED that Respondent shall notify the Commission at least thirty (30) days prior to:

A. any proposed dissolution of Respondent;

B. any proposed acquisition, merger or consolidation of Respondent; or

C. any other change in Respondent including, without limitation, assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of the Order.

VIII.

IT IS FURTHER ORDERED that, for purposes of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request and upon five (5) days notice to Respondent made to its principal United States offices, registered office of its United States subsidiary, or its headquarters address, Respondent shall, without restraint or interference, permit any duly authorized representative of the Commission:

A. access, during business office hours of Respondent and in the presence of counsel, 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 Order, which copying services shall be provided by such Respondent at the request of the authorized representative(s) of the Commission and at the expense of the Respondent; and

B. to interview officers, directors, or employees of such Respondent, who may have counsel present, regarding such matters.

IX.

IT IS FURTHER ORDERED that this Order shall terminate on the earlier of the following dates:

A. the date ten (10) years from the Order Date; or

B. the date on which the last of the May-Davis Patents to expire expires.

By the Commission.

Donald S. Clark
Secretary

SEAL

ISSUED:

CONFIDENTIAL APPENDIX A

Digital Consumer Pregnancy Test Product Core Employees

[Redacted From the Public Record Version But Incorporated By Reference]

CONFIDENTIAL APPENDIX B

Water Soluble Consumer Pregnancy Test Product Core Employees

[Redacted From the Public Record Version But Incorporated By Reference]