IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

FEDERAL TRADE COMMISSION, **Plaintiff,** **v.** **ACTAVIS, INC., et al.,** **Defendants.**	**Case Number: 1:09-cv-955-TWT**

Joint Motion for Entry of Stipulated Order for Permanent Injunction

Plaintiff Federal Trade Commission ("FTC") and Defendant AbbVie Products LLC (f/k/a Solvay Pharmaceuticals, Inc.), by their respective attorneys, respectfully move this Court to enter the accompanying Stipulated Order for Permanent Injunction ("Stipulated Order"). Entry of the Stipulated Order will end the litigation. A copy of the Stipulated Order is attached as Exhibit A. As grounds for this request, the parties state as follows:

1. On May 28, 2009, the FTC filed its Second Amended Complaint against Defendants, which included Solvay Pharmaceuticals, Inc. ("Solvay"),

pursuant to Section 13(b) of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 53(b). The Complaint alleges that Solvay engaged in unfair methods of competition in violation of Section 5 of the FTC Act by entering reverse-payment agreements that foreclosed competition from generic equivalents of the brand-name drug AndroGel, a testosterone replacement therapy.

2. In its Complaint, the FTC seeks a permanent injunction to prevent Solvay from "engaging in similar and related conduct in the future."

3. On February 16, 2010, Solvay became a wholly owned subsidiary of Abbott Laboratories ("Abbott").

4. Following an Abbott corporate re-organization, Solvay became a wholly owned indirect subsidiary of AbbVie Inc. Solvay is now known as AbbVie Products LLC.

5. AbbVie Products LLC has reached a settlement with the FTC. In doing so, AbbVie Products LLC admits only the facts necessary to establish the personal and subject matter jurisdiction of this Court in this matter only.

6. AbbVie Inc. agrees to be bound by the terms of the Stipulated Order to the extent that it has any rights to the Relevant Solvay Legacy Products. Relevant Solvay Legacy Products is defined in the Stipulated Order as products or

compounds Solvay may have been marketing or developing prior to being acquired by Abbott.

7. The Stipulated Order applies for a period of 10 years and prohibits AbbVie Products LLC or AbbVie Inc. from entering into agreements with certain terms in connection with patent settlements relating to any Relevant Solvay Legacy Product. The Stipulated Order provides for the parties to bear their respective costs in this action.

8. By February 27, 2019, the FTC, AbbVie Products LLC, and AbbVie had signed the Stipulated Order. On February 28, the Commission voted 4-0, with one Commissioner recused, to accept the Stipulated Order. AbbVie Products LLC and the FTC jointly request that the Court enter the attached Stipulated Order and place it on the public record, thereby bringing this litigation to an end.

Respectfully Submitted,

February 28, 2019

/s/ Markus H. Meier

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Exhibit A

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA

FEDERAL TRADE COMMISSION,
Plaintiff,
v.
ACTAVIS INC.,
PAR PHARMACEUTICAL COMPANIES, INC.,
PADDOCK LABORATORIES, INC., and
ABBVIE PRODUCTS LLC (f/k/a SOLVAY PHARMACEUTICALS, INC.),
Defendants.

Case No.: 09-cv-955

STIPULATED ORDER FOR PERMANENT INJUNCTION

The Federal Trade Commission ("Commission") filed its Second Amended Complaint for Injunctive and Other Equitable Relief ("Complaint") in this matter pursuant to Section 13(b) of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 53(b). The Commission, AbbVie Products LLC (f/k/a/ Solvay Pharmaceuticals, Inc.), and AbbVie Inc., but only to the extent of AbbVie Inc.'s business related to Relevant Solvay Legacy Products, by their respective attorneys, have reached an agreement to resolve this case through settlement, and without trial or final adjudication of any issue of fact or law, and stipulate to entry of this Stipulated Order for Permanent Injunction ("Order") to resolve all matters in dispute in this action.

FINDINGS

1. This Court has jurisdiction over the parties and the subject matter of this action.

2. Venue for this matter is proper in this Court under 15 U.S.C. § 22 and 28 U.S.C. § 1391(b) and (c), and under Section 13(b) of the FTC Act, 15 U.S.C. § 53(b).

3. The Complaint alleges that AbbVie Products engaged in anticompetitive acts that constitute an unfair method of competition in violation of Sections 5(a) and 13(b) of the FTC Act, 15 U.S.C. §§ 45(a) and 53(b), by entering an agreement that foreclosed competition from generic equivalents of the brand-name drug AndroGel®.

4. This Order does not constitute any evidence against AbbVie or any other entity, or an admission of liability or wrongdoing by AbbVie or any other entity, in this case or in any other litigation. This Order shall not be used in any way, as evidence or otherwise, in any other litigation or proceeding; *provided that*, nothing in this provision prevents the Commission or AbbVie from using this Order in any proceeding regarding enforcement or modification of this Order or as otherwise required by law.

5. AbbVie waives all rights to appeal or otherwise challenge or contest the validity of this Order.

6. AbbVie waives any claim that it may have under the Equal Access to Justice Act, 28 U.S.C. § 2412, concerning the prosecution of this action through the date of this Order, and agrees to bear its own costs and attorney fees in this litigation.

7. Entry of this Order is in the public interest.

STIPULATIONS

1. AbbVie stipulates that, in return for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, AbbVie agrees to be fully bound by the terms of this Order.

2. AbbVie stipulates that it will not object to the Commission's right to seek relief under this Order against AbbVie to the same extent the Commission can seek relief against AbbVie Products.

3. AbbVie stipulates that it is the corporate parent of AbbVie Products LLC.

4. AbbVie stipulates that all stipulations herein are made on behalf of AbbVie, including AbbVie Products.

5. AbbVie stipulates that it shall comply with the provisions of this Order pending its entry by the Court.

6. AbbVie and the Commission have agreed to stipulate to entry of this Order to finally resolve this action, *Federal Trade Commission v. Actavis, Inc.*, No. 09-cv-955 (N.D. Ga.), between AbbVie Products and the Commission.

7. The Commission stipulates that it will not file litigation or any other proceedings against AbbVie or any related entity based on the conduct alleged by the Commission in the Resolved Claims, other than any legal proceedings regarding enforcement or modification of this Order.

I.

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

A. "Commission" means the United States Federal Trade Commission.

B. "AbbVie" means AbbVie Inc. and any joint venture, subsidiary, division, group, or affiliate Controlled currently or in the future by AbbVie (including AbbVie Products), their successors and assigns, and the respective directors, officers, employees, agents, and representatives acting on behalf of each, but only as related to Relevant Solvay Legacy Products.

C. "AbbVie Products" means AbbVie Products LLC (f/k/a/ Solvay Pharmaceuticals, Inc.), any joint venture, subsidiary, division, group, or affiliate Controlled currently or in the future by AbbVie Products LLC, their successors and assigns, and the respective directors, officers, employees, agents, and representatives acting on behalf of each.

D. "505(b)(2) Application" means an application filed with the United States Food and Drug Administration pursuant to Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(b)(2).

E. "ANDA" means an Abbreviated New Drug Application filed with the United States Food and Drug Administration pursuant to Section 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j).

F. "Authorized Generic" means a Drug Product that is manufactured pursuant to an NDA and Marketed in the United States under a name other than the proprietary name identified in the NDA.

G. "Brand/Generic Settlement" means any agreement or understanding that settles a Patent Infringement Claim in or affecting Commerce in the United States.

H. "Brand/Generic Settlement Agreement" means a written agreement that settles a Patent Infringement Claim in or affecting Commerce in the United States.

I. "Branded Subject Drug Product" means a Subject Drug Product Marketed in the United States under the proprietary name identified in the NDA for the Subject Drug Product.

J. "Commerce" has the same definition as it has in 15 U.S.C. § 44.

K. "Control" or "Controlled" means the holding of more than fifty percent (50%) of the common voting stock or ordinary shares in, or the right to appoint more than fifty percent (50%) of the directors of, or any other arrangement resulting in the right to direct the management of, the said corporation, company, partnership, joint venture, or entity.

L. "Contingent Supply Agreement" means a Supply Agreement that terminates within thirty (30) days after the Generic Filer, after good faith commercially reasonable efforts, (i) has final FDA approval and (ii) can manufacture commercial quantities of the Generic Subject Drug Product using good faith, commercially reasonable efforts;

provided, however, the Generic Filer may take delivery of, market, and sell quantities of Authorized Generic ordered prior to termination of the Supply Agreement ***so long as*** the total quantity of Authorized Generic delivered to the Generic Filer following termination of the Supply Agreement: (i) does not exceed the total quantity expected to be needed by the Generic Filer (as reflected in forecasts provided to the NDA Holder prior to termination of the Supply Agreement) during the eight (8) months following (x) termination of the Supply Agreement, if termination occurs after the Generic Entry Date, or (y) the Generic Entry Date, if termination occurs before the Generic Entry Date; and (ii) is delivered within eight (8) months of termination of the Supply Agreement.

M. "Drug Product" means a finished dosage form (e.g., tablet, capsule, solution, or patch), as defined in 21 C.F.R. § 314.3(b), approved under a single NDA, ANDA or 505(b)(2)

Application, that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients.

N. "Exception" means the following in, or connected with, a Brand/Generic Settlement:

1. compensation for saved future litigation expenses, ***but only if*** the total compensation the NDA Holder agrees to provide to any Generic Party during the sixty (60) day period starting thirty (30) days before and ending thirty (30) days after executing the Brand/Generic Settlement Agreement does not exceed a maximum limit, which is initially set at seven million dollars ($7,000,000) and shall be increased (or decreased) as of January 1 of each year following entry of this Order by an amount equal to the percentage increase (or decrease) from the previous year in the annual average Producer Price Index for Legal Services (Series Id. PCU5411--5411--) published by the Bureau of Labor Statistics of the United States Department of Labor or its successor;

2. the right to manufacture (including through use of a contract manufacturer), import, use, or Market, as of an agreed upon Generic Entry Date(s): (i) Generic Product(s) in the United States under an ANDA or 505(b)(2) Application (x) that is controlled by the Generic Filer and was not transferred to the Generic Filer by the NDA Holder, or (y) to which the Generic Party has a license from a party other than the NDA Holder; or (ii) an Authorized Generic of the Subject Drug Product; provided that this Exception shall apply regardless of whether or not the Generic Filer must pay for the right to Market and, if so, the terms and conditions governing such payment;

3. the right of the Generic Filer to sublicense any of its rights relating to the Subject Drug Product;

4. provisions to facilitate, by means other than the transfer of goods or money, the Generic Filer's ability to secure or maintain final regulatory approval, or commence or continue the Marketing, of a Generic Product, by, *inter alia*, providing covenants, waivers, permissions, releases, dismissals of claims, and/or authorizations;

5. release, waiver, or limitation of a claim for damages or other monetary relief based on prior Marketing, manufacturing (including through the use of a contract manufacturer), importation or use of the Generic Subject Drug Product, ***but only if*** the NDA Party and the Generic Party do not agree, and have not agreed, to another Brand/Generic Settlement for a different Drug Product during the sixty (60) day period starting thirty (30) days before and ending thirty (30) days after the execution of the Brand/Generic Settlement Agreement; or

6. a continuation or renewal of a pre-existing agreement between an NDA Party and a Generic Party ***but only if***: (i) the pre-existing agreement was entered into at least 90 days before the relevant Brand/Generic Settlement Agreement, (ii) the terms of the renewal or continuation, including the duration and the financial terms, are substantially similar to those in the pre-existing agreement, and (iii) entering into the continuation or renewal is not expressly contingent on agreeing to a Brand/Generic Settlement; or

7. a license to non-U.S. patents to manufacture or Market a pharmaceutical product outside the United States that has the same active ingredients and method of delivery as the Subject Drug Product.

O. "Exempted Agreement" means a Materials Agreement or Supply Agreement that meets all of the following conditions:

1. the price is above the Fully Allocated Manufacturing Cost, meaning:

   a. if the Agreement is a Materials Agreement, the Materials Price charged by an NDA Party for Materials provided through the Materials Agreement is at or above the Fully Allocated Manufacturing Cost incurred by the NDA Party per unit of the relevant Materials, or

   b. if the Agreement is a Supply Agreement, the Supply Price charged by the NDA Party for the Authorized Generic of the Subject Drug Product is at or above the Fully Allocated Manufacturing Cost incurred by the NDA Party per unit of the Authorized Generic of the Subject Drug Product provided under the agreement;

2. the Brand/Generic Settlement Agreement containing or incorporating the Materials Agreement or Supply Agreement is the only Brand/Generic Settlement Agreement that the NDA Party and the Generic Party have entered, or agreed to enter, during the sixty (60) day period starting thirty (30) days before and ending thirty (30) days after the execution of the Brand/Generic Settlement Agreement;

3. within fourteen (14) days after signing the Brand/Generic Settlement Agreement containing or incorporating the Materials Agreement or Supply Agreement, AbbVie Submits to the Monitor a full and complete copy of the Brand/Generic

Settlement Agreement, including any Materials Agreement and/or Supply Agreement;

4. within fourteen (14) days after the NDA Holder provides to the Generic Filer the Materials Price or Supply Price, as applicable, AbbVie Submits to the Monitor notification of the relevant Materials Price or Supply Price;

5. within thirty (30) days after beginning supply under the relevant Materials Agreement or Supply Agreement, the NDA Holder Submits to the Monitor:

   a. if a Materials Agreement, a verified written statement containing (i) the Fully Allocated Manufacturing Cost per unit for the Materials and (ii) a detailed calculation of the Fully Allocated Manufacturing Cost for the Materials, stated separately by cost component and on a per-unit basis; and

   b. if a Supply Agreement, a verified written statement containing (i) the Fully Allocated Manufacturing Cost per unit for the relevant Authorized Generic of the Subject Drug Product and (ii) a detailed calculation of the Fully Allocated Manufacturing Cost for the Authorized Generic of the Subject Drug Product, stated separately by cost component and on a per-unit basis; and

6. if the NDA Party is not AbbVie, the Materials Agreement or Supply Agreement, as applicable, requires the NDA Party to (i) provide the notification required by subparagraph I.O(5) and (ii) cooperate with any reasonable request by the Monitor or staff of the Commission for documents and information to determine the relevant Fully Allocated Manufacturing Cost, including without limitation and subject to any demonstrated legally recognized privilege, providing the Monitor

reasonable access to personnel, books, documents, and records kept in the ordinary course of business;

provided that, notwithstanding subparagraph I.O(5) or subparagraph I.O(6), a Materials Agreement or Supply Agreement in which AbbVie is the Generic Party shall also be considered an Exempted Agreement if it complies with subparagraphs I.O(1) to (4) ***and***:

a. if a Materials Agreement, AbbVie Submits to the Monitor within thirty (30) days of beginning to receive the Materials, a verified written statement containing (i) AbbVie's best estimate of what would be the Fully Allocated Manufacturing Cost per unit for the Materials if manufactured or sourced by the Generic Party, including a separate estimate of each cost component on a per-unit basis, and (ii) a description of the terms and conditions of any agreement(s), offer(s), purchase order(s), or price quote(s) AbbVie has entered into or received for supply of the Materials in connection with manufacture of the Subject Drug Product and other facts and circumstances, if any, that AbbVie deems relevant to understanding such terms and conditions; and

b. if a Supply Agreement, it is a Contingent Supply Agreement and AbbVie Submits to the Monitor within thirty (30) days of beginning to receive the Authorized Generic, a verified written statement containing (i) AbbVie's best estimate of what would be the Fully Allocated Manufacturing Cost per unit for the Subject Drug Product if manufactured by a Generic Party and (ii) a detailed calculation of the estimated Fully Allocated Manufacturing Cost, including an estimate of each cost component on a per-unit basis.

P. "Fully Allocated Manufacturing Cost" means: (1) direct costs incurred to produce or, if applicable, to acquire, the Subject Drug Product or Materials, determined in accordance with GAAP, as consistently applied in accordance with past practice and in the ordinary course of business, including, but not limited to (x) acquisition costs or (y) if applicable, materials, labor, manufacturing costs, packaging, labeling, testing, quality control, storage, insurance, and product maintenance; (2) the cost to ship the Subject Drug Product or Materials to the Generic Filer, and (3) administrative and overhead expenses associated with production or, if applicable, the acquisition of the Subject Drug Product or Materials, including, but not limited to, administrative labor costs, maintenance, information technology, quality assurance, insurance, depreciation of the equipment, and depreciation of the facility, allocated in accordance with past practice and in the ordinary course of business. To the extent the NDA Holder does not allocate administrative and overhead expenses associated with the Subject Drug Product to the Subject Drug Product, the NDA Holder shall do so at a proportion of the NDA Holder's COGS of the Subject Drug Product to the NDA Holder's total COGS (for purposes of this definition, COGS means the NDA Holder's cost of goods sold, determined in accordance with GAAP, as consistently applied in accordance with past practice and in the ordinary course of business).

Q. "Generic Entry Date" shall mean the date in a Brand/Generic Settlement Agreement, whether certain or contingent (such as, for example, contingent on the Marketing of the Subject Drug Product by another company), on or after which a Generic Filer is authorized by the NDA Holder to begin manufacturing, using, importing or Marketing

the Generic Subject Drug Product under the patents held by or licensed to (now or in the future) the NDA Holder that cover the Subject Drug Product.

R. "Generic Filer" means a party to a Brand/Generic Settlement who controls an ANDA or 505(b)(2) Application for the Subject Drug Product or has the exclusive right under such ANDA or 505(b)(2) Application to distribute the Subject Drug Product.

S. "Generic Party" means the Generic Filer, its parents, and any joint venture, subsidiary, division, group, or affiliate Controlled (for clarity, currently or in the future) by the Generic Filer or its parent, and their successors and assigns.

T. "Generic Product" means a Drug Product manufactured and/or Marketed under an ANDA or a 505(b)(2) Application.

U. "Generic Subject Drug Product" means the Generic Product that is the subject of the Patent Infringement Claim being resolved by the Brand/Generic Settlement.

V. "Market," "Marketed," or "Marketing" means the promotion, offering for sale, sale, or distribution of a Drug Product.

W. "Materials" means components or ingredients used in the manufacturing of a Subject Drug Product, including, but not limited to, hard-to-source excipients, hard-to-source active pharmaceutical ingredients, hard-to-source packaging, devices, or kits for injectables.

X. "Materials Agreement" means provisions in, or incorporated into, a Brand/Generic Settlement Agreement providing for the supply of Materials to the Generic Party by the NDA Party for securing and/or maintaining regulatory approval, or manufacturing and Marketing by the Generic Filer of the Subject Drug Product, including the terms and conditions of any such supply.

Y. "Materials Price" means the total actual per-unit price charged by the NDA Holder for Materials provided through a Materials Agreement, including any transfer price and royalty to be paid by the Generic Filer, net of any discounts, allowances, rebates, or other reductions.

Z. "Monitor" means an individual appointed pursuant to the terms of Section IV below.

AA. "NDA" means a New Drug Application filed with the United States Food and Drug Administration pursuant to Section 505(b) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(b), including all changes or supplements thereto that do not result in the submission of a new NDA.

BB. "NDA Holder" means a party to a Brand/Generic Settlement that controls the NDA for the Subject Drug Product or has the exclusive right to distribute the Branded Subject Drug Product in the United States.

CC. "NDA Party" means the NDA Holder, its parents, and any joint venture, subsidiary, division, group, or affiliate Controlled (for clarity, currently or in the future) by the NDA Holder or its parent, their successors and assigns.

DD. "No-AG Commitment" means any agreement with, or commitment or license to, the Generic Party that prohibits, prevents, restricts, requires a delay of, or imposes a condition precedent upon the research, development, manufacture, regulatory approval, or Marketing of an Authorized Generic by the NDA Party or a Third Party,

provided however, that an agreement by the Generic Party to pay royalties to the NDA Party for the right to Market the Generic Subject Drug Product or an Authorized Generic of the Subject Drug Product, including agreement on the terms and conditions governing payment of such royalties, shall not be considered a No-AG Commitment.

EE. "Patent Infringement Claim" means any allegation threatened in writing or included in a complaint or in a motion for leave to file an amended complaint filed with a court of law that a Generic Product may infringe one or more U.S. Patents held by, or licensed to, an NDA Holder.

FF. "Payment by the NDA Party to the Generic Party" means a transfer of value, other than a No-AG Commitment, by the NDA Party to the Generic Party (including, but not limited to, money, goods, or services), regardless of whether the Generic Party purportedly transfers value in return, where such transfer is either (i) expressly contingent on entering a Brand/Generic Settlement Agreement, or (ii) agreed to during the sixty (60) day period starting thirty (30) days before and ending thirty (30) days after executing a Brand/Generic Settlement Agreement. For clarity, an Exception, as defined herein, shall not be a Payment by the NDA Party to the Generic Party.

GG. "Person" means any individual, partnership, joint venture, firm, corporation, association, trust, unincorporated organization, or other business, and any subsidiaries, divisions, groups, or affiliates thereof.

HH. "Relevant Solvay Legacy Products" means, to the extent AbbVie has any rights, (1) the Solvay AndroGel Products, (2) Solvay's Cardiometabolics Business, (3) Solvay's Neuroscience Business, (4) Solvay's Pancreatic Enzymes Business, and (5) Solvay's Women's and Men's Health Business. For purposes of clarity, AbbVie makes no representations about its current rights to any product or compound listed in these definitions.

II. "Resolved Claims" means antitrust claims based on the conduct alleged in *FTC v. Actavis, Inc.*, 09-cv-955 (N.D. Ga.) ("FTC Georgia Action"), including but not limited to

claims of unfair competition under Section 5 of the FTC Act, that were or could have been included in the FTC Georgia Action or which arise from or are related to allegations included in the FTC Georgia Action. For clarity, "Resolved Claims" shall not include claims asserted in *FTC v. AbbVie Inc.*, et al, No. 14-cv-5151-HB (E.D. Pa.), which alleges a different reverse-payment agreement than at issue in the FTC Georgia Action.

JJ. "Solvay AndroGel Products" means AndroGel (NDA No. 21015), AndroGel 1.62% (NDA No. 22309), any future product Marketed under an AndroGel brand name, and/or any future testosterone gel manufactured or Marketed by AbbVie.

KK. "Solvay's Cardiometabolics Business" means Marinol (NDA No. 18651), any future product Marketed under a Marinol brand name, Aceon (NDA No. 20184), Aquatag (NDA No. 16001), Teveten (NDA No. 20738), SLV306 (daglutril), SLV320, SLV337, SLV338, SLV341, SLV342, SLV344, SLV352, and/or SLV356.

LL. "Solvay's Neuroscience Business" means Duopa (NDA No. 203952), Luvox (NDA No. 20243), Luvox CR (NDA No. 22033), and any products resulting from SLV308 (pardoprunox), SLV334, SLV338, SLV351, SLV354, and/or SLV357, or Solvay's development projects relating to anatibant, bifeprunox, or gabapentin.

MM. "Solvay's Pancreatic Enzymes Business" means Creon (NDA No. 20725), any future products Marketed under a Creon brand name, and/or any product resulting from SLV339 (lipase) or SLV340 (lipase, protease, amylase).

NN. "Solvay's Women's and Men's Health Business" means Prometrium (NDA No. 20843), any future product Marketed under a Prometrium brand name, and/or Gynorest (NDA No. 17388).

OO. "Submit to the Commission" or "Submitted to the Commission" means to file with the Office of the Secretary of the Commission and send an electronic copy to the Compliance Division of the Commission at bccompliance@ftc.gov.

PP. "Submit to the Monitor" or "Submitted to the Monitor" means to deliver to the Monitor appointed pursuant to the Order or, if no Monitor is appointed under this Order, to Submit to the Commission.

QQ. "Subject Drug Product" means the Drug Product for which one or more Patent Infringement Claims are settled under a given Brand/Generic Settlement. For purposes of this Order, the Drug Product of the NDA Holder and the Generic Filer to the same Brand/Generic Settlement shall be considered to be the same Subject Drug Product.

RR. "Supply Agreement" means provisions in, or incorporated into, a Brand/Generic Settlement Agreement providing for the supply of the Subject Drug Product to the Generic Party by the NDA Party for the Marketing by the Generic Party of an Authorized Generic on or after the Generic Entry Date, including the terms and conditions of any such supply.

SS. "Supply Price" means the total actual per-unit price charged by the NDA Holder for supply provided through a Supply Agreement, including any transfer price and royalty to be paid by the Generic Filer for the right to sell an Authorized Generic of the Subject Drug Product, net of any discounts, allowances, rebates, or other reductions.

TT. "Third Party" means any Person other than the NDA Party and/or the Generic Party.

UU. "U.S. Patent" means any patent issued by the United States Patent and Trademark Office, including all renewals, derivations, divisions, reissues, continuations, continuations-in part, modifications, or extensions thereof.

II.

IT IS FURTHER ORDERED that, in connection with any actions in or affecting Commerce,

A. AbbVie shall cease and desist from, either directly or indirectly, or through any corporate or other device, individually or collectively entering into a Brand/Generic Settlement covering a Relevant Solvay Legacy Product that includes:

1. (i) a No-AG Commitment and (ii) an agreement by the Generic Filer not to research, develop, manufacture, or Market the Subject Drug Product for any period of time; or

2. (i) any Payment by the NDA Party to the Generic Party that is not an Exempted Agreement and (ii) an agreement by the Generic Filer not to research, develop, manufacture, or Market the Subject Drug Product for any period of time,

provided that any agreement entered into by an entity prior to that entity becoming part of AbbVie is not subject to the terms of this Order.

III.

IT IS FURTHER ORDERED that:

A. Nothing in this Order shall prohibit AbbVie from entering a written agreement otherwise prohibited by Paragraph II(A) ***so long as*** either of the following two conditions is met:

1. Prior to entering the agreement, AbbVie Submits to the Commission a request for approval to enter the agreement and (a) within thirty (30) days of the Commission's receipt of the request for approval under this paragraph, the Director of the Bureau of Competition (or his or her designee) has not notified AbbVie in writing that, after considering the request in good faith, Commission staff believes the agreement raises substantial questions regarding violation of

Section 5 of the FTC Act or any other applicable law that the FTC has authority to enforce and of the reasons for such a belief; or (b) AbbVie receives the approval of the Commission to enter the agreement, or

2. Such agreement contains a provision or provisions expressly stating: (a) AbbVie will Submit to the Commission a request for approval to enter the agreement, and (b) the agreement is not effective, and shall not become effective, until and unless (i) thirty (30) days have passed since the request for approval was Submitted to the Commission and the Director of the Bureau of Competition (or his or her designee) has not notified AbbVie in writing that Commission staff believes the agreement raises substantial questions regarding violation of Section 5 of the FTC Act or any other applicable law that the FTC has authority to enforce, or (ii) AbbVie receives the approval of the Commission to effectuate the agreement.

B. Nothing in this Order shall prohibit AbbVie from purchasing, merging with, or otherwise acquiring or being acquired by any party with which it has entered into a Brand/Generic Settlement.

IV.

A. The Commission may appoint a Monitor to ensure that any Materials Agreement or Supply Agreement that AbbVie asserts is an Exempted Agreement meets the requirements of Paragraph I.O of this Order. The Monitor shall serve, without bond or other security, at the expense of AbbVie, on such reasonable and customary terms and conditions to which the Monitor and AbbVie agree and that the Commission approves.

B. The Commission shall select the Monitor, subject to the consent of AbbVie, which consent shall not be unreasonably withheld. If AbbVie has not opposed, in writing and

identifying the reasons for opposing, the selection of any proposed Monitor within fourteen (14) days after notice by the staff of the Commission of the identity of any proposed Monitor, AbbVie shall be deemed to have consented to the selection of the proposed Monitor.

C. The Monitor's duties and responsibilities shall include the following:

1. the Monitor shall act in a fiduciary capacity for the benefit of the Commission;

2. the Monitor shall have the power and authority to perform his/her duties under this Paragraph. The Monitor shall exercise his/her power and authority and carry out his/her duties and responsibilities in a manner consistent with the purposes of this Order and in consultation with the Commission;

3. the Monitor shall have authority to employ, at the expense of AbbVie, such consultants, accountants, attorneys, and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties and responsibilities;

4. the Monitor shall evaluate reports Submitted to the Monitor pursuant to the requirements of Paragraph V and within thirty (30) days from the date the Monitor receives a report, report in writing to the Commission concerning whether any Materials Agreement or Supply Agreement that AbbVie asserts is an Exempted Agreement meets the requirements of Paragraph I.O of this Order.

D. AbbVie shall grant and transfer to the Monitor, and such Monitor shall have, all rights, powers, and authority necessary to carry out the Monitor's duties and responsibilities under this Order, including but not limited to, the following:

1. AbbVie shall cooperate with any reasonable request of the Monitor and shall take no action to interfere with or impede the Monitor's ability to perform his/her duties as provided in this Paragraph;

2. subject to any demonstrated legally recognized privilege, AbbVie shall provide the Monitor full and complete access to personnel, books, documents, records kept in the ordinary course of business, facilities and technical information, and such other relevant information as the Monitor may reasonably request to perform his/her duties under this Paragraph;

3. AbbVie 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 the 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 Monitor; and

4. AbbVie may require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign an appropriate confidentiality agreement related to AbbVie's materials and information received in connection with the performance of the Monitor's duties, *provided however*, such agreement shall not restrict the Monitor from providing any information to the Commission or require the Monitor to report to AbbVie the substance of communications to or from the Commission or any party to a Brand/Generic Settlement Agreement other than AbbVie.

E. The Commission may require the Monitor and each of the 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 Monitor's duties.

F. The Commission may, on its own initiative or at the request of the Monitor, issue such additional orders or directions to the Monitor as may be necessary or appropriate, consistent with the scope of Paragraph IV.A of the Order.

G. If the Commission determines that the Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Monitor. The Commission shall select the substitute Monitor, subject to the consent of AbbVie, which consent shall not be unreasonably withheld. If AbbVie has not opposed, in writing and identifying the reasons for opposing, the selection of any proposed substitute Monitor within fourteen (14) days after notice by the staff of the Commission to AbbVie of the identity of any proposed substitute Monitor, AbbVie shall be deemed to have consented to the selection of the proposed substitute Monitor.

V.

IT IS FURTHER ORDERED that:

A. AbbVie shall Submit to the Commission a verified written report within sixty (60) days after the date this Order is entered, one (1) year after the date this Order is entered, and annually for nine (9) years thereafter, setting forth in detail the manner and form in which it has complied and is complying with this Order. If the Commission has appointed a Monitor, and if AbbVie is providing or receiving product under an Exempted Agreement, AbbVie shall Submit to the Monitor a copy of the report. Among other things and without limitation, AbbVie shall include in each report a copy of each agreement AbbVie has entered with any party to a Brand/Generic Settlement signed by AbbVie relating to Relevant Solvay Legacy Products if:

(i) the Brand/Generic Settlement Agreement includes an agreement by the Generic Filer not to research, develop, manufacture, or Market the Subject Drug Product for any period of time; and

(ii) the agreement was entered within six (6) months of executing the Brand/Generic Settlement Agreement, *provided that*, AbbVie does not need to submit any agreement that was submitted with a prior verified written report.

B. This Order does not alter the reporting requirements of AbbVie pursuant to Section 1112 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

VI.

IT IS FURTHER ORDERED that for the purpose of determining or securing compliance with this Order, subject to any legally recognized privilege, and upon written request and upon reasonable notice to AbbVie, AbbVie shall, without restraint or interference, permit any duly authorized representative of the Commission with respect to a Brand/Generic Settlement involving a Relevant Solvay Legacy Product:

1. access, during office hours and in the presence of counsel, to all facilities and access to inspect and copy all non-privileged business records and documentary material related to compliance with this Order, including without limitation electronically stored information as defined in Rule 2.7(a)(1) and (2), 16 C.F.R. § 2.7(a)(1), and books, ledgers, accounts, correspondence, memoranda, and other records and documents (in whatever form such records and documents are kept) in the possession or under the control of AbbVie, which copying services shall be provided by AbbVie at the request of the authorized representative(s) of the Commission and at the expense of AbbVie; and

2. to interview officers, directors, or employees of AbbVie, who may have counsel present, regarding any such matters.

VII.

IT IS FURTHER ORDERED that AbbVie shall notify the Commission at least 30 days prior to any proposed dissolution, acquisition, merger, or consolidation of AbbVie that might affect compliance obligations arising out of this Order by submitting to the Commission appropriate notification.

VIII.

IT IS FURTHER ORDERED that in the event of a material change in the law governing the antitrust implications of Brand/Generic Settlements, the Commission will consider, in good faith, modifications to this Order proposed by AbbVie.

IX.

IT IS FURTHER ORDERED that this Court shall retain jurisdiction over these matters for purposes of construction, modification, and enforcement of this Order.

X.

IT IS FURTHER ORDERED that this Order shall terminate ten (10) years from the date on which the Order is issued.

XI.

IT IS FURTHER ORDERED that this action shall be dismissed with prejudice. Each party shall bear its own costs.

SO ORDERED this ____ day of _____, 2019

_____
Thomas W. Thrash, Jr.
United States District Judge

SO STIPULATED AND AGREED:

FOR PLAINTIFF FEDERAL TRADE COMMISSION:

Date: 2/26/19

Markus H. Meier
Assistant Director
Health Care Division
Bureau of Competition
Federal Trade Commission

FOR ABBVIE PRODUCTS LLC:

Date: 2/27/19

Laura J. Schumacher
on behalf of AbbVie Inc. as sole member of AbbVie Products LLC

FOR ABBVIE INC.:

Date: 2/27/19

Laura J. Schumacher
Vice Chairman, External Affairs and Chief Legal Officer

Date: 2/27/2019

Rohit Singla
Munger, Tolles & Olson LLP
COUNSEL FOR ABBVIE PRODUCTS LLC
AND ABBVIE INC.