IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

FEDERAL TRADE COMMISSION,

Plaintiff,

v.

ABBVIE INC., ET AL.,

Defendants.

Case Number: 2:14-CV-5151-HB

[PROPOSED] ORDER FOR PERMANENT INJUNCTION AND EQUITABLE MONETARY RELIEF

I.

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

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

B. "Abbott" or "Defendant Abbott" means Abbott Laboratories, its directors, officers, employees, agents, representatives, successors, and assigns; and the joint ventures, subsidiaries, partnerships, divisions, groups, and affiliates controlled by Abbott Laboratories, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.

C. "AbbVie" or "Defendant AbbVie" means AbbVie Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and the joint ventures, subsidiaries, partnerships, divisions, groups, and affiliates controlled by AbbVie Inc., and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.

D. "Besins" or "Defendant Besins" means Besins Healthcare Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and the joint ventures, subsidiaries, partnerships, divisions, groups, and affiliates controlled by Besins Healthcare Inc., and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.

E. "Unimed" or "Defendant Unimed" means Unimed Pharmaceuticals, LLC, its directors, officers, employees, agents, representatives, successors, and assigns; and the joint ventures, subsidiaries, partnerships, divisions, groups, and affiliates controlled by Unimed Pharmaceuticals, LLC, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.

F. "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).

G. "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).

H. "AndroGel 1.62%" means any Drug Product manufactured or sold in the United States under NDA No. 22309.

I. "AndroGel 1.62% Patent" means a claim in any United States patent or patent application, including continuation, continuation-in-part, divisional, or reissue application, that covers the importation, manufacture, use, sale or marketing of AndroGel 1.62%, including claims in U.S. Patent Nos. 6,503,894; 8,466,136; 8,466,137; 8,466,138; 8,486,925; 8,729,057; 8,741,881; 8,754,070; 8,759,329; 9,125,816; and 9,132,089.

J. "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.

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

L. "Direct Cost" means costs not to exceed the cost of labor, material, travel, and other expenditures to the extent the costs are directly incurred in the manufacture of Androgel 1.62%.

M. "Drug Product" means a finished dosage form (e.g., gel, 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. "Excluded Testosterone Product" means a Drug Product that contains active ingredient testosterone but does not contain the penetration enhancer isopropyl myristate ("IPM").

O. "Generic Manufacturer" means any company or person that has filed an ANDA or 505(b)(2) NDA that references AndroGel 1.62%.

P. "Generic Product" means a Drug Product manufactured and/or sold under an ANDA or pursuant to 505(b)(2) Application.

Q. "Monitor" means an individual appointed pursuant to the terms of Section V.

R. "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.

S. "Notice of Ability to License" means a notice to a Generic Manufacturer that is in the form of Exhibit 2.

T. "Notice of Federal Order" means a notice to defendant in a Patent Infringement Action regarding the terms of the Order that is the form of Exhibit 1.

U. "Patent Infringement Action" means a claim, counter-claim or action alleging patent infringement, including infringement pursuant to 35 U.S.C. § 271(e)(2)(A), which is filed in a court of competent jurisdiction in the United States.

II.

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

A. Defendants shall not, jointly or individually, file a Patent Infringement Action asserting that U.S. Patent No. 6,503,894 is infringed by ANDA or 505(b)(2) Application for an Excluded Testosterone Product or importing, manufacturing, using, marketing, selling or distributing the Excluded Testosterone Product.

B. Defendants shall not, jointly or individually, interfere with or delay the regulatory approval, importation or sale of a Generic Product by filing an objectively baseless Patent Infringement Action.

C. If a Defendant files a Patent Infringement Action alleging that a Generic Product infringes a patent licensed to or owned by Defendant, Defendant shall:

1. No later than 5 days after filing such a Patent Infringement Action, deliver to the Commission a verified notice stating that the Patent Infringement Action is an objectively reasonable claim and describing the factual basis for the Patent Infringement Action. The verified notice shall be signed with a notarized signature or sworn statement of the Chief Executive Officer or other officer or employee specifically authorized to perform this function, or self-verified in the manner set forth in 28 U.S.C. § 1746. Defendant shall file the verified notice with the Secretary of the Commission at ElectronicFilings@ftc.gov and submit a copy to the Compliance Division at bccompliance@ftc.gov; and

2. Include with the service of its initial pleading in the Patent Infringement Action on each defendant, a Notice of Federal Order.

III.

IT IS FURTHER ORDERED that

A. Within 30 days of entry of this Order, Defendants shall deliver to each Generic Manufacturer a Notice of Ability to License.

B. Defendants AbbVie, Besins, and Unimed shall each grant a non-exclusive, royalty-free, fully paid-up, perpetual, irrevocable, transferable, and sublicensable license to all of its existing and future rights under any AndroGel 1.62% Patent to any Generic Manufacturers who request such licenses. The licenses shall be granted within 30 days of receiving the request from the Generic Manufacturer.

C. If a Generic Manufacturer granted a license pursuant to Section III.B. of this order requests a supply of AndroGel 1.62% for sale as an Authorized Generic, Defendants AbbVie, Besins and Unimed shall to the first two Generic Manufacturers who make such a request:

1. Supply AndroGel 1.62% pursuant to an agreement that receives the prior approval of the Commission ("Supply Agreement");

2. Within 1 month after receiving a request pursuant to this Paragraph, submit to the Commission for approval a proposed Supply Agreement;

3. Begin supplying AndroGel 1.62% to the Generic Manufacturer within 3 months of receiving a request under this Paragraph, unless otherwise agreed to by the Generic Manufacturer;

4. Supply AndroGel 1.62% to the Generic Manufacturer at Direct Cost, or the price contained in the Supply Agreement;

5. Give priority to Generic Manufacturer's requirements for AndroGel 1.62% over Defendants' own and take all actions that are reasonably necessary to ensure uninterrupted supply of AndroGel 1.62% to the Generic Manufacturer;

6. Allow the Generic Manufacturer to terminate the Supply Agreement, or any portions of it, at any time upon commercially reasonable notice and without cost or penalty; and

7. Supply AndroGel 1.62% for the term of the Supply Agreement,

provided that, the Commission may require Defendants to extend the Supply Agreement if the Commission, in its sole discretion, determines that an extension is warranted and the AndroGel 1.62% Generic Manufacturer is making commercially reasonable efforts to independently manufacturer and market a generic version of AndroGel 1.62%.

IV.

IT IS FURTHER ORDERED that

A. Judgment of $1.472 billion is entered in favor of Plaintiff against Defendants, jointly and severally, as equitable monetary relief.

B. Defendants are ordered to pay $1.472 billion Dollars within 7 days of entry of this Order. Defendants shall pay the Commission by electronic fund transfer in accordance with instructions previously provided by a representative of the Commission.

C. Defendants shall deposit the money paid to the Commission pursuant to this Order into a fund administered by the Commission or its designee for equitable relief, including consumer redress and any attendant expenses for the administration of any redress fund or such other equitable relief as the Commission determines is reasonably related to Defendants' practices alleged in the Complaint. The Commission or its designee shall develop a plan of administration for the fund to identify valid claims and distribute consumer redress. No monies shall be distributed from the fund until this case been fully resolved, including any appeals. After a period of no less than 5 years following availability of the fund, the Commission shall deposit any money not used for equitable relief to the U.S. Treasury as disgorgement.

D. No later than 30 days after receiving a written request by Commission, Defendants, at their own cost and expense, shall provide to Commission information and data reasonably necessary to facilitate use of the money paid to the Commission under this Order for equitable relief, including consumer redress.

V.

IT IS FURTHER ORDERED that

A. The Commission may appoint a Monitor to verify that a Patent Infringement Action complies with the Order, if a defendant in such action has sent the Commission a verified written notice that complies with the requirements contained in a Notice of Federal Order.

B. The Monitor shall serve, without bond or other security, at the expense of Defendants, on reasonable and customary terms and conditions that are consistent with this Order, agreed to by Monitor and Defendants, and approved by the Commission.

C. The Commission shall select the Monitor, subject to the consent of Defendants, who shall not unreasonably withhold consent. Staff of the Commission shall notify Defendants in writing of the identity of the Monitor the Commission proposes to appoint. No later than 14 days after receiving notice of the identity of the proposed Monitor, Defendant shall notify staff if it opposes the selection of the proposed Monitor by sending a written notice of opposition, including the reasons for opposition, to bccompliance@ftc.gov. If a Defendant does not deliver a written notice of opposition within 14 days after being

notified of the identity of the Monitor, the Defendant shall be deemed to have consented to the selection of the proposed Monitor.

D. No later than 30 days after the Commission appoints a Monitor, Defendants shall submit to staff of the Commission a proposed agreement between the Monitor and Defendants. Defendants shall submit the proposed agreement to bcccompliance@ftc.gov.

E. Defendants shall grant and transfer to the Monitor, and the Monitor shall have, all rights, powers, and authority necessary to carry out the Monitor's duties and responsibilities under this Order, and further:

1. Defendants 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, Defendants 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. Defendants shall indemnify the Monitor against losses, claims, damages and liabilities (including reasonable attorney's fees and other expenses incurred in connection with the preparations for, or defense of, any claim, whether or not the claim results in liability) that arise out of, or in connection with, performance of the Monitor's duties;

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

5. Defendants 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 Defendants' materials and information received in connection with the performance of the Monitor's duties,

provided however, such agreement shall not prohibit the Monitor from providing any information to the Commission or require the Monitor to report to Defendants the substance of communications to or from the Commission or any third party.

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

1. The Monitor shall act for the benefit of the Commission;

2. 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; and

3. The Monitor may employ, at the expense of Defendants, such consultants, accountants, attorneys, and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties and responsibilities.

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

H. 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 using the process described in Paragraph V.C. above.

VI.

IT IS FURTHER ORDERED that each Defendant shall submit verified written reports ("compliance reports") in accordance with the following:

A. Each Defendant shall submit:

1. An interim compliance reports 60 days after the Order is issued;

2. Annual compliance reports one year after the date this Order is issued, and annually for the next 10 years on the anniversary of that date; and

3. Additional compliance reports as the Commission or its staff may request,

provided however, Defendants under common ownership may jointly submit required compliance reports.

B. Each compliance report shall set forth in detail the manner and form in which the submitting Defendant intends to comply, is complying, and has complied with this Order.

C. Each Defendant shall verify each compliance report with a notarized signature or sworn statement of the Chief Executive Officer or other officer or employee specifically authorized to perform this function, or self-verified in the manner set forth in 28 U.S.C. § 1746. Each Defendant shall submit an original and 2 copies of each compliance report as required by Commission Rule 2.41(a), 16 C.F.R. § 2.41(a), including a paper original submitted to the Secretary of the Commission and electronic copies to the Secretary at ElectronicFilings@ftc.gov and to the Compliance Division at bccompliance@ftc.gov. In addition, each Defendant shall provide a copy of each compliance report to the Monitor if the Commission has appointed one in this matter.

VII.

IT IS FURTHER ORDERED that each Defendant shall notify the Commission at least 30 days prior to a change in Defendant that may affect the Defendant's compliance obligations arising out of this Order, including any proposed dissolution, acquisition, merger, consolidation or assignment of patents.

VIII.

IT IS FURTHER ORDERED that

A. To determine or secure compliance with this Order and subject to any legally recognized privilege, each Defendant shall, upon written request, 5 days' notice, and without restraint or interference, permit any duly authorized representative of the Commission to

1. Inspect and copy (at the expense of Defendant) all business and other records and all documentary material and electronically stored information as defined in Commission Rules 2.7(a)(1) and (2), 16 C.F.R. § 2.7(a)(1) and (2), in the possession or under the control of the Defendant that relate to compliance with the Order; and

2. Interview officers, directors, or employees of the Defendant, who may have counsel present, regarding matters that relate to compliance with the Order.

IX.

IT IS FURTHER ORDERED that

A. This Court shall retain jurisdiction over this matter for purposes of construction, modification, and enforcement of the Order.

B. In any enforcement proceeding in which the Court finds that the Defendants have violated this Final Judgment, Plaintiff may apply to the Court for a one-time extension of this Final Judgment, seek such other relief as may be appropriate, and shall be entitled to reimbursement of reasonable attorneys' fees, experts' fees, and costs incurred in such enforcement action.

X.

IT IS FINALLY ORDERED that this Order shall terminate 20 years from the date on which it is issued.

SO ORDERED this ____ day of _____, 2018

_____

The Honorable Harvey Bartle III

FTC v. AbbVie, et al.
Exhibit 1

Notice of Federal Order

[Name and address of defendant in Patent Infringement Action]

The Order for Permanent Injunction and Equitable Monetary Relief ("Order") entered in *Federal Trade Commission v. AbbVie, et al.* requires [Defendant] to provide this notice. Attached is a copy of the Order.

The Order, among other things, bars [Defendant] from filing a patent infringement action that is objectively baseless in order to delay the launch of a generic drug in United States. If you believe that the action [Defendant] has filed against you violates the terms of the Order, you may notify the staff of the Federal Trade Commission by delivering a verified written notice to Compliance Division of the Bureau of Competition at bccompliance@ftc.gov. The verified written notice should identify the manner in which you believe [Defendant] has violated the Order and describe the facts that support your belief. The verified notice should be signed with a notarized signature or sworn statement of your Chief Executive Officer or other officer or employee specifically authorized to perform this function, or self-verified in the manner set forth in 28 U.S.C. § 1746.

If you have any questions regarding this notice, please contact the Assistant Director of the Compliance Division of the Bureau of Competition within the Federal Trade Commission, or Susan A. Huber, staff attorney in the Compliance Division. You can reach Ms. Huber and the Assistant Director at bccompliance@ftc.gov.

Encl.

FTC v. AbbVie, et al.
Exhibit 2

Notice of Ability to License

[Name and address of Generic Manufacturer]

The Order for Permanent Injunction and Equitable Monetary Relief ("Order") entered in *Federal Trade Commission v. AbbVie, et al.* requires [Defendant] to provide this notice. Attached is a copy of the Order.

The Order, among other things, requires Defendants AbbVie, Besins and Unimed to license relevant AndroGel 1.62% patents, and provide, upon request, interim product supply to two generic manufacturers who have filed Paragraph IV Notices with respect to an ANDA or 502(b)(2) application concerning a generic Androgel 1.62% product. Since you have filed such a Paragraph IV Notice, you may be able to request a license and, if necessary, a product supply pursuant to the Order.

If you have any questions regarding this notice, please contact the Assistant Director of the Compliance Division of the Bureau of Competition within the Federal Trade Commission, or Susan A. Huber, staff attorney in the Compliance Division. You can reach Ms. Huber and the Assistant Director at bccompliance@ftc.gov.

Encl.