UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

FEDERAL TRADE COMMISSION
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580

Plaintiff,

v.

ABBVIE INC.,
1 North Waukegan Road
North Chicago, Illinois 60064;

ABBOTT LABORATORIES,
100 Abbott Park Road
Abbott Park, Illinois 60064;

UNIMED PHARMACEUTICALS, LLC,
1 North Waukegan Road
North Chicago, Illinois 60064;

BESINS HEALTHCARE, INC.,
607 Herndon Parkway, Suite 210
Herndon, Virginia 20170; and

TEVA PHARMACEUTICALS USA, INC.,
1090 Horsham Road
North Wales, Pennsylvania 19454

Defendants.

Case Number:

COMPLAINT

Complaint for Injunctive and Other Equitable Relief

Plaintiff, the Federal Trade Commission ("FTC"), by its designated attorneys, petitions this Court, pursuant to Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), for a permanent injunction and other equitable relief against Defendants AbbVie Inc., Abbott Laboratories,

Unimed Pharmaceuticals, LLC (collectively, "AbbVie Defendants"), Besins Healthcare, Inc., and Teva Pharmaceuticals USA, Inc., to undo and prevent their unfair methods of competition in or affecting commerce in violation of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a).

I. Nature of the Case

1. This case challenges a course of anticompetitive conduct by Defendants that has cost consumers hundreds of millions of dollars by denying them the opportunity to purchase lower-priced versions of the blockbuster prescription drug AndroGel. AndroGel is a brand-name testosterone replacement therapy for men with low testosterone with annual U.S. sales of over $1 billion. To unlawfully maintain and extend monopoly power on AndroGel, Abbott, Unimed, and Besins filed sham patent infringement litigation against potential competitors Teva and Perrigo Company. In furtherance of this anticompetitive scheme, Abbott and Unimed then entered an illegal agreement with Teva. Defendants' anticompetitive plan to thwart competition has forced consumers and other purchasers to pay hundreds of millions of dollars more than they would have absent such conduct.

2. Unimed (now a wholly-owned subsidiary of AbbVie) and Besins own a narrow pharmaceutical composition patent relating to AndroGel, U.S. Patent No. 6,503,894 (the "'894 Patent"). To obtain this patent, Unimed and Besins were required by the U.S. Patent and Trademark Office ("PTO") to significantly narrow their original claims. The companies' initial, broad claims sought to cover testosterone gel compositions containing *any* penetration enhancer. Penetration enhancers are inactive ingredients that facilitate the delivery of a drug product's active ingredient—testosterone in the case of AndroGel—through the skin and into the bloodstream. Ultimately, Unimed and Besins claimed only the specific formulation for AndroGel, which contains a *single* penetration enhancer known as isopropyl myristate ("IPM").

3. Aware of the patent's narrow scope, Perrigo and Teva designed around the '894 Patent, developing generic versions of AndroGel that contain penetration enhancers other than IPM, and filed applications with the U.S. Food and Drug Administration ("FDA") seeking approval to market their products. The penetration enhancer in Perrigo's product is isostearic acid ("ISA"). The penetration enhancer in Teva's product is isopropyl palmitate ("IPP").

4. In 2009, Unimed, AbbVie's corporate predecessor Solvay Pharmaceuticals, and Besins made a deliberate and considered decision not to assert that Perrigo's generic AndroGel formulation infringed the '894 Patent. An internal business document explained why: "We conducted a thorough analysis based upon . . . the information available to us" and "determined there was not a sufficient basis for filing patent infringement litigation."

5. In 2011, however, faced with the near-term possibility of competition to AndroGel from Teva's and Perrigo's products, AbbVie Defendants and Besins filed sham litigation, suing Perrigo as well as Teva for infringement of the '894 Patent. The reason is obvious: these lawsuits forestalled the possibility of generic competition by triggering automatic 30-month stays on FDA's authority to approve Teva's and Perrigo's products.

6. AbbVie Defendants and Besins filed these infringement lawsuits even though Teva's and Perrigo's products are clearly outside the literal scope of the '894 Patent; each product contains a penetration enhancer other than IPM, the only penetration enhancer claimed in the '894 Patent. AbbVie Defendants and Besins have no reasonable basis to contend that Teva's and Perrigo's penetration enhancers are equivalent to IPM and thus covered by the '894 Patent under the doctrine of equivalents. This is because Unimed and Besins disclosed but did not claim Teva's and Perrigo's penetration enhancers in the '894 Patent and therefore dedicated them to the public. In addition, Unimed and Besins had surrendered Teva's and Perrigo's

penetration enhancers while prosecuting the '894 Patent before the PTO in order to obtain the '894 Patent. AbbVie Defendants and Besins are therefore precluded from arguing equivalence under the well-settled doctrine of prosecution history estoppel.

7. Moreover, AbbVie Defendants and Besins were taking precisely the opposite position before the PTO while attempting to obtain a patent using Perrigo's penetration enhancer. For example, AbbVie Defendants and Besins represented to the PTO that "testosterone gel products with different penetration enhancers cannot be demonstrated as substantially equivalent, i.e., similar compositions" and that Perrigo's penetration enhancer "is not equivalent to and substitutable for" the penetration enhancer claimed in the '894 Patent.

8. Teva and Perrigo both recognize that any claim asserting that their products infringe the '894 Patent is without merit. In the patent litigation, Teva counterclaimed that the lawsuit brought by AbbVie Defendants and Besins was anticompetitive and a sham. Similarly, Perrigo had notified AbbVie Defendants and Besins that Perrigo's product was outside the scope of the '894 Patent and that filing an infringement lawsuit would be a sham.

9. Eventually, Teva concluded that it would be better off by sharing in AbbVie Defendants' monopoly profits from the sale of AndroGel than by competing. Because eliminating competition artificially inflated AndroGel prices and preserved large monopoly profits, AbbVie Defendants could easily afford to compensate Teva for staying out of the AndroGel market by paying Teva more than Teva could have earned selling its lower-priced testosterone gel product. Thus, Teva abandoned its sham litigation claims and settled the infringement lawsuit by entering an agreement with AbbVie Defendants to refrain from launching its alternative to AndroGel until [redacted]. In turn, AbbVie Defendants paid Teva in the form of a highly profitable authorized generic deal for another product, executed on

the same day as the AndroGel patent litigation settlement. This authorized generic deal does not make sense for AbbVie Defendants as an independent business transaction; it only makes sense as a means to induce Teva to drop its patent challenge and refrain from competing with AndroGel for several years.

10. As a result of Defendants' conduct, competition to AndroGel from Teva and Perrigo—which would have begun following FDA approval of Teva's and Perrigo's products in February 2012 and January 2013, respectively—will not occur until at least [redacted], forcing patients and other payers to pay substantially higher prices during this period. Additionally, this conduct has further harmed consumers because it has allowed AbbVie Defendants to shift a significant amount of sales from AndroGel 1%, the original dosage strength of the drug, to AndroGel 1.62%, a reformulated product that is not subject to automatic substitution with generic AndroGel 1% products.

II. Jurisdiction and Venue

11. This Court has subject matter jurisdiction over this action pursuant to 15 U.S.C. §§ 45(a) and 53(b), and 28 U.S.C. §§ 1331, 1337(a), and 1345.

12. This Court has personal jurisdiction over each Defendant pursuant to 15 U.S.C. § 53(b), and because each Defendant has the requisite constitutional contacts with the United States of America.

13. Venue in this district is proper 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). Each Defendant resides, transacts business, committed an illegal or tortious act, or is found in this District.

14. Defendants' general business practices, and the unfair methods of competition alleged herein, are "in or affecting commerce" within the meaning of Section 5 of the FTC Act,

15 U.S.C. § 45.

15. Each Defendant is, and at all times relevant herein has been, a corporation, as "corporation" is defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

III. The Parties

16. Plaintiff FTC is an administrative agency of the United States Government, established, organized, and existing pursuant to the FTC Act, 15 U.S.C. § 41 *et seq.*, with its principal offices in Washington, D.C. The FTC is vested with authority and responsibility for enforcing, inter alia, Section 5 of the FTC Act, 15 U.S.C. § 45, and is authorized under Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), to initiate court proceedings to enjoin violations of any law the FTC enforces and to seek equitable monetary remedies.

17. Defendant Abbott Laboratories (together with its affiliates, "Abbott") is a publicly traded, for-profit company incorporated in Illinois with its principal place of business at 100 Abbott Park Road, Abbott Park, Illinois 60064. On January 1, 2013, Abbott separated into two independent, publicly traded companies—Abbott and AbbVie Inc.—through the distribution of 100 percent of the issued and outstanding common stock of AbbVie Inc. to Abbott's shareholders. Abbott is a diversified medical products company engaged in the business of, among other things, developing, manufacturing, marketing, and distributing medical devices, diagnostic systems and tests, and nutritional products. Prior to January 1, 2013, Abbott's portfolio of products included brand-name pharmaceuticals, including AndroGel. In the twelve months ending December 31, 2012 (the last year before AbbVie's separation), Abbott had net sales of approximately $30.9 billion.

18. Defendant AbbVie Inc. (together with its affiliates, "AbbVie") is incorporated in Delaware with its principal place of business at 1 North Waukegan Road, North Chicago, Illinois

60064. AbbVie has existed since January 1, 2013, as a publicly traded research-based pharmaceutical company with Abbott's former portfolio of proprietary pharmaceuticals and biologics. AbbVie includes the former entities Solvay Pharmaceuticals, Inc. and Solvay Pharma U.S. Holdings, Inc., which Abbott acquired in 2010, as well as Abbott Products, Inc. and Abbott Products U.S. Holdings, Inc. Except where otherwise specified, hereinafter "AbbVie" refers to AbbVie and all corporate predecessors and affiliates. AbbVie is engaged in the business of, among other things, developing, manufacturing, marketing, distributing, and selling brand-name pharmaceutical products, including AndroGel. In the twelve months ending December 31, 2013, AbbVie had net sales of approximately $18.8 billion, of which more than $1 billion were U.S. sales of AndroGel.

19. Defendant Unimed Pharmaceuticals, LLC (together with its affiliates, "Unimed"), a wholly-owned subsidiary of AbbVie, is a corporation organized and existing under the laws of Delaware, with its headquarters and principal place of business at 1 North Waukegan Road, North Chicago, Illinois 60064.

20. Defendant Besins Healthcare Inc. (together with its affiliates, "Besins") is a for-profit corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 607 Herndon Parkway, Suite 210, Herndon, Virginia 20170. Besins includes the former entities Laboratoires Besins-Iscovesco and Besins-Iscovesco U.S., Inc. Besins is a wholly-owned subsidiary of Besins Healthcare S.A., a privately held corporation with its headquarters in Bangkok, Thailand. Besins is engaged in the business of, among other things, developing, manufacturing, marketing, and distributing brand-name pharmaceutical products. Under an agreement with AbbVie, Besins manufactures AndroGel and receives a share of the profits from U.S. sales.

21. Defendant Teva Pharmaceuticals USA, Inc. (together with its affiliates, "Teva") is a for-profit corporation organized and existing under the laws of Delaware, with its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454. Teva is a wholly-owned subsidiary of Teva Pharmaceuticals Industries Ltd., an Israeli corporation, with its principal place of business in Petach Tikva, Israel. Teva is engaged in the business of, among other things, developing, manufacturing, marketing, and distributing generic drug products. In the twelve months ending December 31, 2013, Teva Pharmaceuticals Industries Ltd. had net revenues of approximately $20.3 billion, including approximately $4.1 billion in revenues from U.S. sales of generic pharmaceuticals. Teva products accounted for 15.3 percent of all U.S. generic prescriptions in 2013.

IV. Background

A. The regulatory system governing pharmaceuticals in the United States provides several potential pathways for marketing a generic version of a brand-name drug.

22. The Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act") and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, 21 U.S.C. §§ 355(b)(2), 355(j) and 35 U.S.C. § 271(e), establishes procedures designed to facilitate competition from lower-priced generic drugs, while maintaining incentives for pharmaceutical companies to invest in developing new drugs.

23. A company seeking FDA approval to market a brand-name drug must file a New Drug Application ("NDA") demonstrating the safety and efficacy of its product.

24. A generic drug is the same as a brand-name drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use. A generic drug

must also contain identical amounts of the same active ingredient(s) as the brand-name drug, although its inactive ingredients may vary.

25. A company seeking to market a generic version of a brand-name drug must file either an Abbreviated New Drug Application ("ANDA") or an application pursuant to section 505(b)(2) of the FDCA (a "505(b)(2) application"). A 505(b)(2) application references an approved NDA and may rely on safety and efficacy data of that NDA.

26. When a brand-name drug is covered by one or more patents, a company that intends to market a generic version of that drug prior to expiration of the patents must make a "paragraph IV certification" in its ANDA or 505(b)(2) application, certifying that the patents are invalid, unenforceable, or will not be infringed by the generic drug.

27. If a company makes a paragraph IV certification, it must notify the patent holder of the filing of its ANDA or 505(b)(2) application. If the patent holder initiates a patent infringement suit against the company within 45 days of receiving such notice, the FDA may not grant final approval of the ANDA or 505(b)(2) application until the earliest of (1) patent expiry, (2) district court resolution of the patent litigation in favor of the generic company, or (3) the expiration of an automatic 30-month waiting period.

28. Authorized generic drugs are pharmaceutical products marketed as generic drugs but approved as brand-name drugs under an NDA. An authorized generic drug is manufactured to the brand's specifications.

B. Consumers benefit from generic drugs.

29. The FDA evaluates the substitutability, or therapeutic equivalence, of generic drug products by comparing important profiles of the generic with those of brand-name drugs. Therapeutically equivalent products can be substituted for a brand-name drug with the

expectation that they will produce the same clinical effect and safety profile as the brand-name drug. The FDA considers a generic drug to be therapeutically equivalent to a brand-name drug and assigns it an "AB" therapeutic equivalence rating if it (1) contains the same active ingredient(s), dosage form, route of administration, and strength of the brand-name drug and (2) the application for the product contains sufficient scientific evidence to establish bioequivalence of the product to the brand-name drug.

30. Upon their market entry, AB-rated generic drugs are typically priced significantly lower than the brand-name drug. As more AB-rated generic drugs enter the market, generic prices generally fall even further. Because of these price advantages, state laws facilitate substitution of AB-rated generic drugs for higher-priced brand-name drugs.

31. Many third-party payers of prescription drugs (e.g., health insurance plans, Medicaid programs) have adopted policies to encourage the substitution of AB-rated generic drugs for their brand-name counterparts. As a result of these policies and lower prices, many purchasers routinely switch from a brand-name drug to an AB-rated generic drug upon its introduction. Consequently, AB-rated generic drugs typically capture a significant share of sales, causing a significant reduction of the brand drug's unit and dollar sales.

32. Although most AB-rated drugs are ANDA products, the FDA has assigned AB ratings to some 505(b)(2) products, including the Perrigo product at issue in this case.

33. If the FDA assigns a drug product a "BX" therapeutic equivalence rating, the FDA does not consider it therapeutically equivalent to a brand-name drug, often because the drug application lacks sufficient evidence of bioequivalence to the brand-name drug.

34. Drug products with a BX rating can provide meaningful savings for consumers. Here, both AbbVie and Teva projected that 505(b)(2) testosterone gel products with a BX rating

would be priced significantly lower than brand-name AndroGel and capture significant market share, and AbbVie projected that it would reduce the price of brand-name AndroGel to compete with a BX-rated product.

35. Competition from generic drugs generates large savings for consumers. According to a 2010 Congressional Budget Office report, the retail price of a generic is 75 percent lower, on average, than the retail price of a brand-name drug. The Generic Pharmaceutical Association reported that use of generic versions of brand-name drugs saved the U.S. healthcare system $217 billion in 2012 alone.

C. AndroGel is a highly successful, highly profitable brand-name drug.

36. AbbVie markets a brand-name prescription drug called AndroGel, a pharmaceutical gel containing synthetic testosterone. AndroGel is indicated for testosterone replacement therapy in males for conditions associated with a deficiency or absence of testosterone. Low testosterone is often associated with advancing age, certain cancers, diabetes, and HIV/AIDS, among other conditions, and can result in fatigue, muscle loss, and erectile dysfunction.

37. In August 1995, Unimed licensed the U.S. rights to the testosterone gel formulation used for AndroGel from the corporate parent of Besins, which had developed the formulation. At the same time, Besins agreed to provide commercial supply of AndroGel to Unimed after the FDA approved the product for sale.

38. Unimed filed NDA No. 21-015 for AndroGel in April 1999, which the FDA approved in February 2000. Unimed launched AndroGel 1.0% in the U.S. in June 2000.

39. Solvay Pharmaceuticals, Inc. ("Solvay") acquired Unimed in 1999, and Abbott acquired Solvay in February 2010. Abbott separated into two independent companies, Abbott

and AbbVie Inc., on January 1, 2013. Abbott transferred AndroGel to AbbVie's portfolio of products as part of this corporate reorganization.

40. In April 2011, AbbVie Defendants launched a reformulated product, AndroGel 1.62%. Since the launch of AndroGel 1.62%, AbbVie Defendants have shifted their promotional efforts to the reformulated version of the drug. As of March 2013, approximately two-thirds of all AndroGel prescriptions had correspondingly shifted from AndroGel 1% to AndroGel 1.62%.

41. AndroGel sales have grown substantially over time. In 2000, annual U.S. AndroGel sales were approximately $26 million. In both 2012 and 2013, annual U.S. AndroGel sales (including both AndroGel 1% and AndroGel 1.62%) exceeded $1 billion.

42. Cumulative U.S. sales of AndroGel (including both AndroGel 1% and AndroGel 1.62%) are substantially greater than AbbVie Defendants' and Besins's costs of developing AndroGel.

43. AbbVie sells AndroGel at prices far above AbbVie's cost of obtaining the product, making AndroGel highly profitable. Even accounting for other direct expenses AbbVie allocates to selling and marketing AndroGel, AbbVie's profit margin on AndroGel net sales is substantial.

V. The Narrow '894 Patent

44. Testosterone, the active ingredient contained in AndroGel, is unpatented. Patents covering the synthesis of artificial testosterone expired decades ago. Testosterone was first artificially synthesized in 1935 and has been available in various drug products since the 1950s. Pharmaceutical gel products have also been available for decades.

45. In August 2000, five years after Unimed licensed AndroGel from Besins, employees from Unimed and Besins filed the application that ultimately led to the issuance of the '894 Patent on January 7, 2003. The '894 Patent does not claim testosterone itself or methods

of using testosterone generally, but rather covers the use of particular pharmaceutical gel formulations containing testosterone and other listed ingredients in certain amounts. Namely, the patent claims formulations containing specified amounts of (1) testosterone; (2) ethanol or isopropanol; (3) sodium hydroxide; (4) a gelling agent; and (5) the penetration enhancer IPM.

46. All of the claims of the '894 Patent require IPM in the compositions, formulations, or methods of use thereof.

A. Unimed and Besins initially sought to include all penetration enhancers in their patent claims.

47. Unimed and Besins had to significantly narrow their patent claims over the course of the '894 Patent prosecution, including their claims as to the scope of penetration enhancers in the formulation, in order to convince the PTO to issue the patent.

48. In the written description of their invention filed with their original patent application, Unimed and Besins identified "non-limiting examples" of penetration enhancers that could be used in a testosterone gel, including "C8-C22 fatty acids such as isostearic acid, octanoic acid, and oleic acid [and] lower alkyl esters of C8-C22 fatty acids such as ethyl oleate [and] isopropyl myristate."

49. In their original patent application, Unimed and Besins sought to include all of these penetration enhancers—and more—in the scope of their patent claims. In their broadest form, Unimed and Besins's claims attempted to cover a formulation containing "a penetration enhancer," along with other ingredients.

50. In June 2001, the patent examiner rejected the composition claims in Unimed and Besins's original patent application as obvious over prior art. The examiner stated that prior publications disclosed both the use of testosterone in pharmaceutical products delivered through the skin and the use of various penetration enhancers in pharmaceutical compositions. In

particular, the examiner cited international patent applications filed by Mak et al. (WO 99/24041) and Allen et al. (WO 96/27372). These publications disclosed the use of specific penetration enhancers, including IPM (the penetration enhancer contained in AndroGel), IPP (the penetration enhancer contained in Teva's product), and oleic acid, among others.

B. Unimed and Besins next attempted to include a group of 24 penetration enhancers in their patent claims.

51. In response to the patent examiner's rejection and to secure allowance of the patent, Unimed and Besins amended their claims on October 19, 2001. The amendment narrowed the broadest claims to a testosterone gel formulation containing at least one penetration enhancer selected from a group of 24 specifically listed compounds, which included IPM (the penetration enhancer contained in AndroGel) and ISA (the penetration enhancer contained in Perrigo's product) but not IPP (the penetration enhancer contained in Teva's product).

52. To avoid an obviousness rejection, Unimed and Besins argued that their narrowed claims were patentable because the prior art recognized differences between penetration enhancers and the claimed penetration enhancers were not substitutable with the penetration enhancers disclosed in the prior art.

53. In their arguments and in a declaration from a company executive, Unimed and Besins also pointed to data showing that the AndroGel formulation unexpectedly displayed a "smooth pharmacokinetic profile" and asserted that this profile had led to AndroGel's commercial success. Unimed and Besins did not file data showing that unexpected results would be displayed by a testosterone gel formulation containing a penetration enhancer other than IPM.

54. During a December 6, 2001 interview with the patent examiner, Unimed and Besins discussed the pending claims and the October 19, 2001 amendment. The examiner told Unimed and Besins that two of the 60 pending claims were patentable over prior art. These two

claims recited a formulation with only one penetration enhancer, IPM, in specified amounts. Unimed and Besins argued during the interview that another pending claim, listing both IPM and the penetration enhancer lauryl alcohol, was novel and nonobvious, but the examiner did not accept this argument.

C. Unimed and Besins finally obtain a patent by limiting their claims to a single penetration enhancer, IPM.

55. In response to the patent examiner's rejection and to secure allowance of the patent, Unimed and Besins filed a supplemental amendment on December 21, 2001. The supplemental amendment canceled the prior claims to a testosterone gel formulation containing one of 24 specifically identified penetration enhancers and narrowed the scope of the claimed penetration enhancer to IPM only, the penetration enhancer contained in AndroGel. By disclaiming other penetration enhancers, Unimed and Besins avoided prior art, including Mak et al., cited by the patent examiner of record.

56. By choosing to claim IPM specifically, Unimed and Besins dedicated to the public the rest of the penetration enhancers they disclosed but did not claim, including "C8-C22 fatty acids such as isostearic acid," the penetration enhancer in Perrigo's product, and "esters of C8-C22 fatty acids" such as IPP, the penetration enhancer in Teva's product.

57. The PTO issued a Notice of Allowability for the '894 Patent on August 13, 2002. In describing the reasons for allowance, the patent examiner noted that Unimed and Besins's amendments, including the October 19, 2001 amendment (canceling claims listing "a penetration enhancer") and the December 21, 2001 amendment (canceling claims listing penetration enhancers other than IPM), "all together have been considered and are sufficient to remove the prior art rejection." The examiner further stated that "the prior art does not teach or fairly suggest the instant claimed pharmaceutical composition consisting essentially of the specific ingredients

herein in the particular amounts."

58. The PTO issued the '894 Patent to Unimed and Besins as co-assignees on January 7, 2003. IPM is the only penetration enhancer included in the claims of the '894 Patent.

59. The '894 Patent is listed in the *Approved Drug Products With Therapeutic Equivalence Evaluations* (published by the FDA and commonly known as the "Orange Book") as covering AndroGel. The patent is scheduled to expire in August 2020.

60. Unimed and Besins are the owners of all rights, title, and interest in the '894 Patent.

VI. Perrigo's and Teva's Products

61. After the '894 Patent issued, both Perrigo and Teva, along with its development partner BioSante Pharmaceuticals, developed testosterone gel products that would not infringe that patent.

62. Perrigo developed a testosterone gel formulation containing ISA, a penetration enhancer not claimed in the '894 Patent.

63. Teva and BioSante developed a testosterone gel formulation containing IPP, a penetration enhancer not claimed in the '894 Patent.

A. In 2009, Solvay and Besins decided not to file an infringement suit against Perrigo.

64. In December 2008, the FDA accepted Perrigo's filing of an ANDA seeking approval of a generic version of AndroGel. In connection with this filing, Perrigo sent AbbVie's corporate predecessor Solvay, Unimed, and Besins a paragraph IV certification letter explaining that Perrigo's product did not infringe the '894 Patent because it did not contain IPM, the penetration enhancer claimed in the patent. Perrigo also allowed Solvay, Unimed, and Besins confidential access to portions of Perrigo's ANDA filing that disclosed that Perrigo's product

contained ISA, not IPM.

65. In response to Perrigo's paragraph IV letter, Solvay, Unimed, and Besins retained patent counsel to review potential bases for a patent infringement lawsuit against Perrigo.

66. Following patent counsel's review, Solvay, Unimed, and Besins decided not to file a patent infringement suit against Perrigo. In a July 2009 press release announcing the decision not to sue, Solvay noted that, unlike earlier generic AndroGel products, Perrigo's product "contains a different formulation than the formulation protected by the AndroGel patent" and stated that "[t]his distinction played a role in the company's decision not to file patent infringement litigation at this time."

67. Solvay prepared an internal document to coordinate the communication strategy regarding its decision not to sue Perrigo. This document included prepared responses to various potential questions, including:

> **Why didn't the company initiate a patent infringement suit against Perrigo?**
> We conducted a thorough analysis based upon the contents of the Paragraph IV certification and the information available to us, [*sic*] determined there was not a sufficient basis for filing patent infringement litigation at this time.
>
> **Why not commence patent litigation to trigger the 30-month stay of approval?**
> Solvay Pharmaceuticals takes it [*sic*] obligations under U.S. law very seriously. These obligations include certain pleading requirements that must be satisfied prior to initiating any litigation, including patent infringement litigation.

B. Abbott filed a citizen petition with the FDA, causing Perrigo and Teva to seek approval of their products through NDA filings.

68. Without a 30-month stay of FDA approval in place to forestall Perrigo's market entry, AbbVie Defendants explored other avenues to prevent or limit generic competition. For example, Abbott created a "Cross Functional Team to explore clinical arguments that the use of Isosteric [*sic*] Acid as a penetration enhancer may present safety issues different and distinct than

those associated with a penetration enhancer containing Isopropyl Myristate." One of AbbVie Defendants' goals was to persuade the FDA that it should not approve Perrigo's ANDA.

69. On April 9, 2010, Abbott submitted a citizen petition to the FDA related to Perrigo's ANDA. Abbott asked the FDA to require Perrigo, or any other firm seeking approval for a generic AndroGel product utilizing a penetration enhancer other than IPM, to conduct additional safety studies and file an NDA rather than an ANDA. According to Abbott, generic versions of topical drugs containing different inactive ingredients than the brand-name drug pose "unique scientific challenges" and the FDA could not approve "any pending ANDA for a product containing a different penetration enhancer than AndroGel."

70. The FDA largely granted Abbott's petition on October 4, 2010, stating that specified safety studies would be required for "[testosterone gel] products with penetration enhancers that differ from those used in the [brand-name drug]." The practical effect of this ruling was that Perrigo (and later Teva) had to submit an NDA instead of an ANDA and re-certify that its product did not infringe the '894 Patent.

71. Teva and Perrigo performed the required safety studies and submitted NDAs to the FDA in January 2011 and July 2011, respectively. The testosterone gel products that were the subject of these NDAs contained penetration enhancers other than IPM, the penetration enhancer claimed in the '894 Patent. The formulation for Perrigo's NDA product was almost identical to the formulation for Perrigo's ANDA product—both included ISA as a penetration enhancer.

C. AbbVie Defendants and Besins repeatedly claimed that different penetration enhancers are not equivalent.

72. In multiple venues between 2003 and at least December 2013, AbbVie Defendants and Besins have emphasized the differences between different penetration enhancers contained in testosterone gel formulations.

73. In 2003, Unimed and Besins sued Watson Pharmaceuticals and Paddock Laboratories for infringement of the '894 Patent in the U.S. District Court for the District of Northern Georgia after Watson and Paddock filed ANDAs for generic versions of AndroGel containing paragraph IV certifications. Over the course of that litigation, Watson and Paddock asserted that the pharmaceutical formulation claimed in the '894 Patent was an obvious variant of formulations disclosed in the prior art.

74. Unimed and Besins disputed these claims, emphasizing that it was not obvious, but rather inventive, to identify the particular combination of ingredients claimed in the patent from the many potential combinations of ingredients in the prior art, including many different penetration enhancers. For example, an expert report Unimed and Besins submitted to the district court in the litigation against Watson and Paddock identified the "significant and unpredictable variation associated with the use of different penetration enhancers." The same expert later submitted another report similarly emphasizing that "there are significant differences between each individual drug, each penetration enhancer and the amounts of each ingredient that one could employ."

75. Unimed and Besins also highlighted differences between penetration enhancers before the PTO. Since at least 2009, Unimed and Besins have made renewed attempts to obtain a patent covering a testosterone gel formulation including ISA, the penetration enhancer contained in Perrigo's generic AndroGel product.

76. During prosecution of these patent applications, Unimed and Besins have argued to the PTO that IPM (the penetration enhancer claimed in the '894 Patent) and ISA (the penetration enhancer in Perrigo's product) are not equivalent or substitutable as penetration enhancers. For example, Unimed and Besins asserted to the PTO that:

- "[T]estosterone gel products with different penetration enhancers cannot be demonstrated as substantially equivalent;"
- "[I]t is not routine practice to substitute one penetration enhancer for another . . . . [S]uch substitution is not mere optimization [but] requires careful consideration of the type and amount of penetration enhancer since penetration enhancers can irritate the skin;"
- "[A] skilled artisan would not consider the penetration enhancers as simple substitutions. Rather, a skilled artisan would understand that different penetration enhancers vary in the amount and rate of absorption, as well as, the degree of skin irritation and sensitization and pharmacokinetics;" and
- "[ISA] is not equivalent to and substitutable for [IPM]".

77. AbbVie Defendants also stressed to the FDA the importance of differences among alternative penetration enhancers contained in testosterone gels. In its April 2010 citizen petition, Abbott asked the FDA to require safety studies for Perrigo's product and similar products because of the differences in penetration enhancers. On August 18, 2011, Abbott filed a second citizen petition arguing that FDA could not grant an "A" therapeutic equivalence rating to any generic AndroGel product containing a different penetration enhancer, meaning the generic product would not be automatically substitutable for AndroGel. In a supplement to that petition filed on December 11, 2013, AbbVie asserted that "[f]or topical testosterone products, changes in inactive ingredients such as penetration enhancers are material differences."

VII. Exclusionary Conduct Through Sham Litigations

78. AbbVie Defendants and Besins maintained their market and monopoly power in the United States with respect to AndroGel by filing sham lawsuits against potential competitors Teva and Perrigo.

A. AbbVie Defendants and Besins sued Teva even though Teva's product does not contain IPM.

79. On March 16, 2011, Teva sent AbbVie Defendants and Besins a notice letter stating that Teva had submitted NDA No. 202763 to the FDA for a testosterone gel product. The letter also stated that Teva's application contained a paragraph IV certification that Teva's product did not infringe the '894 Patent. In addition, Teva provided AbbVie Defendants and Besins with an Offer of Confidential Access to Application that allowed them to review Teva's application to confirm that Teva's proposed product did not contain IPM.

80. AbbVie Defendants and Besins, or their representatives, received confidential access to parts of Teva's NDA. As a result, AbbVie Defendants and Besins, or their representatives, learned that the penetration enhancer in Teva's product was not IPM, but rather a different penetration enhancer, IPP.

81. On April 29, 2011, AbbVie Defendants and Besins filed a patent infringement lawsuit against Teva in the U.S. District Court for the District of Delaware (*Abbott Products, Inc. v. Teva Pharmaceuticals*, No. 1:11-cv-00384-HB). The filing of the lawsuit automatically triggered a 30-month stay of FDA approval of Teva's testosterone gel product.

82. AbbVie Defendants and Besins have admitted that Teva's product does not literally infringe the '894 Patent because the product does not contain IPM, the penetration enhancer claimed in the patent. Rather, AbbVie Defendants and Besins asserted that Teva's product infringes the patent under the doctrine of equivalents because Teva's penetration enhancer IPP is equivalent to, and insubstantially different from, IPM.

83. In response to AbbVie Defendants and Besins's complaint, Teva filed antitrust counterclaims. In its counterclaims, Teva asserted that the infringement claims were baseless and a sham because during prosecution of the '894 Patent, Unimed and Besins had surrendered

patent claims that would have covered a testosterone gel containing IPP. According to Teva, AbbVie Defendants and Besins were therefore plainly precluded under the doctrine of prosecution history estoppel from asserting infringement under the doctrine of equivalents. Since 2006, Teva has been a defendant in scores of patent lawsuits but has rarely advanced allegations of sham or baseless patent infringement.

84. On August 1, 2011, Teva filed a motion for summary judgment on the issue of prosecution history estoppel. On October 25, 2011, the district court denied that motion as moot because it had scheduled a trial limited to the estoppel issue. The trial was scheduled to begin May 21, 2012, just 13 months after AbbVie Defendants and Besins filed their complaint.

85. The FDA granted final approval to Teva's product on February 14, 2012, and assigned a BX rating to Teva's product on July 23, 2014.

B. AbbVie and Besins sued Perrigo even though Perrigo's product does not contain IPM.

86. On September 20, 2011, Perrigo sent AbbVie Defendants and Besins a notice letter stating that Perrigo had submitted NDA No. 203098 to the FDA for a testosterone gel product. The letter also stated that Perrigo's application contained a paragraph IV certification that Perrigo's product did not infringe the '894 Patent because it did not contain IPM. In its letter, Perrigo made clear its view that any patent infringement suit against Perrigo would be "objectively baseless and a sham," particularly in light of Solvay and Besins's prior decision not to sue Perrigo due to the differences between Perrigo's formulation and the patented formulation. In addition, Perrigo provided AbbVie Defendants and Besins with an Offer of Confidential Access to Application that allowed them to review Perrigo's application to confirm that Perrigo's proposed product did not contain IPM.

87. AbbVie Defendants and Besins, or their representatives, received confidential

access to parts of Perrigo's NDA. As a result, AbbVie Defendants and Besins, or their representatives, learned that—as in Perrigo's earlier generic AndroGel ANDA product—the penetration enhancer in Perrigo's NDA product was not IPM, but rather a different penetration enhancer, ISA.

88. On October 31, 2011, AbbVie Defendants and Besins filed a patent infringement lawsuit against Perrigo in the U.S. District Court for the District of New Jersey (*Abbott Products, Inc. v. Perrigo Company*, No. 3:11-cv-06357-FLW-LHG). The filing of the lawsuit automatically triggered a 30-month stay of FDA approval of Perrigo's product.

89. AbbVie and Besins have admitted that Perrigo's product does not literally infringe the '894 Patent because the product does not contain IPM, the penetration enhancer claimed in the '894 Patent. Rather, AbbVie and Besins assert that Perrigo's product infringes the patent under the doctrine of equivalents because Perrigo's penetration enhancer ISA is equivalent to, and insubstantially different from, IPM.

90. The FDA granted approval to Perrigo's product on January 31, 2013. The FDA assigned an AB rating to Perrigo's product on July 23, 2014, after Perrigo had filed a lawsuit against the FDA in the U.S. District Court for the District of Columbia on March 21, 2014, for failing to make a timely decision on the therapeutic equivalence rating for Perrigo's product. Absent AbbVie Defendants and Besins's exclusionary conduct, the therapeutic equivalence rating for Perrigo's product would have been determined prior to July 2014.

C. AbbVie Defendants and Besins's lawsuits were sham.

91. AbbVie Defendants and Besins's lawsuits against Teva and Perrigo were objectively baseless. Teva's and Perrigo's products are well outside the scope of the '894 Patent under any theory of infringement.

92. Neither Teva's nor Perrigo's product literally infringes the '894 Patent. Each independent claim of the patent covers only a testosterone gel formulation that contains IPM. Neither Teva's product nor Perrigo's product contains IPM. AbbVie Defendants have admitted that Teva's and Perrigo's products do not literally infringe the '894 Patent.

93. Neither Teva's nor Perrigo's product infringes the '894 Patent under the doctrine of equivalents. AbbVie Defendants and Besins assert that the penetration enhancers used in Teva's and Perrigo's products (IPP and ISA, respectively) are equivalent to and insubstantially different from IPM; however, the doctrine of prosecution history estoppel prohibits them from making this claim. During prosecution of the '894 Patent, Unimed and Besins narrowed their claims from a testosterone gel formulation containing a penetration enhancer selected from a group of compounds—which included Teva's and Perrigo's penetration enhancers—to a formulation containing only one particular penetration enhancer, IPM. This narrowing of claims was necessary for Unimed and Besins to distinguish their claimed formulation from prior art and to obtain a patent.

94. Both Teva's and Perrigo's penetration enhancers were plainly foreseeable at the time Unimed and Besins amended their claims during prosecution of the '894 Patent application. Teva's penetration enhancer was specifically identified in the prior art cited by the patent examiner in the June 2001 office action rejecting all pending claims under consideration, included in a small group of compounds described in the '894 Patent specification, and included in the scope of the patent claims contained in Unimed and Besins's original patent application. Perrigo's penetration enhancer was known in the prior art, specifically listed in the '894 Patent specifications, and specifically listed as one of 24 compounds recited in the October 19, 2001 amendment to Unimed and Besins's patent claims.

95. The amendments narrowing Unimed and Besins's patent claims from a group of penetration enhancers to the single penetration enhancer IPM were not tangential to the alleged equivalents. The patent prosecution history clearly indicates that the patent examiner viewed the claims as obvious over the prior art, which disclosed both the use of various penetration enhancers in pharmaceutical products and delivery of testosterone through the skin. As a result of the patent examiner's review of the prior art, Unimed and Besins were forced to limit their patent claims to the AndroGel formulation, including the penetration enhancer IPM only, the formulation for which they argued and provided evidence of unexpected results and commercial success.

96. Given that IPP (the penetration enhancer in Teva's product) and ISA (the penetration enhancer in Perrigo's product) were known as available technologies at the time Unimed and Besins filed for a patent, Unimed and Besins had an obligation to claim the technologies if they wanted to later assert exclusive rights to their use in a testosterone gel. Where a patent applicant discloses but does not claim known technology, the technology is dedicated to the public.

97. No reasonable litigant, having had access to the confidential information Teva and Perrigo provided AbbVie Defendants and Besins, could reasonably have expected to prevail on the merits of a claim that either Teva's product or Perrigo's product infringes the '894 Patent. AbbVie Defendants and Besins thus had no probable cause for initiating the lawsuits.

98. AbbVie Defendants and Besins commenced the lawsuits against Teva and Perrigo with the subjective and wrongful intent to interfere directly with the business relationships of Teva and Perrigo. AbbVie Defendants and Besins filed the lawsuits not to obtain a favorable outcome on the merits of the claims asserted but to achieve an anticompetitive objective and

maintain their monopoly position through the improper use of judicial process.

99. AbbVie Defendants and Besins knew when they filed the lawsuits that the mere filing of the complaints would trigger automatic 30-month stays of FDA approval of Teva's and Perrigo's drug applications and that AbbVie Defendants and Besins would get the benefit of the stays despite the lack of any reasonable basis for asserting that Teva's or Perrigo's products infringe the '894 Patent. Even with no realistic chance of winning the lawsuits, the 30-month stays were of tremendous value to AbbVie Defendants and Besins because they blocked entry of Teva's and Perrigo's products and gave AbbVie Defendants and Besins time to shift sales away from AndroGel 1% to AndroGel 1.62%, the reformulated product AbbVie Defendants had developed.

100. AbbVie Defendants and Besins are not entitled to *Noerr-Pennington* immunity in connection with their filing and maintenance of these sham lawsuits.

VIII. Exclusionary Conduct and Restraint of Trade Through An Anticompetitive Agreement

101. AbbVie Defendants maintained their market and monopoly power in the United States with respect to AndroGel by entering an anticompetitive agreement with Teva that ensured that entry of lower-priced substitutes for AndroGel would not occur until at least [redacted].

102. AbbVie Defendants' patent lawsuit against Teva was a sham. In the agreement resolving this lawsuit, Teva agreed not to market a competing version of AndroGel until [redacted].

103. This agreement not to compete is not ancillary to a legitimate efficiency-enhancing venture.

104. Teva was willing to agree not to compete until [redacted] because AbbVie

Defendants compensated Teva. This payment was large and unjustified.

105. This anticompetitive agreement harmed competition and consumers by preventing entry of lower-priced substitutes for AndroGel until at least [redacted].

A. The sham lawsuits did not eliminate the threat of Teva's and Perrigo's products to AbbVie Defendants and Besins's monopoly.

106. Because Teva's and Perrigo's testosterone gel products were filed with the FDA via 505(b)(2) applications rather than ANDAs, the FDA was obligated under the Prescription Drug User Fee Act ("PDUFA") to process the applications within a set period of time. In Teva's case, the original date for completion of FDA review was November 14, 2011.

107. Though the FDA was prevented from issuing final approval to Teva's or Perrigo's products due to the 30-month stays triggered by AbbVie Defendants and Besins's sham patent lawsuits, the stay would end upon a victory by the generic firm in the district court. In Teva's case, due to the quick trial schedule set by the district court, Teva was likely to receive final FDA approval in 2012.

108. Because of this dynamic, AbbVie Defendants recognized the threat from Teva's challenge to its monopoly. An internal Abbott scenario planning document prepared in September 2011 modeled entry of Teva's 505(b)(2) product in 2012. Similarly, an October 2011 internal Abbott document stated: "[t]he most likely scenario is an A-rated generic launch sometime near April 2012."

109. Teva also projected entry in the near-to-medium term. An internal Teva forecast from November 2011 projected that Teva would launch its 505(b)(2) product in June 2012. Other Teva forecasts projected somewhat later entry, though none later than October 2013—seven years before expiration of the '894 Patent.

110. A third-party research firm specializing in analysis of pharmaceutical patent

litigation, IPD Analytics, predicted in November 2011 that Teva "likely would have an opportunity to launch" its testosterone gel product in the third quarter of 2012. This prediction was based on the view that "Abbott likely will not be allowed to assert the doctrine of equivalents, and thus will lose on the issue of infringement."

111. With AbbVie Defendants and Besins set to lose the benefit of the 30-month stays their sham lawsuits had triggered, they turned to other ways to preserve their monopoly.

B. AbbVie Defendants paid Teva in the form of the TriCor authorized generic deal to drop its patent challenge and refrain from competing until [redacted].

112. Soon after the district court scheduled a May 2012 trial in their patent infringement case against Teva, AbbVie Defendants approached Teva to discuss a potential settlement. AbbVie Defendants' goal was to secure a generic entry date that would allow AbbVie Defendants time to shift sales to its reformulated product, AndroGel 1.62%.

113. In light of its view that the patent infringement suit was a sham, Teva was not willing to settle for AbbVie Defendants' preferred entry date absent significant compensation. Teva therefore asked AbbVie Defendants whether it would be willing to offer Teva supply of an authorized generic version of TriCor, a cholesterol drug with annual U.S. sales exceeding $1 billion in 2011.

114. A generic version of TriCor had been a significant part of Teva's product pipeline, but as of late 2011, the project was in trouble. Teva had filed ANDAs with the FDA seeking to market generic versions of 145 mg and 48 mg TriCor tablets. Teva was the first generic challenger on the 145 mg strength and therefore potentially entitled to 180 days of generic marketing exclusivity under the Hatch-Waxman Act. In 2009, Teva had secured a license under a patent settlement with Abbott to launch its 145 mg product on July 1, 2012, 180 days before any other generic competitor (including any authorized generic). But over four years after

filing its ANDA, Teva had no viable way of obtaining FDA approval before other competitors were set to launch and had therefore forfeited its 180-day exclusivity rights under applicable Hatch-Waxman provisions. Unless it could secure supply from Abbott, Teva was poised to lose a valuable first-filer opportunity.

115. Abbott had no incentive to increase the likelihood that it would face generic competition from Teva on another of its blockbuster products. If Teva was not able to enter with its own generic TriCor product, then Abbott would not face generic competition to TriCor until January 1, 2013. Abbott was willing, however, to supply Teva with authorized generic product slightly before January 1, 2013, but only if Teva would agree to drop its patent challenge and refrain from competing with its testosterone gel product until [redacted]. Teva agreed.

116. On December 20, 2011, AbbVie Defendants, Besins, and Teva entered written agreements to settle their AndroGel patent litigation. Under the settlement, Teva agreed to refrain from marketing its 505(b)(2) testosterone gel product until [redacted].

117. Abbott simultaneously agreed to grant Teva an option to obtain supply of an authorized generic version of TriCor [redacted] beginning November 10, 2012. If Teva exercised the option, Teva would pay Abbott [redacted]. The November 10, 2012 launch date was not contingent on the launch of any other generic TriCor product or on Teva's ability to obtain FDA approval for its own generic TriCor ANDA.

118. When it learned that Teva had agreed to dismiss the "sham infringement lawsuit," Teva's development partner BioSante Pharmaceuticals directly questioned whether Teva received compensation other than a "worthless" patent license in exchange for delaying the

launch of its testosterone gel product:

> BioSante finds it incomprehensible that Teva would purport to agree to delay the launch of our FDA-approved 1% testosterone gel product (the "Product") until [redacted] in exchange for Abbott's dismissal of a sham infringement lawsuit and a license to a worthless patent that does not even read on the Product and likely is invalid. The terms of the Settlement Agreement are so unreasonable for this industry that BioSante questions whether they in fact express the true consideration for Teva's delayed launch.

BioSante did not know that Teva had been separately compensated via the TriCor authorized generic deal. BioSante eventually dropped its complaints after Teva agreed to pay it over $2 million.

C. The TriCor authorized generic deal was a large payment to Teva.

119. The compensation Abbott agreed to provide Teva via the TriCor authorized generic deal operated as a large payment to Teva. The payment was designed to, and did, induce Teva to settle the AndroGel patent litigation and agree to refrain from marketing its testosterone gel product until [redacted]. Teva's decision to settle was driven not by the strength of AbbVie Defendants and Besins's patent claims, but by the large payment Abbott made to Teva via the TriCor authorized generic deal.

120. Abbott's payment took the form of product supply that was not otherwise available to Teva. This supply was extremely valuable to Teva. At the time of its agreement with Abbott, Teva forecasted that its net sales of authorized generic TriCor under the deal would be nearly $175 million over a four-year period. Teva's actual generic TriCor sales have far exceeded this forecast, making the authorized generic deal worth hundreds of millions of dollars to Teva. These revenues would not have been available to Teva but for its agreement not to launch its testosterone gel product until [redacted].

121. The TriCor authorized generic deal was particularly valuable to Teva because it allowed Teva to launch generic TriCor before any other generic firm, enabling Teva to secure a

valuable first mover advantage. As Teva itself has explained, the first generic entrant for a particular brand-name product typically retains "a larger portion of the generic market than other providers of generic equivalents even after the entry of those other providers to the market." Before its problems with the FDA on its own generic TriCor product, Teva had expected to secure this first mover advantage, and as of the fall of 2011, the investment community continued to view generic TriCor as an important part of Teva's portfolio. Through its deal with Abbott, Teva was able to secure generic TriCor revenues in 2012 and its first mover advantage.

122. The value of the compensation from Abbott to Teva in the TriCor authorized generic deal far exceeds either Teva's, Besins's or AbbVie Defendants' actual or saved litigation costs from settlement of the AndroGel patent litigation.

123. The value of the compensation from Abbott to Teva in the TriCor authorized generic deal exceeds what Teva had projected it was likely to earn had it won the AndroGel patent litigation and marketed its testosterone gel product.

124. The TriCor authorized generic deal was something Teva could not have obtained had it won the AndroGel patent infringement litigation. Even if Teva had prevailed in the AndroGel litigation, it would not have secured a right to sell an authorized generic version of TriCor.

D. The TriCor authorized generic deal is unjustified.

125. While a sweetheart deal for Teva, the TriCor authorized deal cannot be explained as an independent business deal from Abbott's perspective. Instead, the TriCor authorized generic deal made sense for Abbott only as a means to induce Teva to drop its patent challenge and refrain from competing with AndroGel until [redacted].

126. Though authorized generic deals are common in the pharmaceutical industry, it is highly unusual for an authorized generic product to launch significantly before independent

generic entry is expected, other than as consideration in connection with a patent settlement. The reason is a matter of common sense and simple economics: brand-name drug companies who supply the authorized generics have no incentive to compete with themselves and erode their monopoly profits. Authorized generic deals therefore virtually always provide that the product's launch is contingent upon the launch of an independent generic. There is no such contingency in the TriCor authorized generic deal, nor is Teva's launch contingent on Teva's ability to obtain FDA approval for its TriCor ANDA.

127. Through the TriCor authorized generic deal, Abbott facilitated generic entry on one of its blockbuster drugs in November 2012, a month and a half earlier than generic entry was otherwise likely to occur. At the time the deal was entered, Abbott had entered patent settlements with other generic TriCor ANDA filers that prohibited them from marketing generic versions of 145 mg TriCor before January 1, 2013, or from partnering with Teva to do so. Given Teva's failure to secure FDA approval of its own 145 mg generic TriCor ANDA—a fact that was publically known—generic TriCor 145 mg entry could not have occurred until January 1, 2013, absent the TriCor authorized generic deal.

128. The TriCor authorized generic deal also allowed Teva to launch a 48 mg generic TriCor product on November 10, 2012. Under the terms of Abbott's prior patent settlement agreements with Teva and other ANDA filers for a 48 mg generic TriCor product, no 48 mg generic TriCor product, including Teva's product, even if approved, could have otherwise entered the market before January 1, 2013.

129. As a result of the TriCor authorized generic deal, Teva launched authorized generic versions of 145 mg and 48 mg TriCor on or about November 16, 2012. Teva's launch triggered provisions in Abbott's agreements with other generic TriCor ANDA filers allowing

them to launch their own generic TriCor products.

130. The royalty terms in the TriCor authorized generic deal are significantly worse for Abbott than the royalty terms in a typical stand-alone authorized generic agreement. In a typical authorized generic deal, the brand-name firm retains a large majority of the profits generated by the product. For example, just weeks after entering the TriCor deal with Teva, Abbott entered a stand-alone authorized generic deal on another drug that entitled Abbott to royalties of [redacted]. The TriCor authorized generic deal, in contrast, entitles Abbott to royalties of [redacted].

131. The TriCor supply deal lacks any convincing justifications. If Abbott sought to participate in the market for generic TriCor via an authorized generic product, it could have partnered with a company other than Teva and received a royalty [redacted] the royalty it received from Teva. With a different arrangement, Abbott could have profited from generic TriCor sales but also ensured that it did not erode more profitable brand-name TriCor sales by accelerating the entry of generic TriCor.

132. Shortly before entering the deal with Teva, Abbott projected a net loss of roughly $100 million in TriCor revenues if generic TriCor entered the market in November 2012 (as Abbott's deal with Teva provided) rather than January 2013. Abbott's modest income from the TriCor authorized generic deal did not come close to making up this significant loss of revenue. The TriCor authorized generic deal made sense to Abbott only because it achieved a significant delay in generic AndroGel entry, allowing Abbott time to shift sales to AndroGel 1.62% and earning Abbott far more than $100 million in AndroGel monopoly profits.

E. AbbVie Defendants agreement with Teva effectively blocked Perrigo's generic AndroGel entry

133. Almost immediately after filing suit against Perrigo, AbbVie Defendants approached Perrigo to discuss a potential settlement.

134. AbbVie Defendants could not pay Perrigo to delay generic AndroGel entry due to the terms of a FTC consent order Perrigo had entered in 2011. AbbVie Defendants could, however, offer Perrigo the right to launch generic AndroGel upon Teva's entry. This term was valuable to Perrigo because Teva appeared more likely than Perrigo to achieve a quick victory in the patent litigation and end the 30-month stay triggered by AbbVie Defendants and Besins's lawsuit. Teva had obtained a quick May 2012 trial date and, as reflected in Teva's sham antitrust counterclaims, seemed likely to press its position and win the case.

135. AbbVie Defendants and Besins's suit against Perrigo, in contrast, had been filed in a different judicial district and Perrigo believed that its case was unlikely to end before the suit against Teva. A settlement, therefore, provided Perrigo with an opportunity to achieve parity with Teva (that is, the same entry date) without expending any litigation costs. Without a settlement, Perrigo would have been unable to achieve parity with Teva because the 30-month stay blocking FDA approval of Perrigo's product would remain in effect.

136. On December 8, 2011, AbbVie Defendants, Besins, and Perrigo agreed to settle their patent litigation. The terms of the settlement provided that Perrigo could launch generic AndroGel upon the launch of another generic AndroGel product (including Teva's testosterone gel product) or [redacted]. Perrigo's decision to settle was driven not by the strength of AbbVie's patent claims but by the competitive position Perrigo found itself in as a result of the 30-month stay triggered by AbbVie Defendants and Besins's suit and the

opportunity to improve that position by achieving parity with Teva. But as AbbVie Defendants knew—and Perrigo did not—they were in the process of negotiating a deal with Teva that would delay Teva's entry well beyond what Perrigo expected.

137. By securing Teva's agreement to forgo entry, AbbVie Defendants blocked competition from Perrigo as well. Because of the terms of Perrigo's settlement, the Teva agreement effectively protected AbbVie Defendants and Besins against Perrigo's generic AndroGel entry until [redacted].

IX. AbbVie Defendants and Besins's Market and Monopoly Power

138. AbbVie Defendants and Besins have exercised and continue to exercise market and monopoly power in the United States with respect to AndroGel. Direct evidence of this power includes AbbVie Defendants' ability to price AndroGel substantially higher than the projected price of competing versions of AndroGel and to exclude such potential competitors by providing significant compensation to forestall entry.

139. In addition, AbbVie Defendants and Besins's market and monopoly power can be shown through circumstantial evidence, including a high share of a relevant market with substantial barriers to entry. Empirical, documentary, and other evidence demonstrate that the relevant market for antitrust purposes in this case is no broader than testosterone drugs delivered transdermally (through the skin) and approved by the FDA for sale in the United States. For example, AndroGel's marketing director testified under oath that he only considers three other transdermal testosterone products, Testim, Axiron, and Fortesta, to be competitors to AndroGel. Other testosterone drugs, such as those delivered by injection, are not close enough substitutes to prevent AbbVie Defendants and Besins and other market participants from profitably raising prices. AndroGel has consistently accounted for at least 60 percent of transdermal testosterone

drug sales. Substantial barriers to entry exist in the transdermal testosterone drug market, including the need to conduct expensive clinical trials and obtain FDA approval. Even entry of new brand-name competitors has not significantly eroded AbbVie Defendants and Besins's monopoly.

140. Narrower relevant product markets may also exist for purposes of assessing AbbVie Defendants and Besins's conduct and their market and monopoly power, including one consisting of AndroGel and its generic equivalents. A unique competitive relationship exists between brand drugs and their generic equivalents, including AndroGel and generic AndroGel. Although other testosterone drugs may be used to treat low testosterone, the availability of these drugs is not sufficient to prevent the anticompetitive effects from AbbVie Defendants and Besins's conduct. AbbVie Defendants and Besins have consistently held a 100 percent share of sales of AndroGel and its generic equivalents. Possible sellers of generic AndroGel face substantial barriers to entry, including the need to obtain FDA approval, costly specialized equipment and facilities, and AbbVie Defendants and Besins's ability to trigger an automatic 30-month stay of FDA approval by filing a patent infringement lawsuit. Moreover, AbbVie Defendants and Besins's agreements with Teva, Perrigo, and others have diminished the economic incentives to potential generic entrants of challenging the AndroGel formulation patent because the terms of the agreements may allow for immediate entry of generic AndroGel upon the launch of generic AndroGel by any generic manufacturer.

X. Harm to Competition and Consumers

141. AbbVie Defendants and Besins willfully maintained and extended their monopoly power as to AndroGel by filing sham patent infringement litigation against Teva and Perrigo. AbbVie Defendants and Besins's actions in filing sham lawsuits against Teva and Perrigo constitute wrongful and exclusionary conduct. Their conduct had the purpose and effect of

wrongfully preventing competition from lower-cost substitutes for brand-name AndroGel.

142. Absent AbbVie Defendants and Besins's exclusionary conduct through sham litigation, Teva and Perrigo would have been free to launch lower-priced substitutes for AndroGel upon receipt of FDA approval, which Teva received on February 14, 2012, and Perrigo received on January 31, 2013. Because of AbbVie Defendants and Besins's exclusionary conduct, however, Teva and Perrigo cannot launch lower-priced substitutes for AndroGel until [redacted].

143. AbbVie Defendants and Besins's exclusionary conduct has denied, and continues to deny, patients the opportunity to purchase lower-cost versions of AndroGel, forcing patients and other purchasers to pay hundreds of millions of dollars more for AndroGel.

144. The agreement among AbbVie Defendants and Teva that Teva will refrain from marketing its 505(b)(2) testosterone gel product until [redacted] has also harmed competition and consumer welfare.

145. Prior to their agreement, AbbVie Defendants and Teva were potential competitors. Through their agreement, however, AbbVie Defendants and Teva eliminated the potential that (1) Teva would have marketed its testosterone gel product following a district court victory but before a final appellate decision in the AndroGel patent litigation; (2) Teva would have prevailed through appeal in the patent litigation and marketed its testosterone gel product well before [redacted]; or (3) AbbVie Defendants and Teva would have agreed to settle their patent litigation on terms that did not compensate Teva and provided for Teva's entry earlier than [redacted]. Absent AbbVie Defendants and Teva's anticompetitive agreement, one of these events would have transpired.

146. AbbVie Defendants and Teva's agreement to eliminate potential competition until

[redacted] was not based on the strength of the '894 Patent, as AbbVie Defendants' infringement claims were a sham. Instead, Teva was willing to agree not to compete with its testosterone gel product until [redacted] because of the compensation it received from AbbVie Defendants.

147. Entry of Perrigo's and Teva's products would give consumers the choice between brand-name AndroGel and lower-priced substitutes for AndroGel. Many consumers would choose to purchase lower-priced generic drugs instead of higher-priced brand-name AndroGel. Entry of generic versions of AndroGel would quickly and significantly reduce AbbVie's sales of AndroGel, promote economic efficiency, and lead to a significant reduction in the average price purchasers pay for AndroGel and its generic equivalents. Consumers likely would save hundreds of millions of dollars by purchasing generic versions of AndroGel. By filing sham patent infringement lawsuits and entering an anticompetitive agreement, Defendants have retained those potential consumer savings for themselves.

148. Abbott projected that competition from a 505(b)(2) version of AndroGel with a BX rating would cause Abbott to lose substantial sales and cause Abbott to effectively lower its AndroGel price by offering higher rebates to purchasers. Abbott's projections showed that it stood to lose between $585 and $855 million in AndroGel profits if entry of a non-AB-rated, 505(b)(2) product occurred in 2012. Abbott's loss would have been consumers' gain in the form of lower prices.

149. In fact, the consumer harm from Defendants' conduct was much higher than Abbott's projected losses from entry of a competitor with a BX rating. The FDA assigned an AB rating to Perrigo's product, meaning that Defendants' conduct deprived consumers of a lower-priced product, which pharmacists could easily (and in many states, automatically) substitute for

AndroGel, until [redacted].

150. Defendants' conduct with respect to Teva's product, which is BX-rated to AndroGel, also harmed consumers significantly. Teva's contemporaneous forecasts projected that it would have priced a BX-rated product [redacted] of the price of brand-name AndroGel and taken substantial sales from AbbVie Defendants. As Teva asserted in its June 2011 sham litigation counterclaims, "[a]fter approval, Teva USA would sell its testosterone gel product at a substantial discount compared to the prices for branded AndroGel."

151. A significant portion of AndroGel 1% sales has shifted to AndroGel 1.62% since 2012, a shift made possible by Defendants' anticompetitive conduct. Because Teva's and Perrigo's products are not automatically substitutable for brand-name AndroGel 1.62%, consumers may realize fewer benefits from entry of Teva's and Perrigo's products in [redacted] than they would have from earlier entry.

Count I

Monopolization – Against AbbVie, Abbott, Unimed, and Besins

152. Plaintiffs re-allege and incorporate by reference the allegations in all of the paragraphs above.

153. AbbVie Defendants' and Besins's willful maintenance of their monopoly through a course of anticompetitive conduct, including filing sham patent litigation against Teva and Perrigo, constitutes an unfair method of competition in violation of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a).

Count II

Restraint of Trade – Against AbbVie, Abbott, Unimed, and Teva

154. Plaintiffs re-allege and incorporate by reference the allegations in all of the

paragraphs above.

155. The agreement among AbbVie Defendants and Teva that Teva will not compete by marketing its testosterone gel product until [redacted] constitutes an unfair method of competition in violation of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a).

Prayer for Relief

WHEREFORE, Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), empowers this Court to issue a permanent injunction against violations of the FTC Act and, in the exercise of its equitable jurisdiction, to order ancillary equitable relief to remedy the injury caused by Defendants' violations; therefore, the FTC requests that this Court, as authorized by 15 U.S.C. § 53(b), 15 U.S.C. § 26 and its own equitable powers, enter final judgment against Defendants on Counts I and II, declaring, ordering, and adjudging:

1. That AbbVie's, Abbott's, Unimed's, and Besins's course of conduct, including its filing of sham litigation against Teva and Perrigo, violates Section 5(a) of the FTC Act, 15 U.S.C. § 45(a);
2. That the agreement among AbbVie, Abbott, Unimed, and Teva violates Section 5(a) of the FTC Act, 15 U.S.C. § 45(a);
3. That defendants are permanently enjoined from engaging in similar and related conduct in the future; and
4. That the Court grant such other equitable relief as the Court finds necessary, including restitution or disgorgement, to redress and prevent recurrence of defendants' violations of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a), as alleged herein.

Dated: September 8, 2014

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Respectfully Submitted,

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