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. [redacted]

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, [redacted]

[redacted] 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.

[redacted]

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