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

Federal Trade Commission, Plaintiff, v. Watson Pharmaceuticals, Inc., a corporation; Par Pharmaceutical Companies, Inc., a corporation; Paddock Laboratories, Inc., a corporation; and Solvay Pharmaceuticals, Inc., a corporation, Defendants.	Civil Action File No. 1:09-CV-00955-TWT

Second Amended 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 Federal Trade Commission Act, 15 U.S.C. § 53(b) (2005), for a permanent injunction against defendants Watson Pharmaceuticals, Inc., Par Pharmaceutical Companies, Inc., Paddock Laboratories, Inc., and Solvay Pharmaceuticals, Inc., to undo and prevent their

unfair methods of competition in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act, 15 U.S.C. § 45(a).

I. Nature of the Case

1. This case challenges agreements by Watson, Par, and Paddock to delay until 2015 the sale of low-cost generic versions of AndroGel, a widely prescribed branded testosterone replacement drug, in exchange for substantial payments from Solvay.

2. By 2006, AndroGel had grown to be Solvay's top-selling pharmaceutical product, with U.S. sales of over $300 million. The prospect of generic competition, however, threatened Solvay's AndroGel profits. Several years earlier, Watson and Paddock (which then partnered with Par) had filed applications with the U.S. Food and Drug Administration to market generic versions of AndroGel, and by early 2006 Watson had received final approval to market its generic product. Defendants knew that if generic entry were to occur, Solvay's sales would plummet, as generic AndroGel would be priced dramatically lower than branded AndroGel. Solvay's loss, however, would be consumers' gain, as they would save hundreds of millions of dollars by purchasing lower-cost generic alternatives.

3. After Watson and Paddock had announced their plans to sell generic AndroGel, Solvay sued the generic companies for infringing the only patent Solvay had relating to AndroGel. In the ensuing litigation, each of the generic companies vigorously asserted that its product was outside the scope of Solvay's patent, that the patent was invalid, and that Solvay withheld important information from the Patent and Trademark Office in obtaining the patent. Had the patent suit proceeded, Solvay's patent was unlikely to prevent generic entry.

4. Eventually, Defendants recognized that they would each be better off by cooperating and sharing in Solvay's monopoly profits than by competing. Solvay's own financial analysis highlighted this dynamic. From this analysis, Solvay knew that it would need to pay the generic firms to agree to stay off the market until 2015, Solvay's desired generic entry date. At the same time, Solvay knew that – because eliminating price competition would preserve its monopoly profits – it could easily afford to pay the generic firms to delay their entry until 2015.

5. In the end, Watson, Par, and Paddock agreed to share in Solvay's monopoly profits, abandon their patent challenges, and refrain from launching their low-cost generic products to compete with AndroGel for nine years. Together with

Solvay, they also identified ways to transfer the money to the generic firms: via co-promotion arrangements and a back-up supply deal executed on the same day as the companies' patent settlements.

6. As a result of Defendants' agreements, Watson and Par, rather than competing against Solvay, are partnering with Solvay to promote AndroGel and share in monopoly profits – with expected payments of hundreds of millions of dollars collectively. Solvay's substantial payments to Watson, Par, and Paddock – not the strength of Solvay's patent – have prevented generic competition to AndroGel until 2015. These agreements deny consumers the opportunity to purchase lower-cost, generic versions of AndroGel, at a cost of hundreds of millions of dollars a year.

II. Jurisdiction and Venue

7. 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

8. 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.

9. 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.

10. 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.

11. 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

12. Plaintiff Federal Trade Commission 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.

13. Defendant Watson Pharmaceuticals, Inc. (together with its affiliates, "Watson") is a publicly traded, for-profit company, incorporated in Nevada and with its principal place of business located in Corona, California. Watson is engaged in the business of, among other things, developing, manufacturing, marketing, and distributing generic drug products. In the twelve months ending December 31, 2007, Watson had net revenues of approximately $2.5 billion.

14. Defendant Par Pharmaceutical Companies, Inc. (together with its affiliates, "Par") is a publicly traded, for-profit company, incorporated in Delaware and with its principal place of business located in Woodcliff Lake, New Jersey. Par is engaged in the business of, among other things, developing, manufacturing, marketing, and distributing generic drug products. In the twelve months ending December 31, 2007, Par had total revenues of approximately $770 million.

15. Defendant Paddock Laboratories, Inc. (together with its affiliates, "Paddock") is a privately held, for-profit company, incorporated in Minnesota and with its principal place of business located in Minneapolis, Minnesota. Paddock is engaged in the business of, among other things, developing, manufacturing, marketing, and distributing generic drug products.

16. Defendant Solvay Pharmaceuticals, Inc. (together with its affiliates, "Solvay") is incorporated in Georgia and has its principal place of business in Marietta, Georgia. Solvay Pharmaceuticals is a subsidiary of Solvay, S.A., a Belgian company whose shares are listed on the Euronext Brussels stock exchange and traded over-the-counter in the United States via American Depositary Receipts. Solvay includes Unimed Pharmaceuticals, Inc., Solvay's wholly owned subsidiary. Solvay is engaged in the distribution and sale of branded pharmaceutical products, including AndroGel. In the twelve months ending December 31, 2007, Solvay's U.S. net pharmaceutical revenues totaled about $1.2 billion, over $400 million of which were U.S. sales of AndroGel.

IV. Background

A. The regulatory system governing pharmaceuticals in the United States

17. The Federal Food, Drug, and Cosmetic Act, 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(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.

18. A company seeking approval from the U.S. Food and Drug Administration ("FDA") to market a new drug (*i.e.*, a branded drug) must file a New Drug Application ("NDA") demonstrating the safety and efficacy of its product.

19. An "AB-rated" generic drug is one that the FDA has determined to be bioequivalent to a branded drug. A generic drug is considered bioequivalent to a branded drug if it contains the same active pharmaceutical ingredient as the branded drug and there is no significant difference in the quality, safety, and efficacy of the two drugs.

20. A company seeking to market an "AB-rated" generic version of a branded drug must also file an application with the FDA, but may file an Abbreviated New Drug Application ("ANDA").

21. When a branded drug is covered by one or more patents, a generic drug company that intends to market its generic drug prior to expiration of any patents may proceed to seek FDA approval, but must certify in the ANDA that

either (1) the generic version does not infringe the patents on the brand-name drug, or (2) the patents are invalid. This is referred to as a "paragraph IV certification."

22. If a generic drug company makes a paragraph IV certification, it must notify the patent holder of the filing of its ANDA. If the patent holder initiates a patent infringement suit against the generic drug company within 45 days of receiving such notice, the FDA may not grant final approval of the ANDA for the generic drug 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.

23. The Hatch-Waxman Act gives the first generic company filing an ANDA containing a paragraph IV certification a period of protection from competition with other generic versions of the drug. As to drugs for which the first paragraph IV filing was made before December 2003, as is the case here, the FDA may not approve other generic versions of the same drug until 180 days after the earlier of the date on which (1) the first company begins commercial marketing of its generic version of the drug, or (2) an appeals court finds the patent(s) claiming the branded drug invalid or not infringed. This is referred to as "180-day exclusivity."

B. The consumer benefits of generic drugs

24. Although therapeutically the same as its branded counterpart, the first AB-rated generic equivalent to a branded drug is typically priced significantly lower than the brand. Upon the entry of additional AB-rated generic drugs, generic drug prices generally fall even more.

25. Because of these price advantages, states encourage generic competition through laws that allow pharmacists to dispense an AB-rated generic drug when presented with a prescription for its branded equivalent, unless a physician or the patient directs otherwise. These state laws facilitate substitution of lower-priced AB-rated generic drugs for higher-priced branded drugs.

26. 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 branded counterparts.

27. As a result of lower prices and the ease of substitution, many consumers routinely switch from a branded drug to an AB-rated generic drug upon its introduction. Consequently, AB-rated generic drugs typically capture a significant share of their branded counterparts' sales, causing a significant reduction of the branded drugs' unit and dollar sales.

28. Competition from generic drugs generates large savings for consumers. A 1998 Congressional Budget Office Report estimates that in 1994 alone, purchasers saved $8 to $10 billion on prescriptions at retail pharmacies by purchasing generic drugs instead of the equivalent branded drugs. A 2004 FDA study calculates that patients could reduce the daily costs of their medications by more than 50 percent by purchasing generic drugs when available. According to the National Association of Chain Drug Stores, the average retail price for a brand-name prescription was about $119 in 2007, while the average retail price for a generic prescription was about $34.

29. Significant consumer savings can result when generic companies successfully challenge patents and enter prior to patent expiration. For example, a generic company's successful challenge invalidating a patent covering the antidepressant drug Prozac resulted in generic entry 2½ years before patent expiry and about $2.5 billion in estimated consumer savings. A successful challenge invalidating patents covering the cancer drug Taxol resulted in generic entry over 11 years before patent expiry and estimated consumer savings of more than $3.5 billion.

30. There are many other examples of successful patent challenges by generic drug companies. Indeed, empirical studies have shown that when pharmaceutical patent infringement claims are tested in the courts, the alleged

infringer prevails in the majority of cases. An analysis of Federal Circuit decisions from 2002 through 2004 in which the court made a final ruling on the merits of a pharmaceutical patent claim (validity, infringement, or enforceability) found that the alleged infringers had a success rate of 70 percent. An FTC study of all patent litigation initiated between 1992 and 2000 between brand-name drug manufacturers and Paragraph IV generic applicants found similar results: when cases were litigated to a decision on the merits, the generics prevailed in cases involving 73 percent of the challenged drug products.

C. Solvay's AndroGel prescription drug

31. Solvay markets a branded prescription drug called AndroGel. AndroGel is a pharmaceutical gel containing synthetic testosterone. 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.

32. In August 1995, Solvay licensed the U.S. rights to the testosterone gel formulation used for AndroGel from the Belgian pharmaceutical company Besins Healthcare, S.A. (together with its affiliates, "Besins"), which had developed the formulation. At the same time, Besins agreed to provide commercial supply of AndroGel to Solvay after the FDA approved the product for sale.

33. Solvay filed a U.S. New Drug Application for AndroGel in April 1999, which the FDA approved in February 2000. AndroGel is approved for testosterone replacement therapy in men with low 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.

34. Solvay's sales of AndroGel have grown substantially over time. In 2000, U.S. AndroGel sales were approximately $26 million. By 2003, U.S. sales had grown to about $277 million. By 2007, U.S. AndroGel sales were over $400 million.

35. From 2000 through 2007, cumulative U.S. sales of AndroGel were over $1.8 billion. These sales substantially exceeded Solvay's costs of developing AndroGel.

36. AndroGel has consistently been Solvay's highest-selling product. In 2007, sales of AndroGel accounted for about one third of Solvay's U.S. pharmaceutical revenues.

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

D. Solvay's formulation patent

38. Testosterone, the hormone contained in AndroGel, is unpatented. Patents covering the synthesis of artificial testosterone expired decades ago.

39. In August 2000, five years after Solvay licensed AndroGel from Besins, Solvay and Besins employees applied for a U.S. patent relating to AndroGel. The patent did not claim testosterone itself or methods of using testosterone generally, but rather covered the use of a particular pharmaceutical gel formulation containing testosterone and other specified ingredients in certain amounts.

40. As described in a report by the United States Government Accountability Office, patent examiners are generally expected to process an average of 87 patent applications per year and have time quotas of a total of 19 hours to process each application from its filing through its final acceptance or rejection. These time quotas are reinforced by examiners' bonus compensation, which is largely tied to the number of applications processed to completion. The patent application process is an ex parte process in which patent examiners rely upon the information and candor of applicants. The vast majority of all patent applications are ultimately granted.

41. In prosecuting the patent application relating to AndroGel, Solvay submitted to the patent examiner multiple disclosure statements identifying more than 400 articles and patents discussing previous testosterone and hormone therapies, together with copies of each of these hundreds of articles and patents in multiple notebooks, comprising more than three feet of materials for the examiner to attempt to review. In addition, Solvay filed more than 240 additional pages of papers, responses, amendments, and declarations.

42. The patent Solvay prosecuted issued on January 7, 2003 as Patent No. 6,503,894 (the "formulation patent"). Five months later, Solvay requested that the Patent and Trademark Office "correct" many claims of the formulation patent – claims originally requested and advocated by Solvay – by inserting a scientific term that would substantially reduce the amount of one of the components of the formulation and change the coverage of the claims. Nonetheless, Solvay represented that this "correction" would not "alter the substance of the patent in any way that would necessitate reevaluation by an Examiner." The certificate of correction issued some six months later.

43. The formulation patent expires in August 2020. In 2007, Solvay received six months of additional exclusivity from the FDA, until February 2021,

based on Solvay's submission of studies relating to the use of the product in a pediatric population.

V. Potential Generic Competition to AndroGel

A. Generic companies challenge Solvay's formulation patent

44. In May 2003, Watson and Paddock each filed an application with the FDA for approval to market a generic version of AndroGel. As part of their applications, Watson and Paddock certified that their generic products did not infringe Solvay's formulation patent and that the patent was invalid.

45. Watson filed its ANDA before Paddock and was therefore eligible for 180-day exclusivity under the Hatch-Waxman Act.

46. Paddock sought a partner to share the costs and risks associated with litigation, together with the rewards from a successful outcome. Paddock eventually reached a deal with Par, which was a top-ten generic drug company and a veteran of pharmaceutical patent litigation. Under the deal, Par agreed to share litigation costs with Paddock, market Paddock's generic product following launch, and share in the resulting profits. Par agreed to partner with Paddock on generic AndroGel only after conducting diligence on Paddock's ANDA in light of Solvay's formulation patent.

47. In August 2003, Solvay and Besins filed separate patent infringement lawsuits against Watson and Paddock, alleging that each infringed the formulation patent. Under the Hatch-Waxman Act, Solvay's lawsuits triggered automatic 30-month stays of final FDA approval of Watson's and Paddock's generic versions of AndroGel. Under FDA rules, the stays expired in January 2006.

B. Solvay prepares for the threat of generic competition

48. In early 2006, under the direction of a new CEO, Solvay analyzed the financial risk from potential generic competition to AndroGel. Solvay concluded that this risk was substantial. As the company's CEO noted at the time, if generics were to enter, "the economics are obviously not good."

49. Solvay estimated that if generic products were to launch in mid-2006, Solvay would lose about 90 percent of its AndroGel sales within a year. Even factoring in the cost savings to Solvay from not purchasing and promoting AndroGel, Solvay estimated that generic competition would cut its profits by about $125 million a year.

50. Watson projected a similar dramatic impact from generic AndroGel entry. A February 2006 Watson forecast projected that generic AndroGel would sell

for about 25 percent of the price of branded AndroGel within a year of generic entry, and that generic products would capture nearly 80 percent of all prescriptions.

51. Par's forecasts projected even steeper price reductions from generic entry. A Par forecast, also prepared in February 2006, projected that the price of generic AndroGel would fall to 15 percent of the branded price within a year and that 90 percent of all prescriptions would go to generic products.

52. In late January 2006, Watson received final FDA approval for its generic product, meaning the FDA had determined that Watson's generic AndroGel was as safe and effective as branded AndroGel. With final FDA approval, Watson could launch its generic version of AndroGel unless Solvay was able to satisfy the relevant burdens to obtain a preliminary injunction in the patent case to prevent Watson's launch.

53. Solvay realized that Watson's receipt of final FDA approval represented a near-term threat to its AndroGel franchise. Shortly after Watson received FDA approval, Solvay's CEO advised his superiors in Europe that Watson might launch sometime in 2006 even if the patent litigation had not concluded: "The next event will be a court hearing probably in June [2006]. They could then launch if things go well for them."

54. This concern was well-founded. As of February 2006, Watson's forecast for generic AndroGel reflected a generic entry date of January 2007. A February 2006 Par forecast assumed that Watson would launch in March 2006, and Par would follow in September 2006. Par's CEO reported to investment analysts in February 2006 that if generic AndroGel didn't launch in 2006, it "should certainly hit in 2007."

55. Both Watson and Par/Paddock took concrete steps to prepare for a generic launch. Paddock, which had an average annual company-wide equipment budget of about $1 million, spent about $750,000 on commercial manufacturing equipment for generic AndroGel. Watson also ordered commercial manufacturing equipment for generic AndroGel and planned for manufacturing validation in mid-2006 and commercial manufacturing in late 2006.

56. In spite of the threat of generic entry, Solvay did not try to obtain from the court a preliminary injunction to prevent Watson's or Par/Paddock's launch. Rather, Solvay searched for ways to settle its patent disputes and eliminate the near-term threat of generic competition without risking an adverse court decision.

VI. Solvay Pays Watson and Par/Paddock for their Agreement Not to Compete

A. Solvay enters negotiations knowing it will have to compensate Watson and Par/Paddock in exchange for deferred generic competition

57. In preparation for settlement negotiations with Watson and Par, Solvay put together a financial model to analyze its settlement options (hereinafter the "Project Tulip Financial Analysis") (attached as Ex. A). Solvay had already decided that it wanted to defer generic entry until 2015. The 2015 entry date was not based on Solvay's view of the likelihood of prevailing in the patent litigations against its potential generic rivals, but instead was selected for internal business purposes. The purpose of the Project Tulip Financial Analysis was to assess – by evaluating the generics' expected return from continuing to litigate – whether, and under what circumstances, the generic companies would accept this delayed entry date. From the Project Tulip Financial Analysis, Solvay concluded that Watson and Par might agree to a settlement that somewhat deferred generic entry. But if Solvay wanted a settlement that delayed generic entry until 2015, it had to pay Watson and Par.

58. The Project Tulip Financial Analysis also confirmed that Solvay could easily afford to buy Watson's and Par's agreement not to compete. By deferring competition, the parties would preserve monopoly profits that could be shared amongst them – at the expense of the consumer savings that would result from price

competition. Thus, even after paying Watson and Par a share of its profits, Solvay still expected to make more in AndroGel profits by maintaining its monopoly until 2015 than by continuing to litigate.

59. Solvay's Project Tulip Financial Analysis was discussed among the company's CEO and other key executives and formed the basis for Solvay's negotiating strategy. When it negotiated with Watson and Par, Solvay expected that it would need to compensate the generic companies to obtain their agreement not to launch generic AndroGel until 2015.

B. Solvay and Watson agree not to compete but rather to cooperate and share monopoly profits

60. At the beginning of settlement negotiations, Watson proposed that Solvay share AndroGel revenues with Watson through an arrangement under which Watson would co-promote AndroGel to doctors. Just months before, a consulting firm had helped Solvay conduct a comprehensive analysis of Solvay's AndroGel promotion options. That analysis concluded that AndroGel co-promotion was unlikely to make sense for Solvay, and that Watson did not meet the criteria set forth for potential co-promotion partners. Nonetheless, Solvay quickly agreed to consider allocating a portion of AndroGel sales to Watson through a co-promotion arrangement as a means to buy years of protection from competition.

61. Watson was willing to accept Solvay's 2015 generic entry date only if the price was right on the co-promotion arrangement. Watson insisted that it receive a high share of profits from all AndroGel sales to urologists, the group of doctors to which Watson would promote AndroGel. Watson demanded not only a share of incremental AndroGel sales that Watson might help build, but also a majority share of Solvay's established sales and business. Solvay relented. On April 27, 2006, Solvay's CEO reported to his superiors in Europe that Solvay and Watson had "agreed terms on the Urology 'carve-out' . . . as a basis for settlement of the current litigation."

62. Watson agreed not to market generic AndroGel until 2015 even though it knew of Solvay's plans to introduce a "line extension" product that would eliminate or substantially reduce potential sales of generic AndroGel by 2015. Branded pharmaceutical companies frequently introduce a "line extension," or a new branded product that is related to but different from an existing product, to preserve sales of a branded franchise. This is an effective commercial strategy because generic versions of the existing product are not automatically substitutable for the new "line extension" product.

63. In the case of AndroGel, Solvay plans to market a testosterone gel containing 1.62% testosterone – more than the 1% testosterone contained in AndroGel – that would allow patients to achieve similar therapeutic benefits with less volume of gel. Solvay plans to shift sales from AndroGel to its new low volume product before 2015. Solvay told Watson of its plans for a line extension product during settlement negotiations. Watson accepted Solvay's 2015 generic entry date even though a line extension product could have a severe negative impact on its potential sales of generic AndroGel by 2015. Watson would not have accepted the 2015 generic entry date in light of these risks, absent Solvay's sharing of AndroGel monopoly profits through the co-promotion deal.

64. Only after Solvay and Watson had agreed to a generic entry date and a "urology carve-out," including the percentage of urology-based profits that Watson would receive, did the parties negotiate other key terms of the co-promotion arrangement, including the number of sales calls Watson would be required to make to doctors.

65. On September 13, 2006, Solvay, Besins, and Watson entered written agreements to settle their patent litigation. Under the parties' settlement, Watson

agreed to refrain from marketing generic AndroGel until August 31, 2015, or earlier if another generic company launched a generic version of AndroGel before that date.

66. Solvay and Watson simultaneously entered into the co-promotion deal that provided substantial compensation to Watson. Under the deal, Watson agreed to promote AndroGel to urologists and Solvay agreed to share AndroGel profits with Watson through September 2015. At the time it negotiated the deal, Solvay projected that it would pay Watson about $19 million during the first year of its agreement, rising to over $30 million annually by the end of the deal. Under the parties' arrangement, Watson also obtained the right to co-promote any line extension product, and thus share in any profits of that product.

67. The compensation Solvay agreed to provide Watson was designed to, and did, induce Watson to settle the AndroGel patent litigation by agreeing to refrain from marketing generic AndroGel until 2015. Rather than compete, Solvay and Watson agreed to cooperate on AndroGel and share in monopoly profits.

68. Solvay and Watson filed a voluntary stipulation of dismissal terminating their patent litigation in the district court. The parties did not file their settlement and co-promotion agreements with the court, nor were the agreements contingent on court approval.

C. Solvay, Par, and Paddock agree not to compete but rather to cooperate and share monopoly profits

69. Under its partnership with Paddock, Par was responsible for conducting the patent litigation with Solvay and negotiating any settlement.

70. Par, like Watson, was willing to settle the AndroGel patent litigation and stay out of the market for the right price. In the words of a senior Par executive, Par was looking to "extract payments" from Solvay in settlement negotiations.

71. During negotiations, Par quickly accepted Solvay's proposed 2015 generic entry date, contingent on the parties' ability to reach agreement on the value that Par would receive in a settlement.

72. To agree on a value, Solvay and Par exchanged forecasts analyzing the profits Par would make from sales of generic AndroGel beginning in 2007. These forecasts discounted Par's generic AndroGel revenues to reflect Par's probability of prevailing in the patent litigation. According to a senior Solvay executive, Solvay developed these forecasts to "demonstrate to [Par] what [its] options are, either litigate or enter into these – this business arrangement . . . . And if we entered into the business arrangement, we wouldn't be litigating. They go hand in hand."

73. Based on the discounted value of Par's forecasted profits from selling generic AndroGel from 2007 through 2015 – which Par would forgo in a settlement –

Solvay and Par were able to "agree on a value" Par would receive in exchange for settling the litigation. Solvay and Par agreed on the payments Par would receive for deferring entry before agreeing on the other terms of the deal. On May 13, 2006, the parties confirmed by e-mail their "agreed-upon settlement of $12 million per year for 6 years coupled with manufacturing/development and/or a co-promotion between Par and Solvay."

74. About two weeks after Solvay agreed to pay Par $12 million per year for six years, the parties met to discuss what type of business arrangement would accompany the settlement. The parties considered a number of options, including co-promoting various Solvay drugs; manufacturing AndroGel or serving as a back-up manufacturer; and assisting in development of new AndroGel formulations. Ultimately, the parties decided that Par would co-promote AndroGel to doctors and receive $10 million annually, and Paddock would serve as a back-up manufacturer for AndroGel and receive $2 million annually. As a Besins executive stated in an e-mail, a "backup manufacturer strategy [was] a partial way to compensate Parr [sic] for not entering the market."

75. After Solvay and Par had agreed to the 2015 generic entry date and $12 million per year in payments, and settled on the concept of AndroGel co-promotion,

the parties negotiated other key terms of the co-promotion arrangement. In an initial term sheet, Solvay proposed that Par perform at least 90,000 sales calls a year and promote AndroGel first in each call. Under this proposal, Solvay would have paid Par about $110 per sales call, about the same amount Solvay had received in another co-promotion arrangement it had entered. Solvay ultimately agreed, however, to accept substantially fewer sales calls – only 30,800 – and Par did not even commit to promoting AndroGel in the first position. Under the final agreement, Solvay agreed to pay Par over $300 per sales call.

76. On September 13, 2006, the same day the Solvay/Watson agreements were signed, Solvay, Besins, Par, and Paddock entered written agreements to settle their patent litigation. Under the parties' settlement, Par and Paddock agreed to refrain from marketing generic AndroGel until August 31, 2015, or earlier if another generic company launched a generic version of AndroGel before that date.

77. Solvay and Par simultaneously entered into co-promotion and back-up manufacturing deals which provided substantial compensation to Par and Paddock. Under the co-promotion deal, Solvay agreed to pay Par $10 million per year for six years and Par agreed to promote AndroGel to primary care doctors. Under the back-up manufacturing deal, which Par signed but assigned to Paddock, Solvay agreed to

pay Paddock $2 million per year for six years and Paddock agreed to serve as a back-up manufacturer for AndroGel. Solvay also agreed to reimburse Paddock for any capital expenditures associated with meeting FDA requirements to manufacture AndroGel.

78. At the same time Par signed its agreements with Solvay, it agreed to pay $6 million up front to Paddock, which was accomplished by transferring title of Paddock's ANDA to Par. This payment was necessary to obtain Paddock's assent to the patent settlement.

79. The compensation Solvay agreed to provide Par and Paddock was designed to, and did, induce Par and Paddock to settle the AndroGel patent litigation by agreeing to refrain from marketing generic AndroGel until 2015. Rather than compete, Solvay, Par and Paddock agreed to cooperate on AndroGel and share in monopoly profits.

80. The district court hearing the patent litigation dismissed Solvay's patent lawsuit against Paddock under a consent judgment filed by the parties. The parties did not file their settlement, co-promotion, and back-up manufacturing agreements with the court, nor were the agreements contingent on court approval.

D. Solvay's business deals with Watson and Par/Paddock make economic sense only as payments to defer generic entry

81. The co-promotion and back-up manufacturing deals induced Watson, Par, and Paddock to agree to refrain from marketing generic AndroGel until 2015 and provided Solvay the means to share preserved AndroGel monopoly profits with its potential competitors.

82. Solvay's co-promotion deals with Watson and Par are not independent business transactions, for at least the following reasons:

- Prior to settlement discussions with Watson and Par, Solvay had not been looking for a co-promotion partner. Its 2006 business plan for AndroGel assumed "no co-promotion during plan period"; two prior AndroGel co-promotion efforts had been canceled because they had "no significant impact" on sales trends; and a late 2005 analysis from a consulting firm had concluded that future AndroGel co-promotion offered "little revenue upside."
- Solvay's payments to Watson and Par far exceed the value of the services provided. Solvay projected that it would pay Watson more than $19 million annually, or over $300 per sales call. Solvay agreed to pay Par $10 million per year, also over $300 per sales call. By contrast,

Solvay had previously entered an AndroGel co-promotion deal involving projected payments of around $30-$45 per sales call. A senior Watson executive has stated that even $150 per call would be a "ridiculous" rate – and yet Watson and Par are receiving more than twice that rate from Solvay.

- Other terms of the co-promotion deals also depart from industry standards. Among other things, unlike Solvay's previous AndroGel co-promotion agreements, Solvay cannot terminate either deal early if co-promotion does not improve AndroGel sales.
- Before agreeing to the co-promotion deals, Solvay did not analyze how the Watson or Par co-promotion efforts would affect AndroGel sales – as it did before entering into earlier AndroGel co-promotion agreements.
- When it entered the co-promotion deals, Solvay examined the "Estimated Impact of Settlement" on Solvay's budget and accounted for co-promotion as a cost of settlement rather than a profitable business deal.

83. Solvay was willing to enter into the co-promotion deals only because Watson and Par agreed to refrain from competing with generic AndroGel until 2015.

84. Solvay's back-up manufacturing deal with Paddock is not an independent business transaction, for at least the following reasons:

- The back-up manufacturing deal guarantees Paddock $2 million per year for six years, regardless of whether Paddock ever manufactures AndroGel or ever becomes FDA-qualified to manufacture AndroGel.
- Before settlement discussions with Par, Solvay had considered and rejected several options for AndroGel back-up manufacturing. Solvay had concluded that the $10-12 million in capital expenditures required to qualify a back-up manufacturer could not be justified in light of the reliable source of supply from Besins.
- Before entering the back-up manufacturing deal, Solvay conducted no diligence on Paddock's manufacturing facilities. A later site visit showed that Paddock was not able to manufacture AndroGel using Besins' already-FDA-approved process, requiring substantial and lengthy efforts to conform Paddock's facilities and processes to meet FDA-approved standards. Solvay has paid Paddock $2 million per year since September 2006 despite the fact that Solvay did not even apply for the required FDA approval for Paddock to serve as a back-up

manufacturer until November 2008. Under the parties' deal, Solvay must also reimburse Paddock for any capital expenditures in connection with its qualification efforts.

85. Solvay was willing to enter into the back-up manufacturing deal only because Par and Paddock agreed to refrain from competing with generic AndroGel until 2015.

VII. Solvay's Patent Was Unlikely to Prevent Generic Competition to AndroGel

86. Over the course of their patent litigation with Solvay and Besins, Watson and Par/Paddock developed persuasive arguments and amassed substantial evidence that their generic products did not infringe the formulation patent and that the patent was invalid and/or unenforceable. As a result, Solvay was not likely to prevail in each of its patent lawsuits to prevent competition to AndroGel.

87. Watson and Par/Paddock argued that the scope of the formulation patent was limited, and that their products were outside the scope of the patent claims. They assembled evidence that their generic products did not infringe the patent because their products contained ingredients that the patent did not cover, or amounts of ingredients outside the amounts covered by the patent.

88. Watson and Par/Paddock also argued that the formulation patent was invalid. Among other things, these firms developed evidence that:

- The patent was invalid under 35 U.S.C. § 102(b) for prior commercial sale or public use of the patented invention, in that Besins offered the invention for sale to Solvay in 1995 – a fact that Solvay and Besins withheld from the Patent and Trademark Office.
- The patent was invalid as obvious under 35 U.S.C. § 103 because the gel formulations and related methods covered by the patent were obvious variations of existing products and methods. As a Paddock executive noted in a 2006 e-mail characterizing the views of Paddock's CEO, Paddock was "providing [testosterone] gel formulations to customers over 10 years ago, so the patent simply cannot be valid."
- Many of the patent claims were invalid under 35 U.S.C. § 112 for failure to meet the "written description" requirement.

89. The generic firms also argued that the certificate of correction, which changed the scope of some of the patent claims, was invalid and, because the certificate of correction issued after Solvay filed its patent suits, the certificate did not apply to the pending litigations. Watson further argued that the patent was

unenforceable based on evidence that Solvay and Besins did not disclose their 1995 commercial supply agreement to the patent examiner when they applied for the formulation patent.

90. By late 2005, Watson and Par/Paddock had filed motions for summary judgment on two of these issues, and addressed others in claim construction briefing and expert reports.

91. Solvay and Besins bore the burden of proving that Watson and Par/Paddock each infringed the formulation patent – in other words, that the generic products were within the scope of the patent claims. Solvay and Besins had not met their burden when the litigation ended in settlements.

92. Solvay and Besins were unlikely to prevent generic entry through their patent lawsuits. To do so, Solvay and Besins had to prove infringement by both Watson and Par/Paddock, and also had to defeat each of the generics' invalidity and unenforceability arguments. If either Watson or Par/Paddock had prevailed on any one of these issues, Solvay's formulation patent could not have blocked generic entry, and consumers would have saved millions of dollars a year.

VIII. The AndroGel Settlements Harm Competition and Consumer Welfare

93. Prior to their settlement, Solvay and Watson were potential competitors. By entering into their agreement, Solvay and Watson eliminated the potential that (1) Watson would have entered "at risk" and marketed generic AndroGel before a final appellate decision in the AndroGel patent litigation; (2) Watson would have prevailed in the patent litigation and marketed generic AndroGel after the litigation but well before 2015; or (3) Solvay and Watson would have agreed to settle their patent litigation on terms that did not compensate Watson, but provided for generic entry earlier than 2015.

94. Prior to their settlement, Solvay and Par/Paddock were potential competitors. By entering into their agreement, Solvay and Par/Paddock eliminated the potential that (1) Par/Paddock would have entered "at risk" and marketed generic AndroGel before a final appellate decision in the AndroGel patent litigation; (2) Par/Paddock would have prevailed in the patent litigation and marketed generic AndroGel after the litigation but well before 2015; or (3) Solvay and Par/Paddock would have agreed to settle their patent litigation on terms that did not compensate Par/Paddock, but provided for generic entry earlier than 2015.

95. If Solvay had settled with Watson only, Par had ample financial incentive to continue to challenge Solvay's patent. During settlement negotiations with Solvay, Par prepared forecasts that showed the risk to Solvay if it settled with Watson and not with Par – that risk being that Par would continue to litigate and prevail. Par's forecasts also showed that, even as a generic applicant entering six months after Watson, Par expected to earn significantly more in generic AndroGel profits than its expected costs of litigation.

96. Defendants eliminated this potential competition and harmed consumers by entering agreements that compensated Watson and Par/Paddock for agreeing to refrain from marketing generic AndroGel until 2015. Defendants' agreements to eliminate potential competition until 2015 were based not on the strength of Solvay's patent, but on the compensation Solvay provided to Watson, Par, and Paddock in exchange for a 2015 generic entry date. Absent compensation, Watson and Par/Paddock would not have agreed to refrain from competing until 2015.

97. Moreover, absent the compensation Solvay agreed to provide, generic competition to AndroGel would have occurred before 2015 because (1) Watson and/or Par/Paddock would have marketed generic AndroGel before a final appellate decision in the AndroGel patent litigation; (2) Solvay would not have prevailed

against each of Watson and Par/Paddock in the patent litigation; or (3) Solvay would have agreed to settle the patent litigation on terms that did not compensate Watson and Par/Paddock, but provided for generic entry earlier than 2015.

98. Entry of generic AndroGel would give consumers the choice between branded AndroGel and lower-priced generic versions of AndroGel. Many consumers would choose to purchase lower-priced, generic drugs instead of higher-priced, branded AndroGel. Entry of generic versions of AndroGel would quickly and significantly reduce Solvay'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 would save hundreds of millions of dollars a year by purchasing generic versions of AndroGel. Through their anticompetitive agreements, Defendants have retained those potential consumer savings for themselves.

99. The ability to launch generic versions of AndroGel in 2015 will likely provide little benefit to consumers because Solvay plans to switch sales from AndroGel to its new branded product, a low volume version of AndroGel, well before 2015. Generic AndroGel would not be automatically substitutable for Solvay's new branded product. Moreover, Solvay has even considered pulling

AndroGel from the market before generics enter in 2015, which would likely eliminate altogether the market for generic AndroGel.

100. The Hatch-Waxman Act was designed to promote generic competition while preserving incentives for branded innovation. Exclusion payment settlements, including Defendants', distort the careful balance achieved by the Hatch-Waxman Act by eliminating generic companies' incentives to compete.

101. Exclusion payments are not a natural by-product of incentives created by the Hatch-Waxman Act. Rather, pharmaceutical patent litigation can be, and often is, resolved without exclusion payments from branded companies to generic companies. For instance, in fiscal year 2004, following FTC enforcement actions challenging exclusion payments, 14 pharmaceutical patent settlements were filed with the FTC under the Medicare Modernization Act and none involved an exclusion payment.

102. Through its exclusion payment settlements, Solvay bought protection from competition not contemplated by the Hatch-Waxman Act – with consumers paying the price for its anticompetitive conduct.

IX. Solvay's Market and Monopoly Power

103. Solvay has exercised and continues to exercise market and monopoly power in the United States with respect to AndroGel. Direct evidence of this power includes Solvay's ongoing ability to price AndroGel substantially higher than the projected price of competing generic versions of AndroGel and to exclude potential competitors by providing significant compensation to forestall entry.

104. In addition, Solvay'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 and documentary 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. Other testosterone drugs, such as those delivered by injection, are not close enough substitutes to prevent Solvay and other market participants from profitably raising prices. AndroGel has consistently accounted for more than 70 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.

105. Narrower relevant product markets may also exist for purposes of assessing Defendants' conduct and Solvay's market and monopoly power, including one consisting of AndroGel and its generic equivalents. A unique competitive relationship exists between branded 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 Defendants' conduct. Solvay has 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 Solvay's ability to trigger an automatic 30-month stay of FDA approval by filing a patent infringement lawsuit. Moreover, Defendants' agreements have diminished the economic incentives to potential generic entrants of challenging the AndroGel formulation patent, since the terms of the agreements allow for immediate entry of generic AndroGel by Watson and Par/Paddock upon the launch of generic AndroGel by any other generic manufacturer.

Count I

Restraint of Trade – Against Watson and Solvay

106. Plaintiffs reallege and incorporate by reference the allegations in all of the paragraphs above. The agreement between Watson and Solvay that Watson will not compete by marketing a generic version of AndroGel until 2015, in exchange for compensation, is an unfair method of competition that violates Section 5(a) of the FTC Act, 15 U.S.C. § 45(a).

Count II

Restraint of Trade – Against Par, Paddock, and Solvay

107. Plaintiffs reallege and incorporate by reference the allegations in all of the paragraphs above.

108. The agreement among Par, Paddock, and Solvay that Par/Paddock will not compete by marketing a generic version of AndroGel until 2015, in exchange for compensation, is an unfair method of competition that violates Section 5(a) of the FTC Act, 15 U.S.C. § 45(a).

Count III

Monopolization – Against Solvay

109. Plaintiffs reallege and incorporate by reference the allegations in all of the paragraphs above.

110. At all times relevant to this complaint, Solvay has had monopoly power in the United States with respect to AndroGel.

111. Solvay has willfully maintained its monopoly power through its agreements with Watson, Par, and Paddock that those companies will not compete by marketing generic versions of AndroGel until 2015, in exchange for compensation. Entry of a generic version of AndroGel would eliminate Solvay's monopoly with respect to AndroGel. At the time of the agreements, Watson and Par/Paddock were threats to enter with generic versions of AndroGel before 2015. Eliminating this threat of generic entry is conduct that is reasonably capable of contributing significantly to Solvay's continued monopoly power. Solvay has willfully maintained its monopoly and excluded competition through its anticompetitive conduct. Solvay has unlawfully extended its monopoly not on the strength of its patent, but rather by compensating its potential competitors.

112. Solvay's acts are anticompetitive and constitute 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-III, declaring, ordering, and adjudging:

1. That the agreement between Watson and Solvay violates Section 5(a) of the FTC Act, 15 U.S.C. § 45(a);
2. That the agreement among Par, Paddock, and Solvay violates Section 5(a) of the FTC Act, 15 U.S.C. § 45(a);
3. That Solvay's course of conduct, including its agreements with Watson, Par, and Paddock, violates Section 5(a) of the FTC Act, 15 U.S.C. § 45(a);

4. That Defendants are permanently enjoined from engaging in similar and related conduct in the future; and

5. That the Court grant such other equitable relief as the Court finds necessary 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: May 28, 2009

Respectfully submitted,

/s/ Cindy A. Liebes

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L.R. 7.1 (D) Certificate of Font Compliance

I hereby certify that the foregoing has been prepared with one of the font and point selections approved by the Court in Local Rule 5.1 (C), Northern District of Georgia, specifically Times New Roman 14 point.

Respectfully submitted this 28th day of May, 2009.

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