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UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA

CV 09 - 00598 AHM

Federal Trade Commission; and

The State of California, ex rel Attorney General Edmund G. Brown, Jr.

Plaintiffs,

v.

Watson Pharmaceuticals, Inc., a corporation;

Par Pharmaceutical Companies, Inc., a corporation;

Paddock Laboratories, Inc., a corporation; and

Solvay Pharmaceuticals, Inc., a corporation,

Defendants.

Case No.

CIVIL COMPLAINT – PUBLIC VERSION

Complaint for Violations of Federal Trade Commission Act, Sherman Act, Cartwright Act, and California Unfair Competition Act

Plaintiffs, the Federal Trade Commission and the State of California ex rel Attorney General Edmund G. Brown, Jr., by their designated attorneys, complain against defendants Watson Pharmaceuticals, Inc., Par Pharmaceutical Companies, Inc., Paddock Laboratories, Inc., and Solvay Pharmaceuticals, Inc., as follows:

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. Solvay could not be confident that its patent alone would 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. [redacted]

5. In the end, Watson, Par, and Paddock agreed to share in Solvay's monopoly profits, abandon their patent challenges, and refrain from competing with low-cost generic products 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 more than [redacted] 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. This Court also has supplemental jurisdiction over the State of California's state law claims under 28 U.S.C. § 1367 because those claims are so related to the federal claims that they form part of the same case or controversy. The exercise of supplemental

jurisdiction avoids unnecessary duplication and multiplicity of actions and is in the interests of judicial economy, convenience, and fairness.

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, and a substantial part of the events giving rise to Plaintiffs' claims arose 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. Plaintiff the State of California ex rel Attorney General Edmund G. Brown, Jr. brings this action as parens patriae in its sovereign capacity to redress injury to California's welfare and general economy, and as the chief law enforcement officer of the State of California.

14. 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.

15. 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.

16. 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.

17. Defendant Solvay Pharmaceuticals, Inc. (together with its affiliates, "Solvay") is incorporated in Delaware 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 [redacted], over $400 million of which were U.S. sales of AndroGel.

IV. Background

A. The regulatory system governing pharmaceuticals in the United States

18. 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.

19. 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.

20. 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.

21. 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").

22. 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."

23. 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.

24. 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

25. 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.

26. 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 directs, or the patient requests, otherwise. These state laws facilitate substitution of lower-priced AB-rated generic drugs for higher-priced branded drugs.

27. 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.

28. 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.

29. 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. And, 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.

30. 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. Another 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.

31. 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

32. 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.

33. 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.

34. 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.

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

36. From 2000 through 2007, cumulative U.S. sales of AndroGel were over [redacted]. These sales substantially exceeded Solvay's costs of developing AndroGel.

37. AndroGel has consistently been Solvay's highest-selling product. In 2007, sales of AndroGel accounted for about [redacted] of Solvay's U.S. pharmaceutical revenues.

38. 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

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

40. 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.

41. 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.

42. 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.

43. 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 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.

44. The formulation patent expires in August 2020. Solvay recently received regulatory exclusivity from the FDA based on pediatric studies that would provide Solvay with an additional six months of exclusivity beyond the expiration of its patent, through February 2021.

V. Potential Generic Competition to AndroGel

A. Generic companies challenge Solvay's formulation patent

45. 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.

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

47. With its ANDA, 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. [redacted]

48. In August 2003, Solvay and Besins filed patent infringement lawsuits against Watson and Paddock, alleging that each infringed the formulation patent.

Under the Hatch-Waxman Act, Solvay's lawsuits triggered automatic 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

49. In early 2006, under the direction of a new CEO, [redacted]

50. [redacted]

51. [redacted]

52. [redacted]

53. 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.

54. Solvay realized that Watson's receipt of final FDA approval represented a near-term threat to its AndroGel franchise. [redacted]

55. [redacted] Par's CEO told investment analysts in February 2006 that if generic AndroGel didn't launch in 2006, it "should certainly hit in 2007."

56. [redacted]

57. 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 considered ways to settle its patent disputes and eliminate the near-term threat of generic competition without risking a potential 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

58. [redacted]

[redacted]

59. [redacted] By deferring competition, the parties would preserve monopoly rents that could be shared amongst them – at the expense of the consumer savings that would result from price competition. [redacted]

60. [redacted]

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

61. At the beginning of settlement negotiations, [redacted] But because Solvay

wanted to protect its AndroGel revenues for another nine years, until 2015, Solvay quickly agreed to consider allocating a portion of AndroGel sales to Watson.

62. Watson was willing to accept Solvay's 2015 generic entry date, however, only if the price was right on the co-promotion arrangement. [redacted]

63. [redacted] 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. In the case of AndroGel, Solvay plans to develop and 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, in part because generic versions of AndroGel will not be automatically substitutable for Solvay's new branded product. [redacted] 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 substantial sharing of AndroGel profits through the co-promotion deal.

64. [redacted]

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 a co-promotion deal which provided substantial compensation to Watson. Under the deal, Watson agreed to promote AndroGel to urologists and Solvay agreed to share AndroGel profits with Watson [redacted]

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, [redacted]

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

69. [redacted]

70. Par, like Watson, was willing to settle the AndroGel patent litigation with Solvay for the right price. [redacted]

71. [redacted]

72. [redacted]

73. [redacted]

74. [redacted]

[redacted]

Ultimately, the parties decided that Par would co-promote AndroGel to doctors and receive $10 million annually, [redacted] 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. [redacted]

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, Par agreed to promote AndroGel to primary care doctors and Solvay agreed to pay Par $10 million per year for six years. Under the back-up manufacturing deal, which Par signed [redacted]

[redacted]

78. At the same time Par signed its agreements with Solvay, it agreed to transfer $6 million up front to Paddock through a transfer of 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, [redacted]

D. Solvay paid Watson and Par/Paddock through business deals that made sense only when linked to deferred generic entry

81. The co-promotion and back-up manufacturing deals served to induce 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:

- [redacted]

[redacted]

- Solvay's payments to Watson and Par far exceed the value of the services provided. [redacted]

- Other terms of the co-promotion deals also depart from industry standards. Among other things, [redacted]

- [redacted]

- [redacted]

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 [redacted] is not an independent business transaction, for at least the following reasons:

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 amassed substantial evidence that their generic products did not infringe the formulation patent and that the patent was invalid and/or unenforceable.

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 argued 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. [redacted]
- Many of the patent claims were invalid under 35 U.S.C. § 112 for failure to meet the "written description" requirement.

89. Watson argued that the patent was unenforceable because Solvay and Besins did not disclose their 1995 commercial supply agreement to the patent examiner when they applied for the formulation patent. The generic firms also argued that the certificate of correction that changed the scope of some of the patent claims was invalid and/or did not apply to the pending litigation, which was filed before the certificate of correction issued.

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 would not have prevented generic entry.

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 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 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 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 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. 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, the generic entry date that Solvay demanded.

96. 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.

97. 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 likely 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.

98. By eliminating potential competition, Defendants have harmed consumers in California, who constitute some 12 percent of the U.S. population, and the California general economy and welfare.

99. Consumers may realize few benefits from the entry of generic versions of AndroGel in 2015 because of Solvay's plans to switch sales from AndroGel to a

new branded product, a low volume version of AndroGel, well before 2015. [redacted] and because generic AndroGel would not be automatically substitutable for Solvay's new branded product, generic entry in 2015 would provide little, if any, consumer savings.

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 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.

107. 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 unreasonable restraint of trade that violates Section 1 of the Sherman Act, 15 U.S.C. § 1, and 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

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

109. 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 unreasonable restraint of trade that violates Section 1 of the Sherman Act, 15 U.S.C. § 1, and 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

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

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

112. 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.

113. Solvay's acts are anticompetitive and constitute unlawful monopolization in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2, and an unfair method of competition in violation of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a).

Count IV

Violation of the Cartwright Act – Against all Defendants

114. The State of California realleges and incorporates by reference the allegations in all of the paragraphs above.

115. From 2006 to present, Defendants conspired, acted in concert, and executed agreements unreasonably restraining competition in the relevant market.

116. The aforementioned practices by Defendants are continuing, and are in violation of the Cartwright Act, Cal. Bus. & Prof. Code §§ 16700, *et seq.*

117. Accordingly, the State of California seeks all relief available under California's Cartwright Act, including injunctions, costs, reasonable attorneys' fees, and any such other equitable or other relief that might be available or just under statute or equity.

118. Further, the State of California seeks injunctive relief against Defendants under Bus. & Prof. Code § 16754.5, both to deter such conduct of Defendants which is the subject of this Complaint, and as may be necessary to restore and preserve fair competition in the relevant market.

Count V

Violation of California Unfair Competition Act – Against All Defendants

119. The State of California realleges and incorporates by reference the allegations in all of the paragraphs above.

120. From 2006 to present, Defendants conspired, acted in concert, and executed agreements unreasonably restraining competition in the relevant market, all in violation of the FTC Act, the Sherman Act, and the Cartwright Act.

121. The aforementioned practices by Defendants were and are continuing, and are anticompetitive, unlawful and unfair acts in violation of the Unfair Competition Act, Cal. Bus. & Prof. Code §§ 17200, *et seq*.

122. As described above, Defendants' acts violate Cal. Bus. & Prof. Code §§ 17200, *et seq*, and the State of California is entitled to civil penalties of up to the maximum amount permitted by Cal. Bus. & Prof. Code § 17206 for each violation of Cal. Bus. & Prof. Code § 17200, and injunctive relief.

123. The State of California is entitled to any other relief the court believes is just.

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.

WHEREFORE, the State of California requests that this Court enter final judgment against Defendants on Counts I-V, declaring, ordering, and adjudging:

1. That the aforesaid conduct and agreements between the Defendants which are the subject of the Counts, violate the Sherman Act, Cartwright Act and California Unfair Competition Act, and should be declared null and void;

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

3. That the Court award a mandatory injunction pursuant to Bus. & Prof. Code Section 16754.5 as may be necessary to restore and preserve fair competition in the market affected by Defendants' conduct;

4. That for each violation of each Defendant of Count V, the Court award the maximum civil penalties allowed by UCL in the amount of $2,500; and

5. That the Court award reasonable attorneys' fees, costs and such other equitable relief as deemed just and equitable or appropriate, to redress Defendants' violation of federal and/or state antitrust law or restore competition.

Dated: January 27 2009

Respectfully submitted,

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