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16
17 **UNITED STATES DISTRICT COURT**
FOR THE CENTRAL DISTRICT OF CALIFORNIA

18
19 **Federal Trade Commission; and**

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

21 Plaintiffs,

22 v.

23 **Watson Pharmaceuticals, Inc., a**
24 corporation;

25 **Par Pharmaceutical Companies, Inc.,**
a corporation;

26 **Paddock Laboratories, Inc., a**
27 corporation; and

28 **Solvay Pharmaceuticals, Inc., a**
corporation,

Defendants.

Case No.

CIVIL COMPLAINT –

PUBLIC VERSION

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

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

7 **I. Nature of the Case**

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

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

23 3. After Watson and Paddock had announced their plans to sell generic
24 AndroGel, Solvay sued the generic companies for infringing the only patent Solvay
25 had relating to AndroGel. In the ensuing litigation, each of the generic companies
26 vigorously asserted that its product was outside the scope of Solvay's patent, that the
27 patent was invalid, and that Solvay withheld important information from the Patent
28

1 and Trademark Office in obtaining the patent. Solvay could not be confident that its
2 patent alone would prevent generic entry.

3 4. Eventually, Defendants recognized that they would each be better off by
4 cooperating and sharing in Solvay's monopoly profits than by competing. [REDACTED]

5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]

10 5. In the end, Watson, Par, and Paddock agreed to share in Solvay's
11 monopoly profits, abandon their patent challenges, and refrain from competing with
12 low-cost generic products for nine years. Together with Solvay, they also identified
13 ways to transfer the money to the generic firms: via co-promotion arrangements and
14 a back-up supply deal executed on the same day as the companies' patent
15 settlements.

16 6. As a result of Defendants' agreements, Watson and Par, rather than
17 competing against Solvay, are partnering with Solvay to promote AndroGel and
18 share in monopoly profits – with expected payments of more than [REDACTED]
19 collectively. Solvay's substantial payments to Watson, Par, and Paddock – not the
20 strength of Solvay's patent – have prevented generic competition to AndroGel until
21 2015. These agreements deny consumers the opportunity to purchase lower-cost
22 generic versions of AndroGel, at a cost of hundreds of millions of dollars a year.

23 **II. Jurisdiction and Venue**

24 7. This Court has subject matter jurisdiction over this action pursuant to 15
25 U.S.C. §§ 45(a) and 53(b), and 28 U.S.C. §§ 1331, 1337(a), and 1345. This Court
26 also has supplemental jurisdiction over the State of California's state law claims
27 under 28 U.S.C. § 1367 because those claims are so related to the federal claims that
28 they form part of the same case or controversy. The exercise of supplemental

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

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

6 9. Venue in this district is proper under 15 U.S.C. § 22 and 28 U.S.C.
7 § 1391(b) and (c), and under Section 13(b) of the FTC Act, 15 U.S.C. § 53(b). Each
8 Defendant resides, transacts business, committed an illegal or tortious act, or is found
9 in this District, and a substantial part of the events giving rise to Plaintiffs' claims
10 arose in this District.

11 10. Defendants' general business practices, and the unfair methods of
12 competition alleged herein, are "in or affecting commerce" within the meaning of
13 Section 5 of the FTC Act, 15 U.S.C. § 45.

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

16 **III. The Parties**

17 12. Plaintiff Federal Trade Commission is an administrative agency of the
18 United States government, established, organized, and existing pursuant to the FTC
19 Act, 15 U.S.C. § 41 *et seq.*, with its principal offices in Washington, D.C. The FTC
20 is vested with authority and responsibility for enforcing, *inter alia*, Section 5 of the
21 FTC Act, 15 U.S.C. § 45, and is authorized under Section 13(b) of the FTC Act, 15
22 U.S.C. § 53(b), to initiate court proceedings to enjoin violations of any law the FTC
23 enforces.

24 13. Plaintiff the State of California ex rel Attorney General Edmund G.
25 Brown, Jr. brings this action as *parens patriae* in its sovereign capacity to redress
26 injury to California's welfare and general economy, and as the chief law enforcement
27 officer of the State of California.

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

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

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

18 17. Defendant Solvay Pharmaceuticals, Inc. (together with its affiliates,
19 “Solvay”) is incorporated in Delaware and has its principal place of business in
20 Marietta, Georgia. Solvay Pharmaceuticals is a subsidiary of Solvay, S.A., a Belgian
21 company whose shares are listed on the Euronext Brussels stock exchange and traded
22 over-the-counter in the United States via American Depositary Receipts. Solvay
23 includes Unimed Pharmaceuticals, Inc., Solvay’s wholly owned subsidiary. Solvay
24 is engaged in the distribution and sale of branded pharmaceutical products, including
25 AndroGel. In the twelve months ending December 31, 2007, Solvay’s U.S. net
26 pharmaceutical revenues totaled about [REDACTED], over \$400 million of which were
27 U.S. sales of AndroGel.

28

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

1 receiving such notice, the FDA may not grant final approval of the ANDA for the
2 generic drug until the earliest of (1) patent expiry, (2) district court resolution of the
3 patent litigation in favor of the generic company, or (3) the expiration of an
4 automatic 30-month waiting period.

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

13 **B. The consumer benefits of generic drugs**

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

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

23 27. Many third party payers of prescription drugs (*e.g.*, health insurance
24 plans, Medicaid programs) have adopted policies to encourage the substitution of
25 AB-rated generic drugs for their branded counterparts.

26 28. As a result of lower prices and the ease of substitution, many consumers
27 routinely switch from a branded drug to an AB-rated generic drug upon its
28 introduction. Consequently, AB-rated generic drugs typically capture a significant

1 share of their branded counterparts' sales, causing a significant reduction of the
2 branded drugs' unit and dollar sales.

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

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

19 31. There are many other examples of successful patent challenges by
20 generic drug companies. Indeed, empirical studies have shown that when
21 pharmaceutical patent infringement claims are tested in the courts, the alleged
22 infringer prevails in the majority of cases. An analysis of Federal Circuit decisions
23 from 2002 through 2004 in which the court made a final ruling on the merits of a
24 pharmaceutical patent claim (validity, infringement, or enforceability) found that the
25 alleged infringers had a success rate of 70 percent. An FTC study of all patent
26 litigation initiated between 1992 and 2000 between brand-name drug manufacturers
27 and Paragraph IV generic applicants found similar results: when cases were litigated
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1 to a decision on the merits, the generics prevailed in cases involving 73 percent of the
2 challenged drug products.

3 **C. Solvay's AndroGel prescription drug**

4 32. Solvay markets a branded prescription drug called AndroGel. AndroGel
5 is a pharmaceutical gel containing synthetic testosterone. Testosterone was first
6 artificially synthesized in 1935 and has been available in various drug products since
7 the 1950s. Pharmaceutical gel products have also been available for decades.

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

13 34. Solvay filed a U.S. New Drug Application for AndroGel in April 1999,
14 which the FDA approved in February 2000. AndroGel is approved for testosterone
15 replacement therapy in men with low testosterone. Low testosterone is often
16 associated with advancing age, certain cancers, diabetes, and HIV/AIDS, among
17 other conditions, and can result in fatigue, muscle loss, and erectile dysfunction.

18 35. Solvay's sales of AndroGel have grown substantially over time. In
19 2000, U.S. AndroGel sales were approximately [REDACTED]. By 2003, U.S. sales had
20 grown to about [REDACTED]. By 2007, U.S. AndroGel sales were over \$400 million.

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

24 37. AndroGel has consistently been Solvay's highest-selling product. In
25 2007, sales of AndroGel accounted for about [REDACTED] of Solvay's U.S.
26 pharmaceutical revenues.

27 38. Solvay sells AndroGel at prices far above Solvay's cost of obtaining the
28 product from Besins, making AndroGel highly profitable for Solvay. Even

1 accounting for other direct expenses Solvay allocates to selling and marketing
2 AndroGel, Solvay's profit margin on AndroGel net sales is substantial.

3 **D. Solvay's formulation patent**

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

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

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

20 42. In prosecuting the patent application relating to AndroGel, Solvay
21 submitted to the patent examiner multiple disclosure statements identifying more than
22 400 articles and patents discussing previous testosterone and hormone therapies,
23 together with copies of each of these hundreds of articles and patents in multiple
24 notebooks, comprising more than three feet of materials for the examiner to attempt
25 to review. In addition, Solvay filed more than 240 additional pages of papers,
26 responses, amendments, and declarations.

27 43. The patent Solvay prosecuted issued on January 7, 2003 as Patent No.
28 6,503,894 (the "formulation patent"). Five months later, Solvay requested that the

1 Patent and Trademark Office “correct” many claims of the formulation patent by
2 inserting a scientific term that would substantially reduce the amount of one of the
3 components of the formulation and change the coverage of the claims. Nonetheless,
4 Solvay represented that this “correction” would not “alter the substance of the patent
5 in any way that would necessitate reevaluation by an Examiner.” The certificate of
6 correction issued some six months later.

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

11 **V. Potential Generic Competition to AndroGel**

12 **A. Generic companies challenge Solvay’s formulation patent**

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

17 46. Watson filed its ANDA before Paddock and was therefore eligible for
18 180-day exclusivity under the Hatch-Waxman Act.

19 47. With its ANDA, Paddock sought a partner to share the costs and risks
20 associated with litigation, together with the rewards from a successful outcome.
21 Paddock eventually reached a deal with Par, which was a top-ten generic drug
22 company and a veteran of pharmaceutical patent litigation. Under the deal, Par
23 agreed to share litigation costs with Paddock, market Paddock’s generic product
24 following launch, and share in the resulting profits. [REDACTED]

25 [REDACTED]
26 [REDACTED]
27 48. In August 2003, Solvay and Besins filed patent infringement lawsuits
28 against Watson and Paddock, alleging that each infringed the formulation patent.

1 Under the Hatch-Waxman Act, Solvay's lawsuits triggered automatic stays of final
2 FDA approval of Watson's and Paddock's generic versions of AndroGel. Under
3 FDA rules, the stays expired in January 2006.

4 **B. Solvay prepares for the threat of generic competition**

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

6 [REDACTED]
7 [REDACTED]
8 [REDACTED]

9 50. [REDACTED]

10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]

14 51. [REDACTED]

15 [REDACTED]
16 [REDACTED]
17 [REDACTED]

18 52. [REDACTED]

19 [REDACTED]
20 [REDACTED]
21 [REDACTED]

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

28

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

3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 55. [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED] Par’s CEO told investment
11 analysts in February 2006 that if generic AndroGel didn’t launch in 2006, it “should
12 certainly hit in 2007.”

13 56. [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]

19 57. In spite of the threat of generic entry, Solvay did not try to obtain from
20 the court a preliminary injunction to prevent Watson’s or Par/Paddock’s launch.
21 Rather, Solvay considered ways to settle its patent disputes and eliminate the near-
22 term threat of generic competition without risking a potential adverse court decision.

23 **VI. Solvay Pays Watson and Par/Paddock for their Agreement Not to Compete**
24 **A. Solvay enters negotiations knowing it will have to compensate Watson and**
25 **Par/Paddock in exchange for deferred generic competition**

26 58. [REDACTED]
27 [REDACTED]
28 [REDACTED]

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[REDACTED]

59. [REDACTED]

[REDACTED]

[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]

[REDACTED]

60. [REDACTED]

[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]

[REDACTED]

[REDACTED] But because Solvay

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

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

5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]

12 63. [REDACTED]
13 [REDACTED]
14 [REDACTED]

15 Branded pharmaceutical companies frequently introduce a "line extension," or a new
16 branded product that is related to but different from an existing product, to preserve
17 sales of a branded franchise. In the case of AndroGel, Solvay plans to develop and
18 market a testosterone gel containing 1.62% testosterone – more than the 1%
19 testosterone contained in AndroGel – that would allow patients to achieve similar
20 therapeutic benefits with less volume of gel. Solvay plans to shift sales from
21 AndroGel to its new low volume product before 2015, in part because generic
22 versions of AndroGel will not be automatically substitutable for Solvay's new
23 branded product. [REDACTED]

24 [REDACTED] Watson accepted Solvay's 2015 generic entry date even
25 though a line extension product could have a severe negative impact on its potential
26 sales of generic AndroGel by 2015. Watson would not have accepted the 2015
27 generic entry date in light of these risks, absent Solvay's substantial sharing of
28 AndroGel profits through the co-promotion deal.

1 64. [REDACTED]

2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 65. On September 13, 2006, Solvay, Besins, and Watson entered written
7 agreements to settle their patent litigation. Under the parties' settlement, Watson
8 agreed to refrain from marketing generic AndroGel until August 31, 2015, or earlier
9 if another generic company launched a generic version of AndroGel before that date.

10 66. Solvay and Watson simultaneously entered into a co-promotion deal
11 which provided substantial compensation to Watson. Under the deal, Watson agreed
12 to promote AndroGel to urologists and Solvay agreed to share AndroGel profits with
13 Watson [REDACTED]

14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 67. The compensation Solvay agreed to provide Watson was designed to,
19 and did, induce Watson to settle the AndroGel patent litigation by agreeing to refrain
20 from marketing generic AndroGel until 2015. Rather than compete, Solvay and
21 Watson agreed to cooperate on AndroGel and share in monopoly profits.

22 68. Solvay and Watson filed a voluntary stipulation of dismissal terminating
23 their patent litigation in the district court. The parties did not file their settlement and
24 co-promotion agreements with the court, [REDACTED]

25 [REDACTED]
26
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1 **C. Solvay, Par, and Paddock agree not to compete, but rather to cooperate**
2 **and share monopoly profits**

3 69. [REDACTED]
4 [REDACTED]

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

7 [REDACTED]
8 71. [REDACTED]

9 [REDACTED]
10 [REDACTED]

11 72. [REDACTED]
12 [REDACTED]

13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]

18 73. [REDACTED]
19 [REDACTED]

20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

25 [REDACTED]
26 74. [REDACTED]

27 [REDACTED]
28 [REDACTED]

1 [REDACTED]
2 [REDACTED]
3 Ultimately, the parties decided that Par would co-promote AndroGel to doctors and
4 receive \$10 million annually, [REDACTED]

5 [REDACTED] As a Besins executive stated in an e-
6 mail, a “backup manufacturer strategy [was] a partial way to compensate Parr [sic]
7 for not entering the market.”

8 75. [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]

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

23 77. Solvay and Par simultaneously entered into co-promotion and back-up
24 manufacturing deals which provided substantial compensation to Par and Paddock.
25 Under the co-promotion deal, Par agreed to promote AndroGel to primary care
26 doctors and Solvay agreed to pay Par \$10 million per year for six years. Under the
27 back-up manufacturing deal, which Par signed [REDACTED]
28 [REDACTED]

1 [REDACTED]

2 [REDACTED]

3 78. At the same time Par signed its agreements with Solvay, it agreed to
4 transfer \$6 million up front to Paddock through a transfer of title of Paddock's
5 ANDA to Par. This payment was necessary to obtain Paddock's assent to the patent
6 settlement.

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

12 80. The district court hearing the patent litigation dismissed Solvay's patent
13 lawsuit against Paddock under a consent judgment filed by the parties. The parties
14 did not file their settlement, co-promotion, and back-up manufacturing agreements
15 with the court, [REDACTED]

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

18 81. The co-promotion and back-up manufacturing deals served to induce
19 Watson, Par, and Paddock to agree to refrain from marketing generic AndroGel until
20 2015 and provided Solvay the means to share preserved AndroGel monopoly profits
21 with its potential competitors.

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

- 24 • [REDACTED]
- 25 [REDACTED]
- 26 [REDACTED]
- 27 [REDACTED]
- 28 [REDACTED]

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[REDACTED]

[REDACTED]

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

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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

[REDACTED]

[REDACTED]

- [REDACTED]

[REDACTED]

[REDACTED]

- [REDACTED]

[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:

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- [REDACTED]
- [REDACTED]
- [REDACTED]

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.

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

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

- 8 • The patent was invalid under 35 U.S.C. § 102(b) for prior commercial
9 sale or public use of the patented invention, in that Besins offered the
10 invention for sale to Solvay in 1995 – a fact that Solvay and Besins
11 withheld from the Patent and Trademark Office.
- 12 • The patent was invalid as obvious under 35 U.S.C. § 103 because the
13 gel formulations and related methods covered by the patent were
14 obvious variations of existing products and methods. [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
- 18 • Many of the patent claims were invalid under 35 U.S.C. § 112 for
19 failure to meet the “written description” requirement.

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

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

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

5 92. Solvay and Besins were unlikely to prevent generic entry through their
6 patent lawsuits. To do so, Solvay and Besins had to prove infringement by both
7 Watson and Par/Paddock, and also had to defeat each of the generics' invalidity and
8 unenforceability arguments. If either Watson or Par/Paddock had prevailed on any
9 one of these issues, Solvay's formulation patent would not have prevented generic
10 entry.

11 **VIII. The AndroGel Settlements Harm Competition and Consumer Welfare**

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

19 94. Prior to their settlement, Solvay and Par/Paddock were potential
20 competitors. By entering into their agreement, Solvay and Par/Paddock eliminated
21 the potential that (1) Par/Paddock would have marketed generic AndroGel before a
22 final appellate decision in the AndroGel patent litigation; (2) Par/Paddock would
23 have prevailed in the patent litigation and marketed generic AndroGel well before
24 2015; or (3) Solvay and Par/Paddock would have agreed to settle their patent
25 litigation on terms that did not compensate Par/Paddock, but provided for generic
26 entry earlier than 2015.

27 95. Defendants eliminated this potential competition and harmed consumers
28 by entering agreements that compensated Watson and Par/Paddock for agreeing to

1 refrain from marketing generic AndroGel until 2015. Defendants' agreements to
2 eliminate potential competition until 2015 were based not on the strength of Solvay's
3 patent, but on the compensation Solvay provided to Watson, Par, and Paddock in
4 exchange for a 2015 generic entry date. Absent compensation, Watson and
5 Par/Paddock would not have agreed to refrain from competing until 2015, the generic
6 entry date that Solvay demanded.

7 96. Moreover, absent the compensation Solvay agreed to provide, generic
8 competition to AndroGel would have occurred before 2015 because (1) Watson
9 and/or Par/Paddock would have marketed generic AndroGel before a final appellate
10 decision in the AndroGel patent litigation; (2) Solvay would not have prevailed
11 against each of Watson and Par/Paddock in the patent litigation; or (3) Solvay would
12 have agreed to settle the patent litigation on terms that did not compensate Watson
13 and Par/Paddock, but provided for generic entry earlier than 2015.

14 97. Entry of generic AndroGel would give consumers the choice between
15 branded AndroGel and lower-priced generic versions of AndroGel. Many consumers
16 would choose to purchase lower-priced generic drugs instead of higher-priced
17 branded AndroGel. Entry of generic versions of AndroGel would quickly and
18 significantly reduce Solvay's sales of AndroGel, promote economic efficiency, and
19 lead to a significant reduction in the average price purchasers pay for AndroGel and
20 its generic equivalents. Consumers likely would save hundreds of millions of dollars
21 a year by purchasing generic versions of AndroGel. Through their anticompetitive
22 agreements, Defendants have retained those potential consumer savings for
23 themselves.

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

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

1 new branded product, a low volume version of AndroGel, well before 2015. [REDACTED]

2 [REDACTED]
3 [REDACTED] and because generic AndroGel would not be automatically
4 substitutable for Solvay's new branded product, generic entry in 2015 would provide
5 little, if any, consumer savings.

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

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

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

19 **IX. Solvay's Market and Monopoly Power**

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

25 104. In addition, Solvay's market and monopoly power can be shown through
26 circumstantial evidence, including a high share of a relevant market with substantial
27 barriers to entry. Empirical and documentary evidence demonstrate that the relevant
28 market for antitrust purposes in this case is no broader than testosterone drugs

1 delivered transdermally (through the skin) and approved by the FDA for sale in the
2 United States. Other testosterone drugs, such as those delivered by injection, are not
3 close enough substitutes to prevent Solvay and other market participants from
4 profitably raising prices. AndroGel has consistently accounted for more than 70
5 percent of transdermal testosterone drug sales. Substantial barriers to entry exist in
6 the transdermal testosterone drug market, including the need to conduct expensive
7 clinical trials and obtain FDA approval.

8 105. Narrower relevant product markets may also exist for purposes of
9 assessing Defendants' conduct and Solvay's market and monopoly power, including
10 one consisting of AndroGel and its generic equivalents. A unique competitive
11 relationship exists between branded drugs and their generic equivalents, including
12 AndroGel and generic AndroGel. Although other testosterone drugs may be used to
13 treat low testosterone, the availability of these drugs is not sufficient to prevent the
14 anticompetitive effects from Defendants' conduct. Solvay has consistently held a
15 100 percent share of sales of AndroGel and its generic equivalents. Possible sellers
16 of generic AndroGel face substantial barriers to entry, including the need to obtain
17 FDA approval, costly specialized equipment and facilities, and Solvay's ability to
18 trigger an automatic 30-month stay of FDA approval by filing a patent infringement
19 lawsuit. Moreover, Defendants' agreements have diminished the economic
20 incentives to potential generic entrants of challenging the AndroGel formulation
21 patent, since the terms of the agreements allow for immediate entry of generic
22 AndroGel by Watson and Par/Paddock upon the launch of generic AndroGel by any
23 other generic manufacturer.

24 **Count I**

25 **Restraint of Trade – Against Watson and Solvay**

26 106. Plaintiffs reallege and incorporate by reference the allegations in all of
27 the paragraphs above.

1 107. The agreement between Watson and Solvay that Watson will not
2 compete by marketing a generic version of AndroGel until 2015, in exchange for
3 compensation, is an unreasonable restraint of trade that violates Section 1 of the
4 Sherman Act, 15 U.S.C. § 1, and an unfair method of competition that violates
5 Section 5(a) of the FTC Act, 15 U.S.C. § 45(a).

6 **Count II**

7 **Restraint of Trade – Against Par, Paddock, and Solvay**

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

10 109. The agreement among Par, Paddock, and Solvay that Par/Paddock will
11 not compete by marketing a generic version of AndroGel until 2015, in exchange for
12 compensation, is an unreasonable restraint of trade that violates Section 1 of the
13 Sherman Act, 15 U.S.C. § 1, and an unfair method of competition that violates
14 Section 5(a) of the FTC Act, 15 U.S.C. § 45(a).

15 **Count III**

16 **Monopolization – Against Solvay**

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

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

21 112. Solvay has willfully maintained its monopoly power through its
22 agreements with Watson, Par, and Paddock that those companies will not compete by
23 marketing generic versions of AndroGel until 2015, in exchange for compensation.
24 Entry of a generic version of AndroGel would eliminate Solvay’s monopoly with
25 respect to AndroGel. At the time of the agreements, Watson and Par/Paddock were
26 threats to enter with generic versions of AndroGel before 2015. Eliminating this
27 threat of generic entry is conduct that is reasonably capable of contributing
28 significantly to Solvay’s continued monopoly power. Solvay has willfully

1 maintained its monopoly and excluded competition through its anticompetitive
2 conduct. Solvay has unlawfully extended its monopoly not on the strength of its
3 patent, but rather by compensating its potential competitors.

4 113. Solvay's acts are anticompetitive and constitute unlawful
5 monopolization in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2, and an
6 unfair method of competition in violation of Section 5(a) of the FTC Act, 15 U.S.C. §
7 45(a).

8 **Count IV**

9 **Violation of the Cartwright Act – Against all Defendants**

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

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

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

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

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

24 **Count V**

25 **Violation of California Unfair Competition Act – Against All Defendants**

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

28

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

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

7 122. As described above, Defendants' acts violate Cal. Bus. & Prof. Code
8 §§ 17200, *et seq.*, and the State of California is entitled to civil penalties of up to the
9 maximum amount permitted by Cal. Bus. & Prof. Code § 17206 for each violation of
10 Cal. Bus. & Prof. Code § 17200, and injunctive relief.

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

13 **Prayer for Relief**

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

- 21 1. That the agreement between Watson and Solvay violates Section 5(a) of
22 the FTC Act, 15 U.S.C. § 45(a);
23 2. That the agreement among Par, Paddock, and Solvay violates Section
24 5(a) of the FTC Act, 15 U.S.C. § 45(a);
25 3. That Solvay's course of conduct, including its agreements with Watson,
26 Par, and Paddock, violates Section 5(a) of the FTC Act, 15 U.S.C.
27 § 45(a);
28

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

3 5. That the Court grant such other equitable relief as the Court finds
4 necessary to redress and prevent recurrence of Defendants' violations of
5 Section 5(a) of the FTC Act, 15 U.S.C. § 45(a), as alleged herein.

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

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

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

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

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

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

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25 Dated: January __, 2009
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Respectfully submitted,

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