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RECEIVED-CLERK
U.S. DISTRICT COURT

2007 DEC -4 A 9 19

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Attorneys for Plaintiff
Savient Pharmaceuticals, Inc.

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

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	:	
SAVIENT PHARMACEUTICALS, INC.	:	
	:	Civil Action No. <u>06 CV 5782 (PGS)</u>
Plaintiff,	:	
	:	
v.	:	
	:	
SANDOZ, INC. and UPSHER-SMITH	:	
LABORATORIES, INC.	:	
	:	
Defendants.	:	
-----	X	

VERIFIED COMPLAINT FOR PATENT INFRINGEMENT

The Plaintiff, Savient Pharmaceuticals, Inc. ("Savient"), and Paul Hamelin, through their attorney, Donald L. Rhoads, Esq. for their verified complaint against Defendants Sandoz, Inc. ("Sandoz") and Upsher-Smith Laboratories, Inc. ("Upsher-Smith") (collectively

referred to as “Defendants”) alleges as follows based on personal knowledge as to the conduct alleged except where stated to be upon information and belief:

Nature of the Action

1. This is an action for willful patent infringement that arises under the United States Patent Laws, 35 U.S.C. §§ 100 *et seq.* This action relates to Savient’s Oxandrin® drug products for which Defendants are making, using, selling, and/or offering for sale and/or actively inducing, encouraging, contributing to, aiding and abetting others to make, use, sell and/or offer to sell generic versions of Oxandrin®. By this action, and the accompanying Order to Show Cause, Savient seeks a preliminary injunction and pending the appointment of such injunction, an immediate temporary restraining order preventing Defendants from making, using, selling or offering for sale generic Oxandrin ® (oxandrolone).

The Parties

2. Plaintiff Savient is a corporation organized under the laws of the State of Delaware, having its principal place of business at One Tower Center, Fourteenth Floor, East Brunswick, New Jersey 08816.

3. On information and belief, the corporate headquarters of Sandoz’s generic drug business is located at 506 Carnegie Center, Suite 400, Princeton, New Jersey 08540. Additionally, on information and belief, Sandoz maintains a large research and development operation directed to its generic drug operations at 2400 Route 130 North, Dayton, New Jersey 08810.

4. On information and belief, Upsher-Smith is a Minnesota corporation having its principal place of business in 6701 Evenstad Drive, Maple Grove, Minnesota 55369.

Upsher-Smith is engaged in discovery, development and marketing of brand name and generic drugs.

Jurisdiction and Venue

5. This Court has jurisdiction over the subject matter under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202. Venue is proper in this Court under 28 U.S.C. §§ 1391(b), 1391(c), and 1400(b).

6. On information and belief, Sandoz maintains a substantial presence in this judicial district and has continuous and systematic contact with New Jersey. Accordingly, Sandoz is subject to personal jurisdiction in this judicial district and venue is proper.

7. On information and belief, Upsher-Smith maintains a substantial presence in this judicial district and has continuous and systematic contact with New Jersey. Accordingly, Upsher-Smith is subject to personal jurisdiction in this judicial district and venue is proper.

The Patents

8. On February 16, 1999, United States Patent No. 5,872,147, entitled "Use of Oxandrolone in the Treatment of Chronic Obstructive Pulmonary Disease" ("the '147 Patent"), duly and legally issued from the U.S. Patent Office and was subsequently assigned to Savient. A copy of the '147 Patent is attached as Exhibit A.

9. On July 18, 2000, United States Patent No. 6,090,799, entitled "Method for Ameliorating Muscle Weakness/Wasting in a Patient Infected with Human Immunodeficiency Virus-Type 1" ("the '799 Patent"), duly and legally issued from the U.S. Patent Office and was subsequently assigned to Savient. A copy of the '799 Patent is attached as Exhibit B.

10. On June 10, 2003, United States Patent No. 6,576,659, entitled "Use of Oxandrolone in the Treatment of Burns and Other Wounds" ("the '659 Patent"), duly and legally issued from the U.S. Patent Office and was subsequently assigned to Savient. A copy of the '659 Patent is attached as Exhibit C.

11. On December 30, 2003, United States Patent No. 6,670,351, entitled "Method for Ameliorating Muscle Weakness/Wasting in a Patient Infected with Human Immunodeficiency Virus-Type 1" ("the '351 Patent"), duly and legally issued from the U.S. Patent Office and was subsequently assigned to Savient. A copy of the '351 Patent is attached as Exhibit D.

12. On December 22, 2004, United States Patent No. 6,828,313, entitled "Use of Oxandrolone in the Treatment of Burns and Other Wounds" ("the '313 Patent"), duly and legally issued from the U.S. Patent Office and was subsequently assigned to Savient. A copy of the '313 Patent is attached as Exhibit E.

13. At all time from the issuance of the '147, '799, '659, '351, and '313 patents (collectively "the Patents"), Savient or one of its predecessors in interest has been the lawful owner of all rights, title and interest in and to the Patents, including the right to bring actions and recover damages for infringements thereof. As set forth below, Defendants' actions constitute direct infringement, inducement of infringement and contributory infringement of the '147, '799, '659, '351 and '313 Patents in violation of 35 U.S.C. § 271(b) and (c).

Count I: Infringement of the '147 Patent

14. Savient is the approved holder of NDA 13-718 for 2.5 mg and 10 mg oxandrolone tablets. Savient sells 2.5 mg and 10 mg tablets of oxandrolone under the brand name Oxandrin® and markets Oxandrin® for methods described in the Patents. On information and belief, the FDA has approved Defendants' ANDAs for generic 2.5 mg and 10 mg oxandrolone. On information and belief, as a result of the FDA's approval of Defendants' ANDAs, Defendants are marketing, selling and offering to sell generic oxandrolone tablets.

15. The '147 Patent relates to the administration of oxandrolone to treat patients with chronic obstructive pulmonary disease or adult respiratory distress syndrome.

16. On information and belief, Defendants' generic oxandrolone tablets have been manufactured, used, and sold to be administered to practice the method recited by one or more claims of the '147 Patent. Further, such use of oxandrolone tablets will result in direct infringement of the '147 Patent.

17. On information and belief, this infringing use of generic oxandrolone tablets under the '147 Patent will occur at Defendants' active behest, and with its intent, knowledge and encouragement, and Defendants will actively induce, encourage, contribute to,

aid and abet this administration with knowledge that it is in contravention of Savient's rights under the '147 Patent.

18. As a result, Defendants will directly and indirectly infringe the claims of the '147 Patent by direct infringement, inducement of infringement and contributory infringement under 35 U.S.C. §§ 271(b) and (c). Savient has been damaged by Defendants' infringement and will suffer additional and irreparable damages unless this Court enjoins Defendants from continuing its infringement pursuant to 35 U.S.C. § 283.

19. On information and belief, Defendants' infringement of the '147 Patent is willful, entitling Savient to an assessment of treble damages pursuant to 35 U.S.C. § 284.

Count II: Infringement of the '799 Patent

20. Savient repeats and incorporates by reference, as if fully set forth herein, the allegations contained in paragraphs 1 through 19 above.

21. The '799 Patent relates to the administration of oxandrolone to ameliorate HIV-associated myopathy and muscle weakness in AIDS patients.

22. On information and belief, Defendants' generic oxandrolone tablets have been manufactured, used, and sold to be administered to practice the method recited by one or more claims of the '799 Patent. Further, such use of oxandrolone tablets will result in direct infringement of the '799 Patent.

23. On information and belief, this infringing use of generic oxandrolone tablets under the '799 Patent will occur at Defendants' active behest, and with its intent, knowledge and encouragement, and Defendants will actively induce, encourage, contribute to, aid and abet this administration with knowledge that it is in contravention of Savient's rights under the '799 Patent.

24. As a result, Defendants will directly and indirectly infringe the claims of the '799 Patent by direct infringement, inducement of infringement and contributory infringement under 35 U.S.C. §§ 271(b) and (c). Savient has been damaged by Defendants' infringement and will suffer additional and irreparable damages unless this Court enjoins Defendants from continuing its infringement pursuant to 35 U.S.C. § 283.

25. On information and belief, Defendants' infringement of the '799 Patent is willful, entitling Savient to an assessment of treble damages pursuant to 35 U.S.C. § 284.

Count III: Infringement of the '659 Patent

26. Savient repeats and incorporates by reference, as if fully set forth herein, the allegations contained in paragraphs 1 through 25 above.

27. The '659 Patent relates to the administration of oxandrolone to treat patients with skin wounds and burns.

28. On information and belief, Defendants' generic oxandrolone tablets have been manufactured, used, and sold to be administered to practice the method recited by one or more claims of the '659 Patent. Further, such use of oxandrolone tablets will result in direct infringement of the '659 Patent.

29. On information and belief, this infringing use of generic oxandrolone tablets under the '659 Patent will occur at Defendants' active behest, and with its intent, knowledge and encouragement, and Defendants will actively induce, encourage, contribute to, aid and abet this administration with knowledge that it is in contravention of Savient's rights under the '659 Patent.

30. As a result, Defendants will directly and indirectly infringe the claims of the '659 Patent by direct infringement, inducement of infringement and contributory

infringement under 35 U.S.C. §§ 271(b) and (c). Savient has been damaged by Defendants' infringement and will suffer additional and irreparable damages unless this Court enjoins Defendants from continuing its infringement pursuant to 35 U.S.C. § 283.

31. On information and belief, Defendants' infringement of the '659 Patent and is willful, entitling Savient to an assessment of treble damages pursuant to 35 U.S.C. § 284.

Count IV: Infringement of the '351 Patent

32. Savient repeats and incorporates by reference, as if fully set forth herein, the allegations contained in paragraphs 1 through 31 above.

33. The '351 Patent relates to the administration of oxandrolone to ameliorate HIV-associated myopathy and muscle weakness in AIDS patients.

34. On information and belief, Defendants' generic oxandrolone tablets have been manufactured, used, and sold to be administered to practice the methods recited by one or more claims of the '351 Patent. Further, such use of oxandrolone tablets will result in direct infringement of the '351 Patent.

35. On information and belief, this infringing use of generic oxandrolone tablets under the '351 Patent will occur at Defendants' active behest, and with its intent, knowledge and encouragement, and Defendants will actively induce, encourage, contribute to, aid and abet this administration with knowledge that it is in contravention of Savient's rights under the '351 Patent.

36. As a result, Defendants will directly and indirectly infringe the claims of the '351 Patent by direct, inducement and contributory infringement under 35 U.S.C. §§ 271(b) and (c). Savient has been damaged by Defendants' infringement and will suffer additional and

irreparable damages unless this Court enjoins Defendants from continuing its infringement pursuant to 35 U.S.C. § 283.

37. Defendants' infringement of the '351 Patent and is willful, entitling Savient to an assessment of treble damages pursuant to 35 U.S.C. § 284.

Count V: Infringement of the '313 Patent

38. Savient repeats and incorporates by reference, as if fully set forth herein, the allegations contained in paragraphs 1 through 37 above.

39. The '313 Patent relates to the administration of oxandrolone to increase the rate of healing of skin wounds and to increase the rate of weight gain after burn induced weight loss.

40. On information and belief, Defendants' generic oxandrolone tablets have been manufactured, used, and sold to be administered to practice the method recited by one or more claims of the '313 Patent. Further, such use of oxandrolone tablets will result in direct infringement of the '313 Patent.

41. On information and belief, this infringing use of generic oxandrolone tablets under the '313 Patent will occur at Defendants' active behest, and with its intent, knowledge and encouragement, and Defendants will actively induce, encourage, contribute to, aid and abet this administration with knowledge that it is in contravention of Savient's rights under the '313 Patent.

42. As a result, Defendants will directly and indirectly infringe the claims of the '313 Patent by direct infringement, inducement of infringement and contributory infringement under 35 U.S.C. §§ 271(b) and (c). Savient has been damaged by Defendants'

infringement and will suffer additional and irreparable damages unless this Court enjoins Defendants from continuing its infringement pursuant to 35 U.S.C. § 283.

43. Defendants' infringement of the '313 Patent and is willful, entitling Savient to an assessment of treble damages pursuant to 35 U.S.C. § 284.

Prayer for Relief

WHEREFORE, Savient demands judgment against Defendants and respectfully prays that this Court enter orders which:

(a) Preliminarily and permanently enjoin Defendants and its officers, agents, employees and all others in concert or participation with it, including without limitation, its parent corporation and subsidiaries, from further acts of direct infringement, inducement of infringement, and contributory infringement of the '147, '799, '659, '351 and '313 Patents;

(b) Award to Savient the damages it has sustained by reason of Defendants' acts of inducement of infringement and contributory infringement, and the resulting direct infringement, together with pre- and post-judgment interest as allowed by law;

(c) Award to Savient treble the damages assessed pursuant to 35 U.S.C. § 284 by reason of the willful nature of Defendants' infringement;

(d) Declare this case to be "exceptional" and award to Savient its reasonable attorneys' fees pursuant to 35 U.S.C. § 285;

(e) Award to Savient its costs and expenses of this action as allowed by law;
and

(f) Award to Savient such other and further relief as the Court may deem just and proper.

**SAIBER SCHLESINGER SATZ &
GOLDSTEIN, LLC**

Attorneys for Plaintiff Savient Pharmaceuticals, Inc.

DATED: December 4, 2006

By: 

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George Tenreiro

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Attorney for Plaintiff

Of Counsel:

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RULE 11.2 CERTIFICATION

I hereby certify that this matter is not the subject of any other action asserted by the Plaintiff herein, or of any pending arbitration, except for a matter now pending in this District entitled *Savient Pharmaceuticals, Inc. v. Barr Laboratories, Inc.*, Civil Action No. 06-4636 (JAG).

**SAIBER SCHLESINGER SATZ &
GOLDSTEIN, LLC**
Attorneys for Plaintiff Savient Pharmaceuticals, Inc.

DATED: December 4, 2006

By



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RULE 201.1 CERTIFICATION

Pursuant to L. Civ. R. 201.1, the undersigned counsel for the Plaintiff hereby certifies that the amount in controversy, excluding interest, costs and punitive damages exceeds \$150,000, and that this action is not appropriate for compulsory arbitration.

**SAIBER SCHLESINGER SATZ &
GOLDSTEIN, LLC**

Attorneys for Plaintiff Savient Pharmaceuticals, Inc.

DATED: December 4, 2006

By: 

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27. Accordingly, if the Defendants release a generic product prior to the expiration of the Patents, the public interest would be significantly impacted.

28. No matter what a potential damage award is, the losses to Savient from a premature generic entry by the Defendants will never be fully compensable in money damages.

Pursuant to 28 U.S.C. § 1746, I certify under penalty of perjury that the foregoing is true and correct.

Executed this 4th day of December 2006.



Paul Hamelin

VERIFICATION

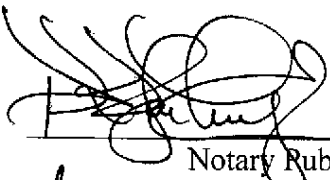
STATE OF _____)
 SS:
COUNTY OF _____)

I, the undersigned, being duly sworn, say. I am the SENIOR VICE PRESIDENT OF COMMERCIAL OPERATIONS of SAVIENT PHARMACEUTICALS, INC. a DELAWARE corporation and a party in this action; I have read the foregoing VERIFIED COMPLAINT and know the contents thereof; and the same is true to my own knowledge, except as to the matters therein stated to be alleged upon information and belief, and as to those matters I believe it to be true. This verification is made by me because the above party is a corporation and I am an officer thereof. The basis for my knowledge and belief is information provided to me by others and/or documents I have reviewed.



Paul Hamelin

Sworn to before me this
4th day of December, 2006



Notary Public
ATTORNEY AT LAW
STATE OF NJ
BAR# 02190-1981