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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SAVIENT PHARMACEUTICALS, INC. Plaintiff, v. SANDOZ, INC. and UPSHER-SMITH LABORATORIES, INC. Defendants.	Civil Action No. 2:06-cv-05782-PGS-RJH

FIRST DECLARATION OF BERNHARD HAMPL

I BERNHARD HAMPL declare that:

1. I am the President and CEO of Sandoz, Inc. ("Sandoz"), 506 Carnegie Center, Princeton, New Jersey 08540. I make this declaration in support of Sandoz, Inc.'s opposition to Savient Phamaceutical, Inc.'s ("Savient") request for a temporary restraining order and a preliminary injunction. I am fully familiar with the facts set forth herein.

A. **REGULATORY MATTERS**

2. On or around November 11, 2003, Sandoz filed ANDA No. 07-6897 ("Sandoz' ANDA") for 2.5 and 10.0 mg oxandrolone tablets -- a generic version of plaintiff Savient's Oxandrin® product. Actually, the ANDA was filed by Eon Labs, Inc., which has since been acquired by Sandoz, Inc.

3. The brand name Oxandrin® product was first approved in 1964. (See Oxandrin® Label and Approval History, attached at Exhibit 1). At that time Savient was not the holder of the NDA for Oxandrin®. It is my understanding that Savient was first established years later, in 1980. *See* Hamelin Decl. at ¶5.

4. Before we proceeded with the preparation and filing of Sandoz' ANDA, we reviewed the Food and Drug Administration's ("FDA") "Approved Drug Products with Therapeutic Equivalence Evaluations" ("Orange Book"), which lists patents which cover brand name products and methods of using them. *See* 21 U.S.C. §355(b)(1).

5. At no time during the preparation and up to the filing of Sandoz' ANDA did the Orange Book list any patents for oxandrolone or for methods of its use. Relying on Savient's listing of no patents in the Orange Book, Sandoz filed a certification with the Food and Drug Administration ("FDA") "that such patent information has not been filed [with FDA]" under 21 U.S.C. §355(j)(2)(A)(vii)(I) ("Paragraph I Certification" filed in Sandoz ANDA, dated November 7, 2003, attached at Exhibit 2). Sandoz proceeded with its ANDA (including substantial investments in time, funding, and other resources) with the understanding that Savient had not listed any patents for its oxandrolone product or for methods of its use.

6. The Physicians' Desk References ("PDR"), including the PDR from 1988, includes the package insert for oxandrolone tablets marketed by Searle & Co. as "Anavar®", and contains an "Indications and Usage" section which reads:

> "Anavar is indicated as adjunctive therapy [1] to promote weight gain after weight loss following extensive surgery, chronic infections, or severe trauma, and in some patients who without definite pathophysiologic reasons fail to gain or maintain normal weight, [2] **to offset the protein catabolism associated with prolonged administration of corticosteroids, and [3] for the relief of the bone pain frequently accompanying osteoporosis.'"**

(Physicians' Desk Reference, 42nd Ed. (1988) at p. 1976, attached at Exhibit 3, emphasis added).[1]

7. The package insert for Sandoz' oxandrolone product, as approved by the FDA, contains only the following Indications and Usage:

> "Oxandrolone is indicated as adjunctive therapy [1] to offset the protein catabolism associated with prolonged administration of corticosteroids, and [2] for the relief of the bone pain frequently accompanying osteoporosis.'"

(Sandoz' FDA-approved package insert for its oxandrolone tablets, attached at Exhibit 4). As is evident, these are two of the three Indications and Usage for oxandrolone tablets that appear in the 1988 PDR. This is the only package insert that will be distributed with Sandoz's generic oxandrolone product.

8. After Sandoz filed its ANDA, Savient listed its method of use patents -- U.S. Patent Nos. 5,872,147; 6.090,799; 6,576,659; 6,670,351; and 6,828,313 -- in the Orange Book. ("Savient patents").

9. Because four of the five Savient patents were belatedly listed by Savient, Sandoz was not required to certify to those patents 21 C.F.R. § 314.94(a)(12)(vi). However, as to the one timely listed patent, 6,828,313, Sandoz certified under 21 U.S.C. § 355(j)(2)(A)(viii) that that patent does "not claim a use for which [Sandoz] is seeking approval". (Sandoz' Paragraph (viii)

[1] All multiple page exhibits have been numbered in the lower right hand corner for ease of reference.

Certification, attached to Exhibit 5, hereto, Sandoz' April 26, 2005 "Patent Amendment", p. 7 (the copy of the certification submitted to the FDA was signed and dated, the attached copy is an unsigned file copy)). Sandoz also carved out from its proposed package insert the methods of use claimed in the Savient patents (Sandoz' May 4, 2005 "Final Printed Labeling Amendment", pp. 5-6, attached at Exhibit 6), and it is that package insert (attached at Exhibit 4) that has been approved by FDA (*see* December 1, 2006 letter from FDA finally approving Sandoz' ANDA, copy attached at Exhibit 7). Note that Exhibit 7, the approval letter from FDA, confirms the manner in which Sandoz treated Savient's Patents, as set forth above.

10. The current package insert for Oxandrin®, as marketed by Savient, is attached at Exhibit 8 hereto.

B. MARKETING MATTERS

11. Sandoz did not, does not and will not market, advertise, promote, use training videos for, solicit, or otherwise provide instructions or indications for any uses if its generic oxandrolone tablets other than the two Indications and Usage listed in the package insert attached hereto at Exhibit 4.

12. Sandoz did not conduct any studies, analyses, or investigations of patient usage of oxandrolone, and has no knowledge of what percentage of patients use oxandrolone for the various usages for which it has been approved or for so-called "off label" usages, i.e., usages for which oxandrolone has not been approved by FDA.

13. As a result of Savient's present motion, Sandoz has not yet shipped any of its finally approved oxalondrone product to Sandoz's customers.

I declare under penalty of perjury that the foregoing is true and correct.

Signed at Princeton, New Jersey on December 5, 2006