

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

JANSSEN PHARMACEUTICALS, INC.,)	
)	
Plaintiff,)	
)	
v.)	C.A. No. _____
)	
VIVUS, INC.,)	
)	
Defendant.)	
)	

COMPLAINT

Plaintiff Janssen Pharmaceuticals, Inc. (“Janssen”) for its complaint of patent infringement against Defendant VIVUS, Inc. (“Defendant” or “Vivus”), hereby alleges as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement of U.S. Patent No. 6,071,537 (“the ‘537 Patent”), arising under the patent laws of the United States, Title 35 of the U.S. Code.

PARTIES

2. Janssen is a Pennsylvania corporation with a principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560.

3. On information and belief, Defendant Vivus is a corporation organized under the laws of the State of Delaware, with a place of business at 351 E. Evelyn Ave., Mountain View, California 94041. Vivus resides in this District, pursuant to 28 U.S.C. § 1391(c).

JURISDICTION AND VENUE

4. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 (federal question) and 1338 (any act of Congress relating to patents).

5. This Court has personal jurisdiction over Vivus because, among other things, Vivus is a corporation formed and existing under Delaware law.

6. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b), (c), and/or 1400(b), because, among other things, Vivus is subject to personal jurisdiction in this judicial district.

THE PATENT-IN-SUIT

7. On June 6, 2000, the United States Patent and Trademark Office duly and lawfully issued the '537 Patent, titled "Anticonvulsant Derivatives Useful in Treating Obesity" (Ex. A). The '537 Patent was assigned to Ortho Pharmaceutical Corp., a predecessor to Janssen. Janssen now owns the '537 Patent. The '537 Patent covers methods for treating obesity by administering certain compounds, including the compound topiramate.

VIVUS'S INFRINGEMENT

8. Vivus is exploiting the invention of the '537 Patent by selling its drug Qsymia.

9. Qsymia is a combination of two active compounds, phentermine and topiramate. According to Vivus, "Qsymia is a prescription medicine that contains phentermine and topiramate . . . that may help some obese adults . . . lose weight and keep the weight off" (Qsymia Medication Guide at 2 (Ex. B)). The FDA has approved Qsymia for use in "chronic weight management in adults with an initial body mass index (BMI)" that is too high (Qsymia Label, Revised April 2013, at 1 (Ex. C)). On information and belief Qsymia has no other approved indications.

10. The '537 Patent is directly infringed when Qsymia, which contains the compound topiramate, is administered for treating obesity, including when it is used for chronic weight management in an obese patient.

11. On information and belief, Vivus has known about the '537 Patent, and known that use of Qsymia would infringe that patent, since prior to July 17, 2012, the date the FDA approved Qsymia for sale in the United States. On information and belief, Vivus requested a license from Janssen under the '537 Patent in 2007. Negotiations between Janssen and Vivus pertaining to an assignment or license under the '537 Patent resumed when Janssen contacted Vivus on July 3, 2012, prior to the FDA's approval of Qsymia. To the best of Janssen's recollection, Vivus never stated during those negotiations that it believed the '537 Patent was invalid or not infringed.

12. Additionally, on information and belief, Vivus has known of the '537 Patent based on the prosecution history of Vivus's own patents. For example, Vivus is listed as the assignee of U.S. Patent No. 7,056,890 ("the '890 Patent"). The '890 Patent issued from Application No. 10/454,368, which was filed on June 3, 2003, and covers the use of a combination of phentermine and topiramate for the treatment of obesity. The inventor of the '890 Patent, Thomas Najarian, assigned that application to Vivus on June 11, 2003. On December 5, 2005, during prosecution of that application, the applicant expressly argued that the invention of the '890 Patent was patentable over a combination of references that included the '537 Patent.

13. Vivus has actively and knowingly induced, and continues to actively and knowingly induce acts of direct infringement by selling Qsymia for use by obese patients and instructing its customers on the appropriate dosage and administration of Qsymia for use in treating obese patients (Ex. C, § 2.1). Vivus's instructions for administering Qsymia, coupled with its knowledge of the '537 patent and its failure to allege that the '537 patent is invalid or not infringed, demonstrate that Vivus has the specific intent to cause infringement of the '537 Patent.

14. In addition, based on Qsymia's approved indication and prescribing information, coupled with Vivus's knowledge of the '537 patent, Vivus makes and sells Qsymia specifically for use in infringing the '537 Patent. On information and belief, Qsymia has no substantial non-infringing uses. Vivus therefore has contributed to and continues to contribute to acts of direct infringement by selling Qsymia.

COUNT FOR PATENT INFRINGEMENT

15. Janssen incorporates by reference paragraphs 1-14 as if fully set forth herein.

16. As set forth above, on information and belief, by selling Qsymia in the United States for the treatment of obesity, Vivus is infringing the '537 Patent, including by actively inducing infringement under 35 U.S.C. § 271(b), and by contributing to infringement under 35 U.S.C. § 271(c).

17. On information and belief, Vivus has been aware of the '537 Patent since prior to July 17, 2012 and its infringement has been deliberate, willful, and in reckless disregard of valid claims of the '537 Patent.

18. Janssen has been and will continue to be injured by, and has suffered and will continue to suffer substantial damages as a result of, Vivus's infringement.

REQUEST FOR RELIEF

Wherefore, Janssen respectfully requests the following relief:

(a) the entry of judgment that Vivus has infringed and continues to infringe the '537 Patent by selling Qsymia;

(b) an award of damages sufficient to compensate Janssen for infringement of the '537 Patent, together with pre- and post-judgment interest and costs as fixed by the Court as provided by 35 U.S.C. § 284;

(c) an award of damages sufficient to compensate Janssen for any ongoing or future infringement of the '537 Patent, in an amount and under terms appropriate for the circumstances;

(d) the entry of a permanent injunction enjoining Vivus, and its officers, directors, employees, agents, and those acting in concert with them, from further infringement of the '537 Patent;

(e) a finding that Vivus's infringement has been willful, and an award to Janssen of increased damages pursuant to 35 U.S.C. § 284;

(f) a finding that this is an exceptional case, and an award to Janssen of its reasonable attorneys' fees, costs, and expenses in this action pursuant to 35 U.S.C. § 285;

(g) such other relief as the Court deems just and proper.

ASHBY & GEDDES

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