

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

BRIGHAM AND WOMEN’S HOSPITAL,
INC. and INVESTORS BIO-TECH, L.P.,

Plaintiffs,

v.

PERRIGO COMPANY and L. PERRIGO
COMPANY,

Defendants.

Civ. No. 13-cv-11640

JURY TRIAL DEMANDED

FIRST AMENDED COMPLAINT

Plaintiffs Brigham and Women’s Hospital, Inc. (“BWH”) and Investors Bio-Tech, L.P. (“IBT”) (collectively “Plaintiffs”) file this Complaint for patent infringement against Perrigo Company and L. Perrigo Company (collectively, “Perrigo” or “Defendants”) under 35 U.S.C. § 271.

BACKGROUND

1. Pepcid Complete® contains a combination of antacid and famotidine, an acid-reducer, for the treatment of episodic heartburn. The development of Pepcid Complete® was the culmination of methods and formulations invented by Dr. M. Michael Wolfe—working at BWH—and taught and claimed in the patent-in-suit, United States Patent No. 5,229,137 (the “137 patent”).

2. When Perrigo sought approval from the Food and Drug Administration (“FDA”) to market its generic version of Pepcid Complete® pursuant to the Hatch-Waxman Act, 21 U.S.C. § 355(j)(1), (j)(2)(A), (j)(7)(A), Perrigo certified against the patents listed in the FDA’s list of Approved Drug Products with Therapeutic Equivalent Evaluations, commonly known as

the “Orange Book,” including the ’137 patent. Perrigo, however, did not make allegations that its proposed generic version of Pepcid Complete® would not infringe the relevant claims of the ’137 patent in its paragraph IV certification. And when the makers of Pepcid Complete® sued Perrigo on another Orange Book patent, Perrigo successfully argued that the teachings in the earlier ’137 patent invalidated the other patent.

3. Through this action, BWH seeks a reasonable royalty for Defendants’ unauthorized and unlawful use of the innovations claimed in the ’137 patent.

THE PARTIES

4. Plaintiff BWH is a Massachusetts hospital having a principal place of business at 75 Francis Street, Boston, Massachusetts 02115. BWH is a teaching affiliate of Harvard Medical School.

5. Plaintiff IBT is a Delaware limited partnership having a principal place of business at 111 Speen Street, Suite 303, Framingham, Massachusetts 01701. IBT is engaged in developing new technology and intellectual property relating to patient care.

6. On information and belief, defendant Perrigo Company is a Michigan corporation having a principal place of business at 515 Eastern Avenue, Allegan, Michigan 49010. Perrigo Company is a health care supplier that develops, manufactures and distributes generic over-the-counter (“OTC”) and prescription pharmaceuticals throughout the United States, including in the Commonwealth of Massachusetts. The Company states on its website that it is the world’s largest store brand manufacturer of OTC pharmaceutical products.

7. On information and belief, defendant L. Perrigo Company is a Michigan corporation having a principal place of business at 515 Eastern Avenue, Allegan, Michigan 49010. L. Perrigo Company is a wholly owned subsidiary of Perrigo Company.

JURISDICTION AND VENUE

8. This is an action for patent infringement arising under the patent laws of the United States, Title 35 of the United States Code. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

9. This Court has personal jurisdiction over each Defendant because each Defendant has, directly or through intermediaries, committed acts within Massachusetts giving rise to this action and/or has established minimum contacts with Massachusetts such that the exercise of jurisdiction would not offend traditional notions of fair play and justice.

10. Venue is proper in this district under 28 U.S.C. §§ 1391 and 1400.

COUNT I: INFRINGEMENT OF U.S. PATENT NO. 5,229,137

11. Plaintiffs incorporate by reference each and every allegation of paragraphs 1-10 of this Complaint, as though fully set forth herein.

12. On July 20, 1993, the '137 patent, entitled "Methods and Pharmaceutical Compositions for Treating Episodic Heartburn," was duly and legally issued. The '137 patent has recently expired.

13. A true copy of the '137 patent is attached hereto as Exhibit A.

14. BWH is and was at all relevant times the sole owner of the entire right, title, and interest in and to the '137 patent, including the right to sue and recover damages for any and all infringement thereof. IBT was at all relevant times the exclusive licensee of the '137 patent.

15. On information and belief, Perrigo holds Abbreviated New Drug Application ("ANDA") No. 77-355, directed to tablets containing 10 mg famotidine, 165 mg magnesium hydroxide, and 800 mg calcium carbonate (the "Perrigo generic product"). The Perrigo generic product is a generic version of the over-the-counter brand product Pepcid Complete®, which has the same amounts of the same active ingredients.

16. The '137 patent is listed in the Orange Book in conjunction with Pepcid Complete®, and at least claim 4 of the '137 patent covers Pepcid Complete®.

17. Plaintiffs have complied with the marking requirements of 35 U.S.C. § 287(a) by, inter alia, following all FDA regulations regarding seeking and obtaining the approval of Pepcid Complete, including listing the '137 patent in the Orange Book in association with Pepcid Complete.

18. On information and belief, the Perrigo generic product is marketed to consumers in the United States under a variety of OTC store brands. The Perrigo generic product was launched in or about the third quarter of 2008.

19. Perrigo's ANDA is the only approved ANDA for a generic version of Pepcid Complete®, as reflected in the Orange Book, and, on information and belief, Perrigo is therefore the source of all FDA-approved generic versions of Pepcid Complete® marketed in the United States.

20. At all relevant times, Perrigo has had actual knowledge of the '137 patent and obtained such knowledge by reference to the Orange Book listing for Pepcid Complete. In connection with its ANDA filing, Perrigo filed a Certification of Invalidity or Non-Infringement of the '137 patent with the FDA. The statement of the factual and legal basis for Perrigo's Certification contains no allegation that the Perrigo generic product does not infringe claim 4 of the '137 patent.

21. Prior to the expiration of the '137 patent, Defendants were directly infringing at least claim 4 of the patent by making, using, importing, selling, and/or offering to sell the Perrigo generic product.

22. Prior to the expiration of the '137 patent, Defendants were inducing infringement of at least claim 4 of the patent by intentionally encouraging acts of direct infringement by others, including, but not limited to, Defendants' customers, with knowledge that their acts were encouraging infringement. Defendants sold and distributed the Perrigo generic product with instructions for its use to treat gastric conditions, including episodic heartburn.

23. Prior to the expiration of the '137 patent, Defendants were contributing to infringement of at least claim 4 of the patent by offering to sell, selling, and/or importing the Perrigo generic product despite knowing that it is especially adapted for a use that infringes the '137 patent and that there is no substantial non-infringing use for the product.

24. As a result of the infringement of the '137 patent, Plaintiffs have been damaged and are entitled to be compensated for such damages, pursuant to 35 U.S.C. § 284, in an amount to be determined at trial, but no less than a reasonable royalty.

WILLFUL INFRINGEMENT

25. On information and belief, Defendants purposefully engaged in their infringing activities despite knowledge of an objectively high likelihood that their actions constituted infringement of a valid claim of the '137 patent, warranting an award of increased damages and a finding that this case is "exceptional" pursuant to 35 U.S.C. §§ 284 and 285.

JURY TRIAL DEMAND

26. Plaintiffs request a jury trial on all appropriate issues.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter:

1. A judgment in favor of Plaintiffs that Defendants have infringed the '137 patent;

2. A judgment and order requiring Defendants to pay Plaintiffs their damages, costs, expenses, and prejudgment and post-judgment interest for Defendants' infringement of the '137 patent as provided under 35 U.S.C. § 284;
3. An award to Plaintiffs of treble damages resulting from the knowing, deliberate, and willful nature of Defendants' prohibited conduct, as provided under 35 U.S.C. § 284;
4. A judgment and order finding that this is an exceptional case within the meaning of 35 U.S.C. § 285 and awarding to Plaintiffs their reasonable attorneys' fees; and
5. Any and all other relief as the Court deems just and proper.

BRIGHAM AND WOMEN'S HOSPITAL, INC.
and INVESTORS BIO-TECH, L.P.
By their attorneys;

Dated: June 2, 2015

/s/ James M. Bollinger
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CERTIFICATE OF SERVICE

I hereby certify that this document, filed through the ECF system, will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (“NEF”) and paper copies will be sent to those indicated as non-registered participants on the date of its filing.

/s/ James M. Bollinger _____

James M. Bollinger