

**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

SMITH & NEPHEW, INC.,

Plaintiff,

V.

HOLOGIC, INC.,

Defendant.

Civil Action No. \_\_\_\_\_

## JURY TRIAL DEMANDED

## COMPLAINT

Plaintiff Smith & Nephew, Inc. (“Smith & Nephew”) by and through counsel, for its Complaint against Defendant Hologic, Inc. (“Hologic”) states and alleges as follows:

## PARTIES

1. Smith & Nephew is a corporation existing and organized under the laws of the State of Delaware, with its principal place of business in Memphis, Tennessee and maintains a place of business at 150 Minuteman Road, Andover, Massachusetts 01810.

2. On information and belief, Hologic is a corporation existing and organized under the laws of the State of Delaware, with a principal place of business at 35 Crosby Drive, Bedford, Massachusetts 01730.

## JURISDICTION AND VENUE

3. This action arises under the Patent Laws of the United States, including *inter alia* 35 U.S.C. §§ 271, 281, 283, 284, and 285. Subject matter jurisdiction is conferred upon this Court by 28 U.S.C. §§ 1331 and 1338(a).

4. This Court has personal jurisdiction over Hologic, and venue is proper in this Court pursuant to 28 U.S.C. §§ 1391 and 1400.

**COUNT I INFRINGEMENT OF U.S. PATENT NO. 8,061,359**

5. Smith & Nephew repeats and incorporates by reference the allegations in paragraphs 1-4 as if fully set forth herein.

6. On November 22, 2011, U.S. Patent No. 8,061,359 (“the ’359 Patent”), entitled “Surgical Endoscopic Cutting Device And Method For Its Use” was duly and lawfully issued by the United States Patent and Trademark Office. A true and correct copy of the ’359 Patent is attached as Exhibit A.

7. Smith & Nephew is the sole and exclusive assignee and owner of the ’359 Patent by virtue of assignments that have been duly and properly recorded by the United States Patent and Trademark Office in its official files. Smith & Nephew holds the right to sue for and recover all damages for infringement thereof.

8. The claims of the ’359 Patent generally recite a method for the removal of tissue from a uterus by inserting an endoscope with specific features into the uterus, followed by inserting a motor driven cutter into the endoscope such that it extends into the uterus, delivering fluid through the endoscope into the uterus, energizing the motor to drive the cutter and to cut tissue within the uterus, and removing cut tissue and fluid through the cutter.

9. Smith & Nephew manufactures, markets, sells and/or offers to sell its TRUCLEAR™ System, primarily comprising a number of separately sold items which are designed to be used together to remove tissue, including polyps and fibroids, from a uterus by inserting an endoscope (also referred to as a “hysteroscope”) into the uterus, followed by inserting a motor driven cutter into the hysteroscope such that the cutter extends into the uterus,

delivering fluid through the hysteroscope into the uterus, energizing the motor to drive the cutter and to cut tissue within the uterus, and removing cut tissue and fluid through the cutter.

10. Hologic, either alone or in conjunction with others, makes, uses, sells, and/or offers to sell its MyoSure® Tissue Removal System (“MyoSure® System”), primarily comprising separately sold items including the MyoSure® Tissue Removal Device, MyoSure® Rod Lens Hysteroscope, and a control unit which drives the MyoSure® Tissue Removal Device. Hologic, either alone or in conjunction with others, makes, uses, sells, and/or offers to sell the MyoSure® System to doctors, hospitals, and/or other customers and/or potential customers for purposes of using the MyoSure® System for the removal of tissue, including fibroids and polyps, from a patient’s uterus. Hologic and Smith & Nephew are direct competitors with respect to the manufacture, use, sale and/or offer to sell products with the intended use of removing polyps and fibroids from the uterus.

11. As stated in materials posted on Hologic’s website ([www.hologic.com](http://www.hologic.com)) and otherwise distributed by Hologic, Hologic sells and/or offers to sell the MyoSure® System to customers for the purpose of using the MyoSure® System in a manner that infringes the methods claimed in the ’359 Patent. There is no substantially non-infringing use of the MyoSure™ System.

12. On November 21, 2011, Smith & Nephew caused a letter to be delivered to Hologic, in which it informed Hologic of the imminent issuance of the ’359 Patent, and further informed Hologic that any continued manufacture, use, sale, and/or offer to sell any component of the MyoSure® System for the purpose of using the method claimed in the ’359 Patent after its issuance would constitute indirect infringement of at least Claims 1, 3 and 4 of the ’359 Patent as

set forth in the claim chart attached to that letter. A copy of the November 21, 2011 letter and the claim chart enclosed therewith is attached hereto as Exhibit B.

13. The '359 Patent issued on November 22, 2011. However, as of the filing of this Complaint, Hologic continues to use, sell, and/or offer to sell the MyoSure® System to customers for the purpose of using the MyoSure® System in a manner that infringes the methods claimed in the '359 Patent. Accordingly, at least as of November 22, 2011, Hologic has contributed to and/or induced the infringement of the '359 Patent by continuing its sale and/or offers to sell the MyoSure® System to customers and/or potential customers, knowing that the MyoSure® System and the various items that comprise the system are especially made or especially adapted to be used in a manner that infringes the '359 Patent, and further knowing that neither device has a substantial non-infringing use. Hologic is thus liable for infringement of the '359 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

14. Upon information and belief Hologic's infringement is continuing. Hologic is aware of the '359 Patent and has willfully infringed. Hologic's continued and willful infringement of the '359 Patent renders this an exceptional case pursuant to 35 U.S.C. § 285.

15. Smith & Nephew has been and continues to be damaged and irreparably harmed by Hologic's manufacture, use, sale, and/or offer to sell the MyoSure® System in direct competition with Smith & Nephew's TRUCLEAR™ System.

#### **PRAYER FOR RELIEF**

WHEREFORE, Smith & Nephew respectfully requests that this Court enter:

1. A judgment that Hologic has infringed the '359 Patent either literally or, in the alternative under the doctrine of equivalents;

2. A preliminary and permanent injunction issued pursuant to 35 U.S.C. § 283, restraining and enjoining Hologic and their officers, agents, attorneys and employees, and those acting in privity or concert with them, from infringement of the '359 Patent for the full term thereof;

3. An award of damages to Smith & Nephew including pre-judgment and post-judgment interest, in an amount adequate to compensate for Hologic's infringement of the '359 Patent, and, if willful infringement is shown, that the damages be trebled pursuant to 35 U.S.C. § 284;

4. An award of costs and expenses in this action to Smith & Nephew;

5. A declaration that this is an exceptional case and an award of attorney's fees, disbursements, and costs of this action pursuant to 35 U.S.C. § 285; and

6. Such other and further relief as the Court may deem just and proper.

#### **DEMAND FOR JURY TRIAL**

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, plaintiff respectfully requests a trial by jury on any issues so triable by right.

November 22, 2011

Respectfully submitted,

**Smith & Nephew, Inc.**

*By Its Attorneys*

/s/ Joseph J. Leghorn

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