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VENTANA MEDICAL SYSTEMS, INC.

IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

VENTANA MEDICAL SYSTEMS, INC., Plaintiff, v. HOLOGIC, INC. Defendant.	Case No. 3:16-cv-002703 **PLAINTIFF VENTANA MEDICAL SYSTEM, INC.'S COMPLAINT FOR DECLARATORY JUDGMENT** DEMAND FOR JURY TRIAL

Plaintiff Ventana Medical System, Inc. ("Ventana"), for its Complaint against Defendant Hologic, Inc. ("Hologic") alleges as follows:

NATURE OF THE ACTION

1. This is a declaratory judgment action arising under the Declaratory Judgment Act, 28 U.S. C. § 2201 *et seq*. and the Patent Laws of the United States, 35 U.S.C. § 1, *et seq*. Ventana seeks a declaration of non-infringement and invalidity of U.S. Patent No. 7,718,369 ("the '369 patent").

PARTIES

2. Ventana is a corporation organized and existing under the laws of the State of Delaware, with its headquarters at 1910 E. Innovation Park Drive, Tucson, Arizona 85755 and an antibody research and production facility located at 4300 Hacienda Drive, Pleasanton, California 94588.

3. Ventana is a world leader of and innovator in tissue-based diagnostic solutions. Ventana's goal is to discover, develop, and deliver medical diagnostic systems and biopsy based cancer tests that shape the future of health. Ventana is a leading supplier of cancer diagnostic systems to the pathology market that manufactures 220 cancer tests with related instruments utilized by healthcare providers to analyze patient samples at the molecular level, including immunohistochemistry tests, and determine the best course of therapy for each individual patient.

4. On information and belief, Hologic, Inc. ("Hologic") is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 250 Campus Drive, Marlborough, Massachusetts, 01752 and an office at 777 Palomar Ave., Sunnyvale, CA 94085.

5. On information and belief, Hologic is the exclusive licensee of the '369 patent pursuant to an April 28, 2006 License Agreement among Gen-Probe Incorporated ("Gen-Probe"), the Regents of the University of Michigan ("The Regents"), and Brigham and Women's Hospital, Inc. ("BWH"). On information and belief Hologic acquired Gen-Probe on or around August 1, 2012 and therefore assumed Gen-Probe's rights under the April 28, 2006 License Agreement.

6. On information and belief, Hologic holds all substantial rights in the '369 patent, and has the first option to police the patent rights associated with the '369 patent, which includes defending any action for declaratory judgment.

7. On information and belief, The Regents and BWH are obligated to provide reasonable

assistance to Hologic in any such actions and, at their sole option, may intervene and assume control of the defense of any such action.

JURISDICTION AND VENUE

8. This lawsuit is a civil action arising under the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, and the Declaratory Judgment Act, 35 U.S.C. §§ 2201 and 2202. Accordingly, this Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

9. This court has personal jurisdiction over the Defendant pursuant to the laws of the State of California, including California's long-arm statute, California Code of Civil Procedure § 410.10 because, upon information and belief, Hologic maintains an office in this judicial district and from it, regularly conducts business in this jurisdiction.

10. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391 and 1400.

THE PATENT-IN-SUIT

11. The '369 patent, entitled "Recurrent Gene Fusions in Prostate Cancer" issued on May 18, 2010. A true and correct copy of the '369 patent is attached as Exhibit 1.

12. The '369 patent generally relates to methods for detecting the presence or absence of certain naturally-occurring fusions of portions of different genes, which are expressed in certain prostate cancers. Detecting these naturally-occurring gene fusions in patients allows a healthcare provider to determine the prognosis of the tumors and aid in the development of therapeutic strategies.

13. The '369 patent has one independent claim and four dependent claims.

14. Independent claim 1 reads:

A method for identifying prostate cancer in a patient comprising:

(a) providing a sample from the patient selected from the group consisting of prostate tissue, blood, urine, semen, prostatic secretions and prostate cells; and

(b) detecting the presence or absence in the sample of a gene fusion having a 5' portion from a transcriptional regulatory region of a TMPRSS2 gene and a 3' portion from an ERG, ETV1 or ETV4 gene,

wherein detecting the presence in the sample of the gene fusion identifies prostate cancer in the patient. *See* Ex. 1 at col. 255, lns. 55-67.

15. The gene fusions detected in step (b) of claim 1 of the ’369 patent occur naturally in samples obtained from subjects with certain prostate tumors.

16. Dependent claim 2 reads:

The method of claim 1, wherein step (b) comprises detecting chromosomal rearrangements of genomic DNA having a 5’ DNA portion from the transcriptional regulatory region of the TMPRSS2 gene and a 3’ DNA portion from the ERG, ETV1 or ETV4 gene. *Id*. at col. 256, lns. 54-59.

17. The chromosomal rearrangements of genomic DNA referenced in claim 2 of the ’369 patent occur naturally in samples obtained from subjects with certain prostate tumors.

18. Dependent claim 3 reads:

The method of claim 1, wherein step (b) comprises detecting chimeric mRNA transcripts having a 5’ DNA portion transcribed from the transcriptional regulatory region of the TMPRSS2 gene and a 3’ RNA portion transcribed from the ERG, ETV1 or ETV4 gene. *Id*. at col. 256, lns. 60-65.

19. The chimeric mRNA transcripts referenced in claim 3 of the ’369 patent occur naturally in samples obtained from patients with certain prostate tumors.

20. Dependent claim 4 reads:

The method of claim 1, wherein step (b) comprises detecting an amino-terminally truncated ERG, ETV1 or ETV4 protein encoded by the fusion of the transcriptional regulatory region of the TMPRSS2 gene to the ERG, ETV1 or ETV4 gene. *Id*. at col. 256, ln. 66 – col. 257, ln. 3.

21. The amino-terminally truncated ERG, ETV or ETV4 proteins referenced in claim 4 of the ’369 patent occur naturally in samples obtained from patients with certain prostate tumors.

22. Dependent claim 5 reads:

The method of claim 1, wherein step (b) comprises detecting a chimeric protein having an amino-terminal portion encoded by the transcriptional regulatory region of the TMPRSS2 gene and a carboxy-terminal portion encoded by the ERG, ETV1 or ETV4 gene. *Id*. at col. 257, ln. 4 – col. 258, ln. 3.

23. The chimeric proteins referenced in claim 5 of the ’369 patent occur naturally in samples obtained from patients with certain prostate tumors.

24. The ’369 patent discloses that “non-amplified or amplified gene fusion nucleic acids can

be detected by any conventional means." *Id*. at col. 22, lns. 35-36.

25. The '369 patent further discloses that "[t]he gene fusions of the present invention may be detected as truncated ETS family member proteins or chimeric proteins using a variety of protein techniques known to those of ordinary skill in the art, including but not limited to: protein sequencing; and immunoassays." *Id*. at col. 23, ln. 66 – col. 24, ln. 3.

26. The '369 patent also discloses that "[i]n some embodiments, reagents (e.g., antibodies) specific for the cancer markers of the present invention are fluorescently labelled." *Id*. at col. 27, lns. 21-23. And "[t]he use of antibodies for in vivo diagnosis is well known in the art." *Id*. at col. 27, lns. 29-30.

27. Thus, the '369 patent acknowledges that detecting the presence or absence of the naturally-occurring gene fusions disclosed in the patent can be accomplished using conventional techniques that were known to persons of ordinary skill in the art when the application that issued as the '369 patent was filed, including the use of monoclonal antibodies specific for the cancer marker disclosed in the '369 patent.

VENTANA'S ANTI-ERG (EPR3864) MONOCLONAL ANTIBODY PRODUCT AND THE APRIL 29, 2008 CO-EXCLUSIVE SUBLICENSE WITH GEN-PROBE

28. Ventana makes, offers to sell, and sells an anti-ERG (EPR3864) monoclonal antibody product ("Ventana's anti-ERG antibody") in the United States that is used by healthcare providers in diagnostic tests for prostate cancer. A copy of the package insert for Ventana's anti-ERG antibody is attached as Exhibit 2.

29. On April 29, 2008, Ventana entered into a Co-Exclusive Sublicense Agreement with Gen-Probe under which Ventana became a sublicensee of the patent application that issued as the '369 patent.

30. On information and belief, Hologic currently holds all of Gen-Probe's rights under the April 29, 2008 Co-Exclusive Sublicense Agreement as a result of Hologic's acquisition of Gen-Probe on or around August 1, 2012.

31. On December 18, 2015, Ventana informed Gen-Probe (now Hologic) that it believed the '369 patent was invalid under 35 U.S.C. § 101 and stopped paying royalties pursuant to the agreement. There is thus an actual and justiciable controversy between Hologic and Ventana with respect to whether Ventana's making, offering to sell, and selling the Ventana anti-ERG antibody will infringe any valid and

enforceable claim of the ’369 patent.

COUNT I

(DECLARATORY JUDGMENT OF INVALIDITY OF THE ’369 PATENT)

32. Ventana incorporates the allegations of paragraphs 1-31 as if fully set forth herein.

33. An actual controversy has now arisen and now exists between the parties concerning the validity of the ’369 patent.

34. All of the claims of the’369 patent are invalid under the United States Patent Act, including pursuant to at least 35 U.S.C. § 101.

35. For example, all of the claims of the ’369 patent are directed to naturally occurring phenomena and contain no “additional features” that transform them into patent-eligible subject matter. As the ’369 patent discloses, detection of the naturally occurring cancer markers covered by the claims could be accomplished using conventional, known techniques.

36. Ventana hereby seeks a declaratory judgment that the ’369 patent is invalid under at least 35 U.S.C. § 101.

PRAYER FOR RELIEF

WHEREFORE, Ventana respectfully requests that:

a. A judgment that the claims of the ’369 patent are invalid;

b. That this case be found an exceptional case under 35 U.S.C. § 285, entitling Ventana to be awarded the attorney fees, costs, and expenses that it incurs in prosecuting this action; and

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

JURY TRIAL DEMAND

Ventana hereby requests a trial by jury, pursuant to Federal Rule of Civil Procedure 38(b), on all issues so triable.

Dated: May 18, 2016

DURIE TANGRI LLP

By: */s/ Adam R. Brausa*
ADAM R. BRAUSA

Attorney for Plaintiff
VENTANA MEDICAL SYSTEMS, INC.

CERTIFICATE OF SERVICE

I certify that all counsel of record are being served on May 18, 2016, with a copy of this document via the Court's CM/ECF system.

/s/ Adam R. Brausa
ADAM R. BRAUSA