

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FOCAL THERAPEUTICS, INC.,
Petitioner,

v.

SENORX, INC.,
Patent Owner.

Case IPR2014-00116
Patent 8,288,745 B2

Before LORA M. GREEN, FRANCISCO C. PRATS, and
JACQUELINE WRIGHT BONILLA, *Administrative Patent Judges*.

BONILLA, *Administrative Patent Judge*.

DECISION
Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

A. Background

Petitioner Focal Therapeutics, Inc. (“Focal Therapeutics”) filed a Petition (Paper 1, “Pet.”) to institute an *inter partes* review of claims 1-30 of U.S. Patent No. 8,288,745 B2 (Ex. 1001 (“the ’745 patent”)). 35 U.S.C. § 311. Patent Owner SenoRx, Inc. (“SenoRx”) filed a Preliminary Response (Paper 6, “Prel. Resp.”). We have jurisdiction under 35 U.S.C. § 314.

The standard for instituting an *inter partes* review is set forth in 35 U.S.C. § 314(a), which provides:

THRESHOLD.—The Director may not authorize an *inter partes* review to be instituted unless the Director determines that the information presented in the petition filed under section 311 and any response filed under section 313 shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.

For the reasons set forth below, we conclude that Focal Therapeutics has shown that, under 35 U.S.C. § 314(a), there is a reasonable likelihood that it would prevail with respect to at least one of the challenged claims. We institute an *inter partes* review of claims 1-12, 14-24, and 26-30 of the ’745 patent.

B. The ’745 Patent (Ex. 1001)

The ’745 patent relates to a method of cancer therapy that partially radiates the breast. Ex. 1001, 1:23-30. The method uses external beam radiation delivered through a radiation source, such as a breast implant. *Id.* at 1:64–2:2; 2:23-36, 47-50. The ’745 patent describes a breast implant, such as the implant disclosed in U.S. Patent No. 6,214,045 B1 (Ex. 1015) (“the Corbitt ’045 patent”), which “functions as a radio-opaque target for external beam stereotactic partial breast radiotherapy.” *Id.* at 2:24-32; 4:28-30.

C. Illustrative Claims

Claims 1 and 18, the only challenged independent claims, are reproduced below.

1. A method of partial breast radiation therapy comprising the steps of:
placing within a breast cavity a substantially radio-opaque implant constructed of biocompatible and biodegradable material, said substantially radio-opaque implant supporting the tissue surrounding the breast cavity; and
directing a radiation beam to said substantially radio-opaque implant serving as a target for delivery of radiation therapy to margins around the breast cavity, such that the radiation beam does not materially irradiate the whole of the breast.

18. A method of partial breast radiation comprising the steps of:
placing within a breast lumpectomy cavity an implant constructed of biocompatible and biodegradable material with a substantially radio-opaque marker contained within the implant, and said implant supporting the tissue surrounding the breast lumpectomy cavity; and
directing a radiation beam to said implant, said substantially radio-opaque marker within said implant serving as a target for delivery of radiation therapy to margins around the breast cavity, such that the radiation beam does not materially irradiate the whole of the breast.

Id. at 5:25-35; 6:31-42.

D. Prior Art Relied Upon

Focal Therapeutics relies upon the following prior art:

Stubbs, U.S. Pub. No. 2009/0024225, published Jan. 22, 2009, claiming priority to a U.S. provisional appl. filed Jul. 16, 2007 (Ex. 1011 (“Stubbs”));

Stubbs, U.S. provisional appl. 60/949,963, filed Jul. 16, 2007 (Ex. 1012 (“Stubbs Provisional”));

Stubbs et al., U.S. Pub. No. 2008/0177179 A1, published Jul. 24, 2008, related to a U.S. provisional appl. filed Dec. 19, 2006 (Ex. 1013 (“Stubbs-Edmundson Publication”));

Stubbs et al., U.S. provisional appl. 60/875,776, filed Dec. 19, 2006 (Ex. 1014 (“Stubbs-Edmundson Provisional”));

The Corbitt ’045 patent (Ex. 1015), issued Apr. 10, 2001; and

Patrick and Stubbs, U.S. Pub. No. 2005/0101860 A1, published May 12, 2005, filed Nov. 7, 2003 (Ex. 1016 (“Patrick-Stubbs”)).

E. Alleged Grounds of Unpatentability

Focal Therapeutics contends that claims 1-30 of the ’745 patent are unpatentable under 35 U.S.C. § 102(e) and § 103(a) based on the following grounds. Pet. 14, 30, 47.

Reference(s)	Basis	Claims Challenged
Stubbs	§ 102(e)	1-30
Stubbs	§ 103(a)	1-30
Stubbs and “Admitted Prior Art” (Ex. 1001)	§ 103(a)	13, 25
Stubbs-Edmundson Publication	§ 102(e)	1-30
Stubbs-Edmundson Publication	§ 103(a)	1-30
Stubbs-Edmundson Publication and the Corbitt ’045 patent	§ 103(a)	1-30
Stubbs-Edmundson Publication and “Admitted Prior Art”	§ 103(a)	13, 25
Stubbs-Edmundson Publication, the Corbitt ’045 patent, and “Admitted Prior Art”	§ 103(a)	13, 25
Patrick-Stubbs and the Corbitt ’045 patent	§ 103(a)	1-30
Patrick-Stubbs, the Corbitt ’045 patent, and “Admitted Prior Art”	§ 103(a)	13, 25

II. ANALYSIS

A. Claim Construction

In an *inter partes* review, a claim in an unexpired patent shall be given its broadest reasonable construction in light of the specification of the patent in which it appears. *See* 37 C.F.R. § 42.100(b) (2013). Under the broadest reasonable construction standard, claim terms are given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007).

Focal Therapeutics offers a claim construction of the phrase “stereotactic radiation machine” recited in certain challenged dependent claims, indicating that the phrase encompasses “all external beam radiation therapy machines that use multi-directional external radiation beams, such as 3DCRT and selected IMRT machines.” Pet. 13-14. Focal Therapeutics’ proposed construction, on the record before us, is reasonable in view of the broadest reasonable construction of the phrase in light of the specification, and we adopt it for the purposes of this decision.

B. Effective Filing Date of the ’745 Patent

All alleged grounds of unpatentability asserted by Focal Therapeutics rely on at least one of three references cited as prior art under 35 U.S.C. § 102(e) or § 102(b): (1) Stubbs, a U.S. patent application publication with an earliest possible effective filing date of July 16, 2007 (Ex. 1011); (2) Stubbs-Edmundson Publication, a U.S. patent application publication with an earliest possible effective filing date of December 19, 2006 (Ex. 1013); and (3) Patrick-Stubbs, a U.S. patent application publication with an earliest possible effective filing date of November 7, 2003, and published on May 12, 2005 (Ex. 1016). If the challenged claims of

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