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Paper 27
Date: June 10, 2020

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ETHICON, INC.,
Petitioner,

v.

BOARD OF REGENTS, THE UNIVERSITY OF TEXAS SYSTEM,
Patent Owner.

IPR2019-00406
Patent 6,596,296 B1

Before SUSAN L. C. MITCHELL, AVELYN M. ROSS,
KRISTI L. R. SAWERT, *Administrative Patent Judges.*

ROSS, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
35 U.S.C. § 314, 37 C.F.R. § 42.4

I. INTRODUCTION

Ethicon, Inc. ("Petitioner") filed a Petition (Paper 2, "Pet.") requesting *inter partes* review of claims 1, 4, 11, 16, 17, 20, and 26 of U.S. Patent No. 6,596,296 B1 (Ex. 1001, "the '296 patent"). The Board of Regents, The University of Texas System ("Patent Owner") filed a Preliminary Response to the Petition (Paper 26, "Prelim. Resp.").

We have authority to determine whether to institute an *inter partes* review. 35 U.S.C. § 314; 37 C.F.R. § 42.4(a). The standard for instituting an *inter partes* review is set forth in 35 U.S.C. § 314(a), which provides that an *inter partes* review may not be instituted "unless the Director determines . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least [one] of the claims challenged in the petition."

For the reasons set forth below, upon considering the Petition and evidence of record, we determine that it is appropriate to exercise discretion under § 314(a). Accordingly, we deny the Petition, and do not institute an *inter partes* review.

A. Related Proceedings

Petitioner identifies the pending district court litigation styled *Board of Regents, The University of Texas System et al. v. Ethicon, Inc. et al.*, 1:17-cv-01084 (W.D. Tex.) ("the Western District of Texas litigation" in the "Western District of Texas"). Pet. 2, *see also* Patent Owner's Mandatory Notices, Paper 7, 1. Petitioner also identifies its co-pending petition, seeking to institute *inter partes* review of U.S. Patent No. 7,033,603 ("the '603 patent") as a related proceeding, and states that the '603 patent is a continuation-in-part of the '296 patent. Pet. 2–3; IPR2019-00407, Paper 2; *see also* Patent Owner's Mandatory Notices, Paper 7, 1.

The '296 patent is asserted against other defendants in the following pending litigations:

> *Board of Regents, The University of Texas System et al. v. Boston Scientific Corporation*, 1:18-cv-00392 (D. Del.);
>
> *Board of Regents, The University of Texas System et al. v. Medtronic, Inc. et al.*, No. 1:17-cv-00942 (W.D. Tex.) (dismissed without prejudice on July 19, 2018).

Pet. 3–4; *see also* Patent Owner's Mandatory Notices, Paper 7, 1. The '296 patent is also the subject of a separate petition for *inter partes* review styled *Medtronic, Inc. et al. v. Board of Regents, the University of Texas System et al.*, IPR2019-00037, Paper 2 (PTAB Oct. 9, 2018).

B. The '296 Patent

The '296 patent, titled "Drug Releasing Biodegradable Fiber Implant," issued on July 22, 2003.[1] Ex. 1001, codes (45), (54). The '296 patent is directed to tissue engineering compositions and, in particular to, "biodegradable polymer fibers capable of the controlled delivery of therapeutic agents." *Id.* at 2:41–45.

According to the '296 patent, "there are several primary avenues investigators are using to engineer tissues" that include creating a scaffold in the form of a three-dimensional polymer network. *Id.* at 1:20–26. "[T]he scaffold may be biodegradable, meaning that over time it will break down both chemically and mechanically." *Id.* at 1:49–51. "[A] polymer scaffolding provides not only the mechanical support, but also the three-dimensional shape that is desired for the new tissue." *Id.* at 2:15–18. The

[1] The '296 patent claims priority to U.S. provisional application No. 60/147,827, which was filed on August 6, 1999. Ex. 1001, code (60). The specific priority date of the challenged claims currently is not at issue in this proceeding, and we need not make any determination in this regard.

'296 patent purports that "[m]ost current methodologies provide no specific means of actively assisting the incorporation of blood vessels into and throughout the polymer matrix." *Id.* at 2:21–23. In contrast, "[t]he present invention provides compositions and methods that promote the directed migration of appropriate cell types into the engineered extracellular matrix." *Id.* at 2:27–30.

The '296 patent describes creating heterogeneous scaffolds by encapsulating therapeutic agents into individual fibers of a three-dimensional fiber matrix. *Id.* at 8:32–35. "The therapeutic agents are released from each individual fiber slowly, and in a controlled manner." *Id.* at 8:36–37.

The '296 patent describes processes for fabricating polymer fibers containing therapeutic agents. *Id.* at 17:36–19:36 (Example 1). "First, a biodegradable polymer . . . [is] dissolved in some appropriate solvent (A) at concentrations ranging from 5 to 30 wt % . . . In this embodiment, solvent (A) has low miscibility with water, and is very miscible with the coagulation bath solvent (B)." *Id.* at 17:42–50. The biodegradable polymer may include "poly(L-lactic acid) (PLLA), poly(DL-lactic acid), polycaprolactone, poly(glycolic acid), polyanhydride, or copolymers or blends of these or other biodegradable polymers." *Id.* at 17:43–46. "Once the polymer is dissolved, an aqueous solution containing both the biomolecules(s) of interest and a surfactant, is added to the polymer solution." *Id.* at 17:52–54. "Using some form of mechanical energy such as sonication, vortexing, or shear forces generated by forcing the liquid through a small orifice, a water-in-oil type emulsion is formed between the aqueous and organic phases." *Id.* at 18:1–4.

The '296 patent further describes extruding the formed emulsion into a coagulation bath containing solvent (B). *Id.* at 18:12–13. "Solvent (B)

must be highly miscible with solvent (A), and must be a non-solvent for the polymer." *Id.* at 18:14–16. The '296 patent explains that:

> Because solvent (A) is highly miscible with coagulating bath solvent (B), it freely diffuses from the polymer solution stream, into the coagulating bath. The polymer, however, is not soluble in solvent (B), and therefore begins to precipitate upon itself, forming the outer sheath of a fiber and trapping virtually all of the dispersed aqueous phase of the emulsion within the forming fiber. In this way, the fiber is loaded with the drug or protein of interest.

Id. at 18:22–30. "Preferred choices of solvent (A) include chloroform and methylene chloride." *Id.* at 17:51–52. Examples of solvent (B) include isopropyl alcohol and hexane. *Id.* at 18:15–22.

C. Illustrative Claims

Petitioner challenges claims 1, 4, 11, 16, 17, 20, and 26 of the '296 patent. Independent claim 1 is the only independent claim challenged and is reproduced below.

> 1. A composition comprising at least one biodegradable polymer fiber wherein said fiber is composed of a first phase and a second phase, the first and second phases being immiscible, and wherein the second phase comprises one or more therapeutic agents.

Ex. 1001, 27:54–58.

D. The Asserted Unpatentability Challenges

Petitioner asserts that claims 1, 4, 11, 16, 17, 20, and 26 would have been unpatentable on the following grounds:

Claim(s) Challenged	35 U.S.C.	Reference(s)/Basis
1, 11, 16, 17, 26	§§ 102 and 103	Song[2]
4, 20	§ 103	Song

[2] Song, US 5,364,627, issued November 15, 1994 (Ex. 1005, "Song").

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