Trials@uspto.gov
571-272-7822

Paper 29
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.

IPR2019-00407
Patent 7,033,603 B2

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

MITCHELL, *Administrative Patent Judge*.

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

A. Background and Summary

Ethicon, Inc. ("Petitioner") filed a Petition (Paper 2, "Pet.") requesting *inter partes* review of claims 1, 2, 6, 11, 13, and 19 of U.S. Patent No. 7,033,603 B2 (Ex. 1001, "the '603 patent"). Pet. 1. The Board of Regents, The University of Texas System ("Patent Owner") did not file a preliminary response.

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 the information presented in the Petition establishes a reasonable likelihood that Petitioner would prevail with respect to at least one of the challenged claims. Accordingly, we grant the Petition, and institute an *inter partes* review.

B. Real Parties in Interest

Petitioner identifies Ethicon, Inc.; Ethicon US, LLC; Ethicon Endo-Surgery, Inc.; Ethicon LLC; Ethicon Holding S.A.R.L.; Ethicon PR Holdings Unlimited Company; Janssen Pharmaceutical; JNJ Irish Investments ULC; JNJ International Investment LLC; OMJ Pharmaceuticals, Inc.; Medical Device Business Services, Inc.; Synthes, Inc.; DePuy Synthes, Inc.; Johnson & Johnson International; and Johnson & Johnson as real-parties-in-interest for this proceeding. Pet. 3. Patent Owner

identifies The Board of Regents, The University of Texas System, a real-party-in-interest as the sole owner of the '603 patent, and TissueGen, Inc., a real-party-in-interest as the exclusive licensee of the '603 patent. Paper 28, 1 (Patent Owner's Mandatory Notices).

C. Related Matters

Petitioner identifies pending parallel 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.), in which Patent Owner and its licensee, TissueGen, Inc., asserted the '603 patent and its parent, U.S. Patent No. 6,596,296 ("the '296 patent") against Petitioner. Pet. 3, Paper 28, 1. Petitioner also identifies its co-pending petition, seeking to institute *inter partes* review of the '296 patent. Pet. 3; IPR2019-00406.

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); and
>
> *Board of Regents v. Boston Scientific Corp.*, No. 18-1700 (Fed. Cir.).

Pet. 3–4; Paper 28, 1. The '603 patent is also the subject of a separate IPR, *Medtronic, Inc. v. Board of Regents, the University of Texas System*, IPR2019-00038, Paper 2 (PTAB), that has been terminated due to settlement. Paper 24, 3.

D. The '603 Patent

The '603 patent, titled "Drug Releasing Biodegradable Fiber for Delivery of Therapeutics," issued on April 25, 2006.[1] Ex. 1001, codes (54), (45). The '603 patent is directed to fiber compositions of gels or hydrogels. *Id*. at Abst. More specifically, the '603 patent involves the composition of a gel or hydrogel loaded biodegradable fibers for delivery of a therapeutic agent. *Id*. at Abst., 1:15–17.

Generally, the drug delivery composition of the '603 patent comprises "at least one fiber, wherein said fiber comprises a first component and a second component, and wherein said first component is a biodegradable polymer and said second component is selected from the group consisting of a gel and a hydrogel." *Id*. at 3:8–13. The '603 patent further describes several variations of the disclosed fiber including where the second component is water, where the fiber comprises an emulsion of a gel or hydrogel, or where the fiber has a gel or hydrogel and a hollow bore. *Id*. at 3:13–26. The '603 patent also describes a scaffold composition comprising one or more fibers with a biodegradable polymer first component and a gel or hydrogel second component. *Id*. at 3:26–31.

[1] The '603 patent is a continuation-in-part of U.S. Application No. 09/632,475, which was filed on August 4, 2000, and is now the '296 patent. Ex. 1001, code (63). The '603 patent also claims priority to U.S. provisional application No. 60/147,827, filed on August 6, 1999. *Id*. at code (60). Although Petitioner asserts that the '603 patent is entitled to a priority date no earlier than May 2, 2003—the priority date of the application that issued as the '603 patent—Petitioner states that resolution of the priority date issue "does not bear on this Petition." Pet. 9, n.1. Because the priority date of the challenged claims currently is not at issue in this proceeding, we need not make any determination in this regard.

Some exemplary drawings depicting these various biodegradable fibers are Figures 3A–3D shown below.

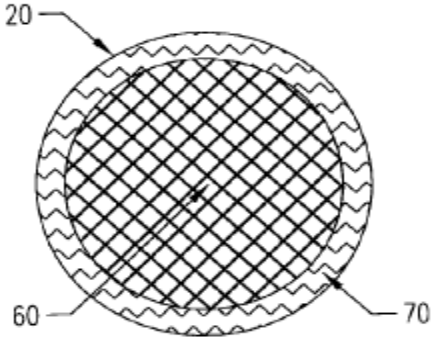

FIG. 3A

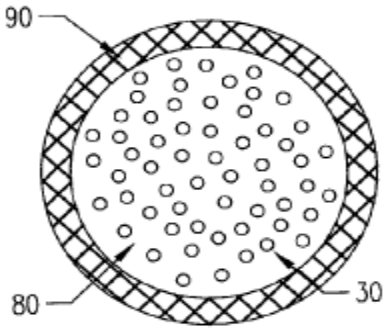

FIG. 3C

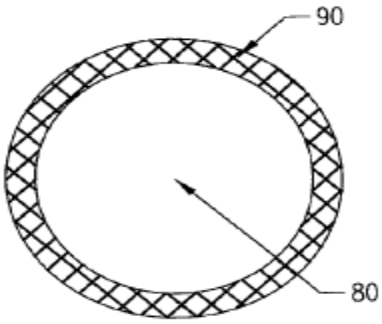

FIG. 3B

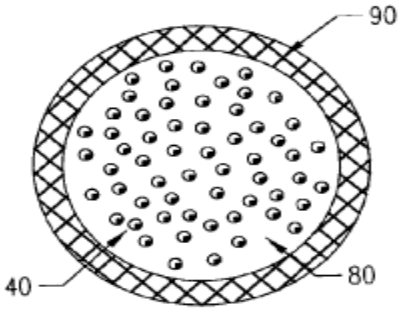

FIG. 3D

The '603 patent describes Figures 3A through 3D depicted above as follows.

> FIG. 3A depicts a bicomponent fiber with a gel or hydrogel bore (60) and a wall comprising a hydrophobic polymer (20) that comprises a drug (70).
>
> FIG. 3B depicts a bicomponent fiber with a polymer bore (80) surrounded by a gel or hydrogel wall (90).
>
> FIG. 3C depicts a bicomponent fiber with a polymer bore (80) comprising a water emulsion (30) that is surrounded by a gel or hydrogel wall (90).
>
> FIG. 3D depicts a bicomponent fiber with a polymer bore (80) comprising a gel or hydrogel emulsion (40) that is surrounded by a gel or hydrogel wall (90).

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.