Trials@uspto.gov
571-272-7822

Paper 9
Date: May 13, 2020

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BAUSCH HEALTH COMPANIES INC. AND
BAUSCH HEALTH US LLC,
Petitioner,

v.

FLOW PHARMA INC.,
Patent Owner.

IPR2020-00165
Patent 8,138,157 B2

Before SUSAN L. C. MITCHELL, ROBERT A. POLLOCK, and JOHN E. SCHNEIDER, *Administrative Patent Judges.*

SCHNEIDER, *Administrative Patent Judge*.

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

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

I. INTRODUCTION

A. Background and Summary

Bausch Health Companies Inc. and Bausch Health US LLC (collectively "Petitioner") filed a Petition to institute an *inter partes* review of claim 1 of U.S. Patent 8,138,157 B2 (Ex. 1001, "the '157 patent"). Paper 1 ("Pet."). Flow Pharma Inc. ("Patent Owner") filed a Preliminary Response. Paper 8. ("PO Resp.").[1] We have jurisdiction under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted unless the information presented in the Petition shows "there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 claim of the claims challenged in the petition." 35 U.S.C. § 314(a) (2018); *see also* 37 C.F.R. § 42.4(a). Upon consideration of the Petition and Preliminary Response, we are persuaded that Petitioner has met its burden of showing a reasonable likelihood that it would prevail in showing that at least one of the challenged claims is unpatentable.

B. Real Parties in Interest

Bausch Health Companies Inc. and Bausch Health US LLC identify themselves as the real parties-in-interest. Petitioner noted that Bausch Health US LLC was formerly known as Valeant Pharmaceuticals North America LLC.

---

[1] On February 19, 2020, Patent Owner filed a document titled "Response." Paper 7. On February 20, 2020, Patent Owner filed a document titled "Preliminary Response." Paper 8. In the Preliminary Response, Patent Owner stated "This preliminary response replaces the one filed on February 18, 2020 which can now be discarded." PO Resp. 1. For purposes of this decision we have only considered the arguments and evidence presented in the document titled "Preliminary Response."

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

C. Related Matters

The parties state that the '157 patent is the subject of litigation in *Flow Pharma, Inc. v. Bausch Health Companies Inc. et al.*, Case No. 4-18-cv-05769 (N.D.Cal.). Pet. ix.; Paper 6, 2.

D. The '157 Patent

The '157 patent generally relates to antimicrobial particles comprising an antimicrobial agent and a biocompatible controlled release polymer. Ex. 1001, col. 2, ll. 29–35. The antimicrobial agent may comprise an antibiotic such as gentamicin. *Id.* at col. 4, ll. 9–12. The polymer may comprise polylactic-co-glycolic acid ("PLGA"). *Id.* at col. 4, ll. 13–15. The particles are designed to release the antimicrobial agent over time ranging from 1 to 7 days. *Id.* col. 2, ll. 45–48.

One embodiment encompasses a method administering the controlled release particles into a wound to provide a therapeutically effective dose of the antimicrobial agent over time. *Id.* at col. 6, ll. 60–67. The wound can be the result of implantation of an orthopedic device. *Id.* In one embodiment the invention includes treating osteomyelitis in connection with surgical implants. *Id.* at col. 9, ll. 31–33. "Osteomyelitis is an infection involving the bone." *Id.* at col. 10, l. 38.

E. Illustrative Claim

The '165 patent has 16 claims. Claim 1, the only claim challenged in the Petition, reads as follows:

> 1. A method of treating osteomyelitis, comprising:
>
> implanting an orthopedic implant into a surgical wound site;
>
> administering to the wound site a formulation comprised of a plurality of particles which particles are comprised of an antimicrobial drug and a biocompatible polymer; and

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

> allowing drug from the formulation to dissolve into the wound site over a period of time not less than one day and not more than seven days and provide a therapeutically effective dose of the drug over the period of time to thereby treat osteomyelitis.

Ex. 1001, col. 28, ll. 29–39.

F. Evidence

Petitioner relies on the following references:

Friess and Schlapp, *Modifying the Release of Gentamicin from Microparticles Using a PLGA Blend,* 7 Pharm. Devel. And Tech. 235 (2002) (Ex. 1016)("Friess").

Ipsen et al., *Gentamicin-collagen sponge for local applications: 10 cases of chronic osteomyelitis followed for 1 year,* 62 Acta Orthop. Scand. 592 (1991) (Ex. 1018) ("Ipsen").

Wachol-Drewek et al., *Comparative investigation of drug collagen implants saturated in antibiotic solutions and a sponge containing gentamicin,* 17 Biomaterials 1733 (1006) (Ex. 1017) ("Wachol-Drewek").

Renvert et al., *Treatment of Incipient Peri-Implant Infections Using Topical minocycline Microspheres Versus Topical Chlorhexidine Gel as an Adjunct to Mechanical Debridement*, 6 J. Int'l Acad. Periodont. 154 (2004) (Ex. 1020) ("Renvert")

Williams et al., *Treatment of Periodontitis be Local Administration of Minocycline Microspheres: A Controlled Test*, 72 Periodontol. 1535 (2001) (Ex. 1019) ("Williams").

Petitioner also relies on the Declarations of Paul Ducheyne, M. Sc., Ph.D. (Ex. 1003) and Timothy G. Donley, DDS, MSD (Ex. 1004).

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

G. Prior Art and Asserted Grounds

Petitioner asserts that claim 1 would have been unpatentable on the following grounds:

Claim(s) Challenged	35 U.S.C. §	References
1	102	Friess
1	103(a)	Friess, Ipsen, Wachol-Drewek
1	103(a)	Renvert, Williams, Friess

II. ANALYSIS

A. Legal Standards

"In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable." *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016) (citing 35 U.S.C. § 312(a)(3) (requiring *inter partes* review petitions to identify "with particularity . . . the evidence that supports the grounds for the challenge to each claim")). This burden of persuasion never shifts to the patent owner. *See Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015) (discussing the burden of proof in *inter partes* review).

1. Anticipation

Section 102(a) provides that "[a] person shall be entitled to a patent unless . . . the claimed invention was patented [or] described in a printed publication . . . before the invention thereof by the applicant for patent." 35 U.S.C. § 102(a) (2002).[2] Accordingly, unpatentability by anticipation

[2] The provisions of the Leahy-Smith America Invents Act ("AIA") regarding novelty and obviousness apply to patents containing at least one claim having an effective filing date on or after March 16, 2013. Pub L. 112–29, 125 Stat. 284 (2011). AS discussed more fully below, the '157 patent has an

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

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.