United States Court of Appeals for the Federal Circuit

SAINT REGIS MOHAWK TRIBE, ALLERGAN, INC., Appellants

v.

MYLAN PHARMACEUTICALS INC., TEVA PHARMACEUTICALS USA, INC., AKORN, INC., Appellees

2018-1638, 2018-1639, 2018-1640, 2018-1641, 2018-1642, 2018-1643

Appeals from the United States Patent and Trademark Office, Patent Trial and Appeal Board in Nos. IPR2016-01127, IPR2016-01128, IPR2016-01129, IPR2016-01130, IPR2016-01131, IPR2016-01132, IPR2017-00599, IPR2017-00576, IPR2017-00578, IPR2017-00579. IPR2017-00583, IPR2017-00585, IPR2017-00586, IPR2017-00594, IPR2017-00596, IPR2017-00598, IPR2017-00600, IPR2017-00601.

Decided: July 20, 2018

JONATHAN MASSEY, Massey & Gail LLP, Washington, DC, argued for appellants. Appellant Allergan, Inc. also represented by THOMAS BRUGATO, JEFFREY B. ELIKAN, ROBERT ALLEN LONG, JR., ALAINA MARIE WHITT, Covington & Burling LLP, Washington, DC. SAINT REGIS MOHAWK TRIBE v. MYLAN PHARM. INC.

ERIC MILLER, Perkins Coie, LLP, Seattle, WA, argued for appellees. Appellee Mylan Pharmaceuticals Inc. also represented by DAN L. BAGATELL, Hanover, NH; SHANNON BLOODWORTH, BRANDON MICHAEL WHITE, Washington, DC; CHARLES CURTIS, ANDREW DUFRESNE, Madison, WI; JAD ALLEN MILLS, STEVEN WILLIAM PARMELEE, Wilson, Sonsini, Goodrich & Rosati, PC, Seattle, WA; RICHARD TORCZON, Washington, DC.

MARK R. FREEMAN, Appellate Staff, Civil Division, United States Department of Justice, Washington, DC, argued for amicus curiae United States. Also represented by COURTNEY DIXON, MARK B. STERN, CHAD A. READLER.

MICHAEL W. SHORE, Shore Chan DePumpo LLP, Dallas, TX, for appellant Saint Regis Mohawk Tribe. Also represented by ALFONSO CHAN, JOSEPH F. DEPUMPO, CHRISTOPHER LIIMATAINEN EVANS; MARSHA K. SCHMIDT, Burtonsville, MD.

JOHN CHRISTOPHER ROZENDAAL, Sterne Kessler Goldstein & Fox, PLLC, Washington, DC, for appellee Teva Pharmaceuticals USA, Inc. Also represented by MICHAEL E. JOFFRE, WILLIAM H. MILLIKEN, PAULINE PELLETIER, RALPH WILSON POWERS, III.

MICHAEL R. DZWONCZYK, Sughrue Mion PLLC, Washington, DC, for appellee Akorn, Inc. Also represented by MARK BOLAND.

YIN HUANG, Zuber Lawler & Del Duca LLP, New York, NY, for amicus curiae New York City Bar Association.

ERIC SHUMSKY, Orrick, Herrington & Sutcliffe LLP, Washington, DC, for amicus curiae Microsoft Corporation.

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Also represented by SAMUEL HARBOURT; E. JOSHUA ROSENKRANZ, New York, NY.

CHARLES DUAN, R Street Institute, Washington, DC, for amici curiae R Street Institute, Electronic Frontier Foundation.

JOHN THORNE, Kellogg, Hansen, Todd, Figel & Frederick, P.L.L.C., Washington, DC, for amici curiae High Tech Inventors Alliance, Computer & Communications Industry Association. Also represented by GREGORY G. RAPAWY.

CHARLES R. MACEDO, Amster Rothstein & Ebenstein LLP, New York, NY, for amicus curiae Askeladden, L.L.C. Also represented by MARK BERKOWITZ, SANDRA A. HUDAK.

ANNA-ROSE MATHIESON, California Appellate Law Group, San Francisco, CA, for amicus curiae America's Health Insurance Plans.

WILLIAM M. JAY, Goodwin Procter LLP, Washington, DC, for amicus curiae The Association for Accessible Medicines. Also represented by JAIME ANN SANTOS; JEFFREY FRANCER, The Association for Accessible Medicines, Washington, DC.

MARIA AMELIA CALAF, Wittliff Cutter, Austin, TX, for amici curiae Software & Information Industry Association, L Brands, Inc., SAS Institute Inc., SAP America, Inc., Internet Association, Xilinx, Inc.

Before DYK, MOORE, and REYNA, *Circuit Judges*. Opinion for the court filed by *Circuit Judge* MOORE.

Concurring opinion filed by *Circuit Judge* DYK.

MOORE, Circuit Judge.

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Mylan Pharmaceuticals, Inc., petitioned for inter partes review ("IPR") of various patents owned by Allergan, Inc., relating to its dry eye treatment Restasis. Teva Pharmaceuticals USA, Inc., and Akorn, Inc. (together with Mylan, "Appellees") joined. While IPR was pending, Allergan transferred title of the patents to the Saint Regis Mohawk Tribe, which asserted sovereign immunity. The Board denied the Tribe's motion to terminate on the basis of sovereign immunity and Allergan's motion to withdraw from the proceedings. Allergan and the Tribe appeal, arguing the Board improperly denied these motions. We affirm.

BACKGROUND

This appeal stems from a multifront dispute between Allergan and various generic drug manufacturers regarding patents related to Allergan's Restasis product (the "Restasis Patents"), a treatment for alleviating the symptoms of chronic dry eye. In 2015, Allergan sued Appellees in the Eastern District of Texas, alleging infringement of the Restasis Patents based on their filings of Abbreviated New Drug Applications. On June 3, 2016, Mylan petitioned for IPR of the Restasis Patents. Subsequently, Teva and Akorn filed similar petitions. The Board instituted IPR and scheduled a consolidated oral hearing for September 15, 2017.

Before the hearing, Allergan and the Tribe entered into an agreement Mylan alleges was intended to protect the patents from review. On September 8, 2017, a patent assignment transferring the Restasis patents from Allergan to the Tribe was recorded with the USPTO. The Tribe moved to terminate the IPRs, arguing it is entitled to assert tribal sovereign immunity, and Allergan moved to withdraw. The Board denied both motions.

Allergan and the Tribe appeal. We have jurisdiction pursuant 28 U.S.C. § 1295(a)(4)(A). Board decisions must be set aside if they are "arbitrary, capricious, an abuse of

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discretion, or otherwise not in accordance with law." 5 U.S.C. § 706.

ANALYSIS

As "domestic dependent nations," Indian tribes possess "inherent sovereign immunity," and suits against them are generally barred "absent a clear waiver by the tribe or congressional abrogation." Okla. Tax Comm'n v. Citizen Band Potawatomi Indian Tribe of Okla., 498 U.S. 505, 509 (1991). This immunity derives from the common law, Santa Clara Pueblo v. Martinez, 436 U.S. 49, 58 (1978), and it does not extend to actions brought by the federal government, see, e.g., E.E.O.C. v. Karuk Tribe Hous. Auth., 260 F.3d 1071, 1075 (9th Cir. 2001); United States v. Red Lake Band of Chippewa Indians, 827 F.2d 380, 383 (8th Cir. 1987). Generally, immunity does not apply where the federal government acting through an agency engages in an investigative action or pursues an adjudicatory agency action. See, e.g., Pauma v. NLRB, 888 F.3d 1066 (9th Cir. 2018) (holding the NLRB could adjudicate unfair labor charges brought by the Board against a tribally-owned business operating on tribal land); Karuk Tribe Hous. Auth., 260 F.3d at 1074 (holding tribe not immune in EEOC enforcement action); cf. Fed. Power Comm'n v. Tuscarora Indian Nation, 362 U.S. 99, 122 (1960) (holding that tribal lands were subject to takings by the Federal Power Commission). There is not, however, a blanket rule that immunity does not apply in federal agency proceedings. Fed. Maritime Comm'n v. S.C. State Ports Auth., 535 U.S. 743, 754–56 (2002) ("*FMC*").

In *FMC*, the Supreme Court considered whether state sovereign immunity precluded the Federal Maritime Commission from "adjudicating a private party's complaint that a state-run port ha[d] violated the Shipping Act of 1984." *Id.* at 747. In answering this question, the Court asked whether Commission adjudications "are the

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