NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

SUMITOMO PHARMA CO., LTD.,
Appellant

v.

KATHERINE K. VIDAL, UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE,
Intervenor

2022-2276

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. IPR2020-01053.

Decided: April 5, 2024

THOMAS SAUNDERS, Wilmer Cutler Pickering Hale and Dorr LLP, Washington, DC, argued for appellant. Also represented by EMILY R. WHELAN, Boston, MA; JOHN A. DRAGSETH, SARAH JACK, MICHAEL J. KANE, Fish & Richardson P.C., Minneapolis, MN; NITIKA GUPTA FIORELLA, Wilmington, DE; TIMOTHY RAWSON, San Diego, CA.

MARY L. KELLY, Office of the Solicitor, United States Patent and Trademark Office, Alexandria, VA, argued for intervenor. Also represented by PETER J. AYERS, KAKOLI CAPRIHAN, MAI-TRANG DUC DANG, FARHEENA YASMEEN RASHEED.

Before TARANTO, HUGHES, and CUNNINGHAM, *Circuit Judges*.

TARANTO, *Circuit Judge*.

Sumitomo Pharma Co., Ltd. (formerly Sumitomo Dainippon Pharma Co., Ltd.), owns U.S. Patent No. 9,815,827, titled "Agent for Treatment of Schizophrenia." The patent claims detail dosing regimens for treating certain psychotic disorders with lurasidone[1] (or a salt thereof), further specifying an absence-of-weight-gain result of following the regimens—weight gain being a recognized adverse side-effect of many antipsychotic drugs, J.A. 3216. Claim 1 is representative for current purposes:

> 1. A method for treating schizophrenia in a patient without a clinically significant weight gain, comprising:
>
> > administering orally to the patient (1R,2S,3R,4S)-N-[(1R,2R)-2-[4-(1,2-benzoisothiazol-3-yl)-1-piperazinylmethyl]-1-cyclohexylmethyl]-2,3-bicyclo[2.2.1]heptanedicarboximide or a pharmaceutically acceptable salt thereof at a dose of from 20 to 120 mg/day such that

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[1] There is no dispute that lurasidone is (1R,2S,3R,4S)-N-[(1R,2R)-2-[4-(1,2-benzoisothiazol-3-yl)-1-piperazinylmethyl]-1-cyclohexylmethyl]-2,3-bicyclo[2.2.1]heptanedicarboximide.

> the patient does not experience a clinically significant weight gain.

'827 patent, col. 10, lines 51–59.

Slayback Pharma LLC successfully petitioned for an inter partes review (IPR) of the '827 patent, and the Patent Trial and Appeal Board eventually held all 75 claims of the '827 patent to be unpatentable for obviousness over a single prior-art reference, U.S. Patent No. 5,532,372 (Saji). *Slayback Pharma LLC v. Sumitomo Dainippon Pharma Co.*, No. IPR2020-01053, 2022 WL 212259 (P.T.A.B. Jan. 20, 2022). For present purposes, we note key aspects of the Board's reasoning, without being complete even as to claim 1, let alone the other claims also held unpatentable.

The Board construed "a patient" (and "the patient") to have its "ordinary and customary meaning of 'one or more patients,' as opposed to a 'patient population.'" *Id.* at *4. The Board then addressed the claim limitations defining the required steps to be performed, finding that Saji sufficiently taught or suggested the use of lurasidone, at the dosages and frequencies of administration claimed in the '827 patent's claims, to treat the claimed psychotic disorders. *Id.* at *5–9. With regard to the claimed absence-of-weight-gain property, the Board did not find that Saji (or any other prior-art reference) affirmatively disclosed the claimed result for a patient so treated, but it noted a suggestion of favorable weight-gain effects for lurasidone made in an article by Horisawa and others. *Id.* at *9–10. Ultimately, though, the Board concluded that the claimed weight-gain property was inherent in the claimed method of treatment, seemingly because its undisputed claim construction of "a patient" as "one or more patients" meant that administering lurasidone in the claimed amounts to even one covered patient who subsequently did not gain weight would meet the claim limitation and because Sumitomo acknowledged that "'there will *always* be some outliers'" in side-effects in a pool of patients. *Id.* at *10

(emphasis added by the Board) (quoting Patent Owner's Sur-Reply before the Board).

After unsuccessfully seeking rehearing and a Precedential Opinion Review, Sumitomo timely appealed. Sumitomo has argued, among other things, that the Board did not properly consider certain safety-related evidence or the Horisawa suggestion and that it made an erroneous, or at least unclear, use of inherency doctrine in addressing at least the motivation-to-modify, reasonable-expectation-of-success, and unexpected-results components of the obviousness analysis. Slayback did not appear on appeal, but the Director of the Patent and Trademark Office intervened to defend the Board's decision. We have statutory jurisdiction under 35 U.S.C. § 141(c) and 28 U.S.C. § 1295(a)(4)(A).

Just before oral argument, the '827 patent expired. The court therefore asked about the issue of mootness at the outset of oral argument. Counsel for Sumitomo explained various facts, and Sumitomo's position, relating to the issue. Oral Arg. at 0:54–1:37.

"On appeal . . . a case becomes moot 'when the issues presented are no longer "live" or the parties lack a legally cognizable interest in the outcome.'" *ABS Global, Inc. v. Cytonome/ST, LLC*, 984 F.3d 1017, 1020 (Fed. Cir. 2021) (quoting *Already, LLC v. Nike, Inc.*, 568 U.S. 85, 91 (2013)). A "case remains live '[a]s long as the parties have a concrete interest, however small, in the outcome of the litigation.'" *MOAC Mall Holdings, LLC v. Transform Holdco LLC*, 598 U.S. 288, 295 (2023) (alteration in original) (quoting *Chafin v. Chafin*, 568 U.S. 165, 172 (2013)); *Chafin*, 568 U.S. at 173 ("[T]he parties must continue to have a personal stake in the ultimate disposition of the lawsuit" (cleaned up)); *cf. TransUnion LLC v. Ramirez*, 594 U.S. 413, 422–30 (2021) (ruling, in the related area of standing, that a case or controversy requires more than a dispute over a statute-based legal right—it requires a concrete

interest in that right). Here, the case is moot if Sumitomo no longer has a concrete interest in the exclusionary right granted by the '827 patent.

We conclude that Sumitomo no longer has such an interest. Given the expiration of the patent, Sumitomo has no interest in any forward-looking exclusion based on the patent. But that does not end the inquiry: As we have explained, a patentee may have a concrete interest in pursuing damages for pre-expiration infringement. *See*, *e.g.*, *Sony Corp. v. Iancu*, 924 F.3d 1235, 1238–39 n.1 (Fed. Cir. 2019). In this case, however, Sumitomo lacks any such concrete interest, as made clear in the colloquy with Sumitomo's counsel at oral argument.

Given the opportunity to discuss such an interest, Sumitomo expressed no interest in seeking damages for direct infringement from any persons who engaged in pre-expiration use of the claimed methods, including those who may have acquired lurasidone from a firm that had not labeled it for a use covered by the '827 patent's claims. Oral Arg. at 0:34–0:54, 41:10–41:28. With respect to firms that might have sold lurasidone in a way that could have constituted indirect infringement if unlicensed—*e.g.*, a firm that "jumped the gun," "a compounding pharmacy," Oral Arg. at 41:10–41:27—Sumitomo noted that there was only a theoretical possibility that such firms even existed: Sumitomo did not affirmatively conjecture that there were any such firms. Oral Arg. at 41:27–41:39. To the contrary, it stated that, as far as it knew, the only firms marketing lurasidone with relevant instructions were firms already under license to Sumitomo, pursuant to settlement agreements with it. *See* Oral Arg. at 0:33–0:41. It made clear, moreover, that, in contrast to what would often be true in different kinds of markets, it was very unlikely that there were such unlicensed firms unknown to it, given the regulatory entry and other requirements in this area. *See* Oral Arg. at 0:28–0:34, 0:42–0:54, 1:04–1:12, 41:10–41:39. The existence of such firms, in this case, presents only "a

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