United States Court of Appeals for the Federal Circuit

ELI LILLY AND COMPANY,
Appellant

v.

LOS ANGELES BIOMEDICAL RESEARCH INSTITUTE AT HARBOR-UCLA MEDICAL CENTER,
Appellee

2016-1547

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. IPR2014-00693.

Decided: February 28, 2017

MARK J. FELDSTEIN, Finnegan, Henderson, Farabow, Garrett & Dunner, LLP, Washington, DC, argued for appellant. Also represented by JOSHUA GOLDBERG, YIEYIE YANG; CHARLES E. LIPSEY, Reston, VA; MARK STEWART, Eli Lilly and Company, Indianapolis, IN.

EWA M. DAVISON, Fenwick & West LLP, Seattle, WA, argued for appellee. Also represented by DAVID KEITH TELLEKSON, ELIZABETH B. HAGAN; VIRGINIA KAY DEMARCHI, AMY HAYDEN, Mountain View, CA.

Before NEWMAN, BRYSON, and MOORE, *Circuit Judges.*

BRYSON, *Circuit Judge.*

This appeal is related to the appeal in *Los Angeles Biomedical Research Institute at Harbor-UCLA Medical Center v. Eli Lilly & Company,* No. 2016-1518, decided today. The same patent (U.S. Patent No. 8,133,903 ("the '903 patent")) and one of the same prior art references (International Patent Application No. WO 01/80860 (published Nov. 1, 2001) (John S. Whitaker et al., applicants) ("Whitaker")) are at issue in both cases. The background discussion set forth in the *Los Angeles Biomedical Research Institute* case will not be repeated here, except to the extent required by the differences in the legal issues presented in the two cases.

I

At the behest of appellant Eli Lilly and Company ("Lilly"), the Patent Trial and Appeal Board instituted *inter partes* review of the claims of the '903 patent, owned by Los Angeles Biomedical Research Institute at Harbor-UCLA Medical Center ("LAB"), for anticipation by Whitaker. Following trial, the Board held that Whitaker did not anticipate the '903 claims because it did not disclose the limitation requiring the administration of a PDE5 inhibitor "at a dosage up to 1.5 mg/kg/day for not less than 45 days."

Before the Board, Lilly relied heavily on Example 6 of Whitaker. That portion of Whitaker discusses a set of studies on the use of phosphodiesterase 5 ("PDE5") inhibitors to treat erectile dysfunction. The studies included some subjects who took a PDE5 inhibitor "greater than 70% of the time" over the course of either 8 or 12 weeks. Whitaker at 34. The Board, however, found that the disclosure that some of the study subjects took the PDE5

inhibitor more than 70% of the time did not constitute a disclosure of daily dosing.

The Board also rejected Lilly's argument that Whitaker explicitly disclosed daily dosing for at least 45 days based on Whitaker's title ("Daily Treatment for Erectile Dysfunction Using a PDE5 Inhibitor").

Finally, the Board concluded that Whitaker's definition of "chronic administration" did not inherently disclose treatment with a PDE5 inhibitor for at least 45 days. Whitaker defines "chronic administration" to mean "regular administration for an extended period, preferably daily for three or more days, and still more preferably daily as long as the patient suffers from erectile dysfunction (in the absence of therapy)." Whitaker at 7. The Board noted that Whitaker discloses that administering daily treatment for as little as three days may effectively treat erectile dysfunction, even if a person of skill in the art would understand that erectile dysfunction can last longer than 45 days in the absence of therapy.

Based on its analysis of Whitaker, the Board concluded that Lilly had failed to show, by a preponderance of the evidence, that Whitaker anticipates claim 1 of the '903 patent. Because dependent claims 2-5 all incorporate the limitations of claim 1, the Board held that those claims were also not anticipated.

II

"To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either expressly or inherently." *Rapoport v. Dement*, 254 F.3d 1053, 1057 (Fed. Cir. 2001). "In the context of anticipation, the question is not whether a prior art reference 'suggests' the claimed subject matter[;] . . . [r]ather, the dispositive question regarding anticipation is whether one skilled in the art would reasonably understand or infer from a prior art reference that every claim element is

disclosed in that reference." *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1055 (Fed. Cir. 2010) (internal brackets and quotation marks omitted).

Lilly's argument boils down to saying that Whitaker's definition of "chronic administration" anticipates daily administration for 45 days or more because a person of skill would understand that erectile dysfunction (in the absence of therapy) can last longer than 45 days. As the Board stated, however, that, "at best, is an obviousness argument." Whitaker's definition of "chronic administration," which is "regular administration for an extended period, preferably daily for three or more days, and still more preferably daily as long as the patient suffers from erectile dysfunction (in the absence of therapy)," does not expressly teach daily treatment for at least 45 days.

The understanding of a person of skill at that time regarding how long a patient would suffer from erectile dysfunction in the absence of therapy says nothing about how long erectile dysfunction would last *with* the therapy at issue in Whitaker that had not before been prescribed—i.e., chronic daily treatment with PDE5 inhibitors, rather than on-demand use. For that reason, Lilly's expert testimony, which was addressed to the former question, does not answer the latter.[1]

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[1] *ClearValue, Inc. v. Pearl River Polymers, Inc.*, 668 F.3d 1340 (Fed. Cir. 2012), on which Lilly relies, does not help Lilly. The prior art reference at issue in that case met every limitation but disclosed a broader range than was recited in the claim. The reference disclosed a process for "clarification" of water with alkalinity of 150 ppm or less, while the claim at issue recited a process for clarification of water with alkalinity of 50 ppm or less. *Id.* at 1344. The court held that the reference anticipated the claim because the patent did not distinguish its narrower

A fair reading of Whitaker's definition of "chronic administration" is that it refers to daily administration for at least three days, and more if the erectile dysfunction persists. That does not disclose the treatment of penile fibrosis for at least 45 days, particularly in light of the fact that the only daily dosing done in Whitaker lasted for at most three weeks. Whitaker at 37 (Example 7).

The reference to a dosing period of 8 or 12 weeks in Whitaker's Example 6 does not provide the necessary disclosure of dosing every day for at least 45 days. In fact, the "daily" dosing referred to in Example 6 included dosing on fewer than 30% of the days. Thus, even in light of the embodiments discussed by Whitaker, the definition of "chronic administration" does not provide the clear disclosure required to prove anticipation.[2]

In *AstraZeneca LP v. Apotex, Inc.*, this Court affirmed the district court's determination that the method claims for once-daily dosing would likely survive an anticipation challenge by a prior advertisement that disclosed twice-daily dosing. 633 F.3d at 1055. The advertisement did not explicitly disclose once-daily dosing, nor did it inher-

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range as "critical." *Id.* at 1344-45. In this case, Whitaker does not disclose a broader range than the "not less than 45 days" treatment period while meeting every other limitation, because it does not disclose a daily treatment regimen that necessarily extends for more than 45 days.

[2] The results reported in Example 6 of Whitaker do not support a conclusion that a strict regimen of daily dosing is superior to dosing on more than half the days. *See* Whitaker at 36-37 (Tables 2-4 report better results for those taking the 10mg dose 50%-70% of the time than for those taking the 10mg dose greater than 70% of the time).

ently do so because, as the expert testified, persons of skill in the art at that time did not have "any information or historical perspective that once a day therapy worked for anyone." *Id.* at 1054.

This case is similar. Whitaker may "suggest" long-term daily treatment by noting the beneficial effects of daily treatment (better erectile response and decreased side effects) in light of Example 6, but that is not enough. To anticipate, a reference must do more than "suggest" the claimed subject matter. *AstraZeneca*, 633 F.3d at 1055. Thus, we hold that substantial evidence supports the Board's finding that Whitaker does not disclose the claimed treatment regimen with sufficient clarity to satisfy the demanding standard for anticipation.[3]

AFFIRMED

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[3] Lilly also argues that LAB's infringement contentions in the related district court proceeding, *Los Angeles Biomed. Research Inst. v. Eli Lilly & Co.*, No. 2:13-cv-08567-JAK-JCG (C.D. Cal.), "confirm anticipation by Whitaker." LAB objects to the court's consideration of those materials in this case. As noted in the related appeal decided today, *Los Angeles Biomedical Research Institute at Harbor-UCLA Medical Center v. Eli Lilly & Co.*, No. 2016-1518, at 19 n.6, we can properly take judicial notice of the records of related district court proceedings, and we therefore deny LAB's motion to strike from the joint appendix the materials filed in the district court action and disregard Lilly's argument. On the merits, as explained in the related appeal, No. 2016-1518, at 19-20, we disagree with Lilly that LAB asserted in the district court proceeding that the '903 patent is infringed regardless of treatment duration.