

NOTE: This disposition is nonprecedential.

**United States Court of Appeals
for the Federal Circuit**

**ELI LILLY AND COMPANY, ELI LILLY EXPORT
S.A., ACRUX DDS PTY LTD.,**
Plaintiffs-Appellants

v.

**PERRIGO COMPANY, PERRIGO ISRAEL
PHARMACEUTICALS LTD., ACTAVIS
LABORATORIES UT, INC., FKA WATSON
LABORATORIES INC., LUPIN
PHARMACEUTICALS, INC., LUPIN LTD.,**
Defendants-Appellees

AMNEAL PHARMACEUTICALS LLC,
Defendant-Cross-Appellant

2016-2555, 2016-2614

Appeals from the United States District Court for the Southern District of Indiana in Nos. 1:13-cv-00851-SEB-DKL, 1:13-cv-01799-JMS-DKL, 1:14-cv-02025-SEB-TAB, Judge Jane Magnus-Stinson, Judge Sarah Evans Barker.

Decided: November 22, 2017

CHARLES E. LIPSEY, Finnegan, Henderson, Farabow, Garrett & Dunner, LLP, Reston, VA, argued for plaintiffs-appellants. Also represented by LAWRENCE SCOTT BURWELL; HOWARD WARREN LEVINE, LAURA POLLARD MASUROVSKY, Washington, DC; ALISSA KEELY LIPTON, Boston, MA; JENNIFER SWAN, Palo Alto, CA; MANISHA A. DESAI, Eli Lilly and Company, Indianapolis, IN.

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MICHAEL KEENAN NUTTER, Winston & Strawn LLP, Chicago, IL, argued for defendants-appellees Actavis Laboratories UT, Inc., Lupin Ltd., Lupin Pharmaceuticals, Inc. Defendant-appellee Actavis Laboratories UT, Inc. also represented by DAN HOANG, KURT A. MATHAS; GEOFFREY P. EATON, Washington, DC.

JOHN T. BATTAGLIA, Fisch Sigler, LLP, Washington, DC, argued for defendant-cross-appellant Amneal Pharmaceuticals LLC. Also represented by JOSEPH FRANKLIN EDELL, ROY WILLIAM SIGLER; CAROLYN ALENCI, VINCENT CAPUANO, ANTHONY JAMES FITZPATRICK, CHRISTOPHER S. KROON, Duane Morris LLP, Boston, MA.

KEITH DAVID PARR, Locke Lord LLP, Chicago, IL, for defendants-appellees Lupin Pharmaceuticals, Inc., Lupin Ltd. Also represented by DAVID BRIAN ABRAMOWITZ, HUGH S. BALSAM, CAROLYN ANNE BLESSING, NINA VACHHANI.

Before CHEN, PLAGER, and HUGHES, *Circuit Judges*.
CHEN, *Circuit Judge*.

INTRODUCTION

This litigation relates to Abbreviated New Drug Applications filed by the defendants for generic equivalents of Eli Lilly's Axiron® testosterone applicator. Eli Lilly, in turn, sued the defendants for patent infringement. After a nine-day bench trial, the district court issued a thorough, well-considered opinion over 200 pages long. Eli Lilly appeals the district court's opinion that claim 20 of U.S. Patent No. 8,435,944 (the '944 patent) is invalid for obviousness under 35 U.S.C. § 103. Amneal cross-appeals the district court's opinion that claims 9 and 10 of U.S. Patent No. 8,807,861 (the '861 patent) are (1) not invalid; and (2) infringed by Amneal's applicator. Because we find no fault in the district court's opinion, we *affirm* on all grounds.

ANALYSIS

I. The '944 Patent

Claim 20 of the '944 patent recites a transdermal delivery method of applying testosterone to the axilla of a patient. We agree with the district court that the prior art (e.g. the Aschkenasy '268 publication and the Cutter 2000 and 2001 references) teach and suggest that applying testosterone to the axilla will increase a patient's testosterone level with a reasonable expectation of success. *See* J.A. 165–69. Eli Lilly's arguments against those references lack merit and/or are based on a misreading of the lower court's opinion. Lilly's primary challenge is that the district court improperly reached a "prima facie" decision of obviousness and improperly treated its secondary considerations as an afterthought. We disagree with Lilly's argument for a few reasons. As an initial matter, it is premised on Lilly having provided weighty objective indicia of non-obviousness. We agree with the district court, however, that Lilly's proffered objective indicia lacked probative weight. *See* J.A. 170–79. In Lilly's briefing below, it advanced two primary bases of

secondary considerations: (1) the prior art teaches away from applying testosterone to the axilla due to concerns over causing an undesired elevated level of dihydrotestosterone (DHT); and (2) the claimed method yielded unexpected results. *Id.* Lilly's expert, however, did not point to any teaching in the prior art that suggested avoiding the axilla as a location for applying and delivering testosterone.

As the district court noted, Eli Lilly's teaching away theory rested on a position that the scrotal skin and the axilla have comparably high 5-alpha reductase activity, which can result in an elevated DHT level. But Lilly's reference to support that assertion, Takayasu, did not include measurements from the scrotal area in its study. *See* J.A. 22797–801.¹ Thus, even if the prior art sought to avoid areas that had the same level of 5-alpha reductase activity as scrotal skin (and we agree with the district court that, at the time of the invention, this was less than clear), Lilly did not present any evidence that the axilla and scrotal skin have comparably high activity.² Thus, the district court correctly found, on this record, that the

¹ Takayasu's measurements of high 5-alpha reductase in the axillary skin were also limited exclusively to samples taken from women and thus may be less probative in the context of testosterone administration to men. *See* J.A. 22800.

² Lilly contended in its briefing below, J.A. 7118–19, and at oral argument that Takayasu itself recognized that the level of 5-alpha reductase was comparably high in the scrotum and axilla by stating that “the activity is high in genital and axillary skin.” J.A. 22798 (citations omitted). But, as the district court recognized, J.A. 75–77, Takayasu only states that the levels are high in both areas—it does not state that levels in the axilla are as high or higher than in the scrotum.

only teaching relating to DHT levels in the axilla was by Cutter, which reported a normal DHT level after application of testosterone to the axilla.

On unexpected results, Eli Lilly makes no meaningful argument contesting the district court's rejection of Lilly's theory of unexpected results. On review, we see no error in the district court's explanation that Lilly's asserted 'seven-fold increase' in skin permeability was based on a flawed extrapolation of data reported in a prior art reference. In sum, the lower court correctly found that Lilly's objective indicia lacked weight. The district court thus could not have committed any reversible legal error in the order of how it considered the evidence, given that Lilly's proffered evidence was unhelpful.

Eli Lilly notes the district court's admitted use of the phrase "prima facie" in several places in the course of the court's discussion of obviousness, and considers that reversible error. But even if Eli Lilly's secondary consideration/objective indicia evidence carried probative weight, there is nothing to indicate that the court reached the ultimate conclusion of obviousness prematurely, or without fully considering all the evidence before it, including the evidence of objective indicia. For that reason we do not see the insertion of that particular phrase as reversible error in this case, since it does not accurately reflect what the district court actually did. *See, e.g., In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1076–77 (Fed. Cir. 2012). Rather, we are satisfied that the district court thoroughly considered all the arguments and evidence presented before reaching its decision that the defendants had met their burden of proof that claim 20 of the '944 patent is invalid for obviousness.

II. The '861 Patent

Claims 9 and 10 of the '861 patent are directed to an applicator with a "resiliently deformable wall" used to

administer a testosterone solution to the axilla. We detect no error in the district court's conclusions that the claims, as construed, are not invalid over the asserted prior art (e.g. Gueret '187 and Gueret '986) and were infringed by Amneal's applicator. On appeal, Amneal argues that (1) these claims are anticipated or obvious over some combination of Gueret '187 and Gueret '986; (2) the district court improperly disregarded other theories of invalidity advanced by other defendants and joined by Amneal; and (3) Amneal's applicator does not infringe because it does not deform "in a blade-like manner."

As to the Gueret references, we are unconvinced by Amneal's arguments that Gueret '187 discloses the double wall required by the claims as construed. As the district court correctly recognized, annular rib 201/202 contains a number of features that are materially different from the double wall of the claims. Amneal does not challenge the district court's finding that annular rib 201/202 does not meet the double wall limitation, and instead contends that annular rib 201/202 and annular rib 204, taken together, form a double wall as required by the claims. We decline to consider this argument because it was not raised below. *See HTC Corp. v. IPCom GmbH & Co., KG*, 667 F.3d 1270, 1281 (Fed. Cir. 2012). Amneal's expert testimony was exclusively directed to an invalidity theory of *removing* annular rib 204 to form a double wall structure from only annular rib 201/202. *See* J.A. 2071–76.³ Amneal offers a plethora of record citations as proof that it had raised below its newly-minted argument. We have carefully reviewed every single one of Amneal's citations

³ Amneal contends that a slide from its expert's demonstrative, J.A. 31906, supports this theory. But that slide plainly does not focus on annular rib 204 *in conjunction with* annular rib 201/202, let alone suggest that those elements, taken together, represent a double wall.

and did not find any testimony or briefing showing it argued that annular rib 204 together with annular rib 201/202 form a double-wall structure. The district court accordingly never addressed this theory.⁴ At bottom, we detect no reversible error in the district court's conclusion that Amneal failed to meet its burden of proving the asserted '861 patent claims invalid.⁵

Amneal also argues that the district court improperly failed to consider arguments that (1) the '861 claims were obvious over the DiPietro reference in combination with the Gueret references; (2) the claims were anticipated by Gueret '986 under a theory that its single wall could fold over to form a double wall; and (3) the claims were invalid for lack of written description if the claims were construed to cover an embodiment in which a single wall of an

⁴ Amneal contends that the district court in fact addressed and rejected this theory. But the record shows that the district court considered annular rib 201/202 and annular rib 204 separately, not in conjunction with one another. J.A. 129.

⁵ Amneal contends that the district court erred by placing a higher burden of proof on Amneal by noting that the asserted prior art references had appeared before the examiner during prosecution of the '861 patent. J.A. 211. We disagree. Despite its imprecise use of the word "burden," we read the district court's opinion as merely stating, as has the Supreme Court, that "new evidence supporting an invalidity defense may 'carry more weight' in an infringement action than evidence previously considered by the PTO." *Microsoft Corp. v. i4i Ltd. P'ship*, 564 U.S. 91, 110 (2011) (quoting *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1360 (Fed. Cir. 1984)).

applicator could fold over to form a double wall.⁶ None of these arguments help Amneal's cause.

The defendants below relied on DiPietro only for the teaching of applying testosterone to the axilla, not for any particular design of an applicator. *See* J.A. 6768–69. And DiPietro itself does not disclose any particular applicator. *See* J.A. 24778–95. Because we hold that none of the Gueret references disclose a double wall, even if the DiPietro reference were considered, the outcome would not differ. It was thus not reversible error for the court to decline to consider theories depending in part on the DiPietro reference. With regard to Amneal's invalidity theories which were contingent upon the district court adopting a construction of the claims that would cover a single wall that could fold over to create a double wall, this wall-folding theory was explicitly rejected by the district court. *See* J.A. 193 n.30. Thus, theories which depend on the rejected wall-folding theory are moot under the district court's claim construction, and it was not error for the district court to not consider these alternative theories.

As to Amneal's argument that its applicator does not infringe because it does not deform in a "blade-like manner," the phrase "blade-like manner" appears nowhere in the claims and appears only in the context of a specific embodiment in the specification. Thus, we agree with the district court that the claims require only that the applicator wall be "resiliently deformable" and do not require a specific mode of resilient deformation. Amneal also argues that the district court itself recognized that the claims require that the applicator deform in a "blade-like manner." We read the district court's statements in the

⁶ Amneal also mentioned, but did not appeal, the district court's lack of consideration of an indefiniteness theory.

record as simple explications of the '861 patent and the expert testimony in the case. *See* J.A. 124 (summarizing expert testimony), 139 (describing the specific embodiment of the patent). Thus, we do not find those isolated statements to conflict with the court's own correct holding that the claims do not require a specific mode of deformation. *E.g.* J.A. 125, 199–200.

CONCLUSION

We have considered all of the appellant's and cross-appellant's other arguments and find them unpersuasive. For the foregoing reasons, the opinion of the district court is

AFFIRMED

COSTS

No costs.