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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

LA JOLLA PHARMACEUTICAL COMPANY, LA JOLLA PHARMA, LLC, and THE GEORGE WASHINGTON UNIVERSITY, Plaintiffs, v. GLAND PHARMA LIMITED, FRESENIUS KABI USA, LLC, and FRESENIUS KABI SWISSBIOSIM GMBH Defendants.	Civil Action No. 2:22-cv-01754 (MEF)(JBC) *Document Electronically Filed*

CORRECTED OPENING BRIEF IN SUPPORT OF PLAINTIFFS' MOTION TO EXCLUDE EXPERT TESTIMONY OF DR. SUTER PURSUANT TO FED. R. EVID. 702

I. INTRODUCTION

Plaintiffs La Jolla Pharmaceutical Company, La Jolla Pharma, LLC, and The George Washington University (collectively, "Plaintiffs") respectfully move the Court to preclude testimony concerning specific invalidity opinions from Dr. Robert E. Suter, expert for Defendants Gland Pharma Limited, Fresenius Kabi USA, LLC, and Fresenius Kabi SwissBioSim GmbH ("collectively, Defendants").

Dr. Suter submitted two expert reports directed to invalidity, ultimately opining that, *inter alia*, claim 3 of U.S. Patent No. 11,096,983 ("the '983 patent") and claim 5 of U.S. Patent No. 10,493,124 ("the '124 patent") (collectively the "Asserted Claims") are invalid based upon the judicially-created doctrine of obviousness-type double patenting ("OTDP"). Dr. Suter's OTDP opinions as to the Asserted Claims are unreliable and should be excluded under Fed. R. Evid. 702.

It is well established that an OTDP inquiry requires a two-step process, with the first step being a determination of the differences between a reference claim and an asserted claim. *See Abbvie Inc. v. Mathilda & Terrence Kennedy Inst. of Rheumatology Trust*, 764 F.3d 1366, 1374 (Fed. Cir. 2014); *see also Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 968 (Fed. Cir. 2001). Without a determination of such differences, the OTDP analysis is flawed and cannot go forward. In the instant case, Dr. Suter failed to consider and address a limitation that appears in his reference claim but that is not present in the Asserted Claims he alleges are invalid for OTDP. His failure to properly conduct step one of the OTDP inquiry—to determine the differences between the reference claim and the Asserted Claims—is thus an application of an incorrect legal standard and is thereby inadmissible under Fed. R. Evid. 702 and the standards set forth in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). The Court should exclude from trial Dr. Suter's OTDP testimony as to the Asserted Claims.

II. LEGAL STANDARDS

Pursuant to Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharms.,* 509 U.S. 579 (1993), an expert may offer opinion testimony at trial if (1) the opinion is based on sufficient facts or data; (2) the testimony is the product of reliable principles and methods; and (3) the witness has applied the principles and methods reliably to the facts of the case. *Micro Chem., Inc. v. Lextron, Inc.*, 317 F.3d 1387, 1391-92 (Fed. Cir. 2003). The court must act as a "gatekeeper" to exclude expert testimony that "is irrelevant or does not result from the application of reliable methodologies or theories to the facts of the case." *Id.* at 1391. In exercising this gatekeeper role, the court must analyze the connection between an expert's conclusion and the facts on which that conclusion is based. *General Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) ("A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered."). The party offering the expert testimony bears the burden of establishing its admissibility by a preponderance of the evidence. *See Bourjaily v. United States*, 483 U.S. 171, 175 (1983).

Expert testimony may be excluded if the opinions are based upon an application of incorrect legal standards. The Federal Circuit "encourage[s]" district courts to exercise their "gatekeeper authority when parties proffer, through purported experts, not only unproven science, but markedly incorrect law." *Hebert v. Lisle Corp.*, 99 F.3d 1109, 1117 (Fed. Cir. 1996); *see also Exela Pharma Scis., LLC v. Eton Pharms., Inc.*, No. 20-CV-365 (MN), 2022 WL 806524, at *1, *4, *8 (D. Del. Feb. 8, 2022) ("An expert's opinion that crucially depends on an incorrect legal theory is not likely to be relevant to the Court's fact-finding. Consequently, courts routinely preclude those portions of an expert's report that are premised on a misunderstanding of the law."); *Sprint Communications Co. L.P. v. Cox Communications Inc.*, 302 F. Supp. 3d. 597, 624 (D. Del. 2017) (excluding an expert's report because it "improperly applies legal principles" such that the

Court had no confidence the expert "has reliably applied the principles and methods to the facts of the case," as required by Fed. R. Evid. 702(d)); *Major Tours, Inc. v. Colorel*, 799 F. Supp. 2d. 376, 409–10 (D.N.J. 2011) (precluding an expert's report after finding that the expert both relied on definitions that were incorrect as a matter of law and made technical errors); *see also Degelman Indus., Ltd. v. Pro-Tech Welding & Fabrication, Inc.*, No. 06-cv-6346, 2011 WL 6754053, at *3 (W.D.N.Y. May 31, 2011), *report and recommendation adopted*, 2011 WL 6752565 (W.D.N.Y. Dec. 23, 2011) (precluding expert's testimony where he "applied the wrong legal standard in reaching his ultimate conclusions of non-infringement").

III. ARGUMENT

An OTDP analysis is a two-step process that requires (1) determining the differences between the claims in the reference patent and the asserted patent, and then (2) determining whether those differences render the claims patentably distinct. *See Abbvie*, 764 F.3d 1374. Moreover, such differences between the reference and asserted claims "cannot be considered in isolation—the claims must be considered as a whole." *Eli Lilly & Co. v. Teva Parenteral Meds., Inc.*, 689 F.3d 1368, 1377 (Fed. Cir. 2012) (discussing the need to consider the claims as a whole in an OTDP analysis); *see also UCB, Inc. v. Accord Healthcare, Inc.*, 890 F.3d 1313, 1324 (Fed. Cir. 2018) (finding that "the district court did not err by focusing its double patenting analysis on the claims' differences, as well as the claims as a whole."); *Gen. Foods Corp. v. Studiengesellschaft Kohle mbH*, 972 F.2d 1272, 1278 (Fed. Cir. 1992) ("Claims must be read as a whole in analyzing a claim of double patenting.").

The only reference claim that Dr. Suter relies on as the basis of his OTDP assertions is claim 23 of U.S. Patent No. 10,548,943 ("the '943 patent") ("Reference Claim") (*see* Ex. A, PTX-007, LAJ_GIA0000100 at LAJ_GIA0000109; col. 6, ll. 7-9). The Reference Claim is a

dependent claim that depends on claim 22 (*see id*. col. 6, ll. 4-6), which depends on claim 20 (*see id*. col. 5, ll. 15-17), which depends on claim 11 (*see id*. at LAJ_GIA0000108; col. 4, ll. 61-62), which depends on claim 1 (*see id*. col. 4, ll. 33-36), such that the Reference Claim includes all of the limitations of these claims from which it depends. *Monsanto Co. v. Syngenta Seeds, Inc.*, 503 F.3d 1352, 1357 (Fed. Cir. 2007) (quoting 35 U.S.C. § 112 (2000)) ("A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.") Important here is that the Reference Claim depends on claim 11, which provides the claim limitation that "the human subject is undergoing treatment with one or more vasopressors." (Ex. A, PTX-007, LAJ_GIA0000100 at LAJ_GIA0000108; col. 4, ll. 61-62.) As such, the Reference Claim *includes* this limitation. But when conducting his OTDP analysis as to the Asserted Claims, Dr. Suter failed to consider and address that the Reference Claim depends on claim 11, and thereby he failed to include the limitation of claim 11 in the scope of the Reference Claim. *See* Ex. B, DTX-184, Opening Expert Report of Robert E. Suter, ¶¶ 1403, 1405, 1408, 1409, 1457, and Exhibit E (regarding the OTDP analysis as to claim 3 of the '983 patent); ¶¶ 1738, 1740, 1742, 1743, 1762, and Exhibit G (regarding the OTDP analysis as to claim 5 of the '124 patent).

Dr. Suter's failure to address that the limitation of claim 11 is a limitation in the Reference Claim is critical, because the Asserted Claims that he alleges are invalid for OTDP over the Reference Claim do not include such a limitation. *See* Ex. C, PTX-009, LAJ_GIA0000110 at LAJ_GIA0000134; the '983 patent, col. 25, ll. 24-26 and Ex. D, PTX-005, LAJ_GIA0000066 at LAJ_GIA0000089; the '124 patent, col. 25, ll. 14-15. In other words, Dr. Suter did not consider this difference between the Reference Claim and the Asserted Claims, the required first step of an

OTDP analysis. And because he did not properly conduct the first step in the OTDP inquiry, it follows that he could not have properly conducted step two, which is to determine whether the differences between the Reference Claim and the Asserted Claims render the claims patentably distinct. Moreover, because Dr. Suter did not consider all of the limitations in the Reference Claim, he could not have conducted his "double patenting analysis on the claims' differences, as well as the claims as a whole." *UCB*, 890 F.3d 1324. Dr. Suter's failure to apply the proper legal principles of OTDP makes his opinions as to OTDP of the Asserted Claims unreliable.

Dr. Suter's OTDP opinions as to the Asserted Claims in his Reply Expert Report Regarding Invalidity of the Asserted Patents fare no better. In an effort to rehabilitate his already fatally-flawed OTDP analysis, he applies an ***infringement*** test to his analysis of patent ***validity***. Specifically, Dr. Suter opines that the Asserted Claims do not exclude or preclude a human subject who is undergoing treatment with one or more vasopressors (the Reference Claim limitation missing from the Asserted Claims), and that someone following all the steps of the Asserted Claims is still infringing those claims even if the human subject is undergoing treatment with one or more vasopressors, which, in his view, renders the claims invalid. *See* Ex. E, DTX-190, Reply Expert Report of Robert E. Suter Regarding Invalidity of the Asserted Claims, ¶¶ 423, 424, 500, 537 (regarding the OTDP analysis as to claim 3 of the '983 patent); ¶¶ 423, 424, 630, 640 (regarding the OTDP analysis as to claim 5 of the '124 patent). But as the Federal Circuit has repeatedly held, an infringement inquiry has no place in an OTDP analysis. *See Research Corp. Technologies, Inc. v. Gensia Labs., Inc.*, 10 Fed. Appx. 856, 862-63 (Fed. Cir. 2001) (rejecting a cross-infringement analysis in OTDP); *see also In re Lonardo* 119 F.3d 960, 967 (Fed. Cir. 2007) (refusing to affirm the PTO's finding of OTDP based upon whether one could not practice the earlier claims without infringing the later-issued claims).

Not only has Dr. Suter failed to properly conduct the appropriate OTDP analysis, he has also wrongly applied a test that has been rejected in an OTDP determination. For these reasons, alone or taken together, Dr. Suter's opinions as to OTDP of the Asserted Claims are unreliable.

IV. CONCLUSION

For the above reasons, Plaintiffs respectfully request that the Court exclude from trial Dr. Suter's opinions and testimony related to OTDP of the Asserted Claims.

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Respectfully submitted,

s/ Charles H. Chevalier

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