REDACTED

IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

ALLERGAN, INC., **Plaintiff,** **v.** **TEVA PHARMACEUTICALS USA, INC., *et al.*** **Defendants.**	**Civil Action No. 2:15-cv-01455-WCB** **LEAD CASE** FILED UNDER SEAL

PLAINTIFF ALLERGAN, INC.'S RESPONSE TO DEFENDANTS' MOTION FOR SUMMARY JUDGEMENT OF NON-INFRINGEMENT

CONFIDENTIAL UNDER PROTECTIVE ORDER

MYLAN - EXHIBIT 1154

Mylan Pharmaceuticals Inc. et al. v. Allergan, Inc.

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I. INTRODUCTION

Defendants' motion for summary judgment should be denied, as it is based on a fundamental misunderstanding of both the facts and the law. Restasis® was the first-ever product that treats the problem underlying dry eye and KCS by increasing the production of a patient's tears. The label for Restasis® and proposed labels for all Defendants' copycat products state that the products are indicated for "increas[ing] tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca." (Dkt. 342, Ex. 4, Restasis® Label AGN_RES0069704-709 at AGN_RES0069705.) There is no dispute that increasing tear production does, in fact, treat KCS and dry eye. A deficiency in tears is the way that physicians diagnose KCS, a form of dry eye, and an increase in tear production is the way to treat those conditions. In fact, there is no other reason to increase tear production other than to treat KCS or dry eye, thereby restoring tears in patients suffering from those conditions.

Yet, according to Defendants, there is not even a factual dispute as to whether claims to "treating KCS," "treating dry eye," and "restoring tear production" are infringed.[1] This argument is specious—Defendants' labels directly instruct physicians and patients to use the products to increase tear production ***in patients with KCS***, which is a subset of dry eye disease, thereby ***treating*** those patients' KCS and dry eye. And it takes no more than the application of

[1] Pursuant to the Court's Order dated January 26, 2017 (Dkt. 265) Allergan further limited its asserted claims on Friday, June 9, reducing the number to 13. The only still-asserted claims at issue in Defendants' motion are claims 13, 16, 22, 26, and 27 of the '191 patent and claim 26 of the '111 patent. Allergan believes that Defendants' motion as to the claims no longer at issue (claims 13, 14, and 24 of the '162 patent, claims 11 and 18 of the '556 patent, and claims 17 and 25 of the '111 patent) is wrong, but Allergan will not address those claims because they are no longer at issue and are now moot.

keratoconjunctivitis sicca," that does not mean that the FDA ultimately made a finding that Restasis® does not treat KCS or dry eye. Defendants ignore that, after the FDA initially rejected the proposed indication, Allergan continued to perform further analysis on the data to demonstrate efficacy, leading the FDA to approve the product with a labeled indication that more precisely describes how the product works and expressly contemplates use in treating KCS (a subset of dry eye). (*See* Ex. 4, Corr. to FDA of Oct. 28, 2002, AGN_RES0066832 at AGN_RES0066836 ("Schirmer wetting is a clinically relevant and appropriate end point for studying dry eye disease."); Dkt. 342 at 12 (Defendants state "KCS [] is a ***subset*** of dry eye.") (emphasis added); Claim Construction Order, Dkt. 214 at 13 (defining KCS as "***a type of*** dry eye disease involving an absolute or partial deficiency in aqueous tear production") (emphasis added); *see also* Dkt. 342, Ex. 4, Restasis® Label AGN_RES0069704-709 at AGN_RES0069705.)

Moreover, as discussed above, the FDA has also allowed Allergan to market Restasis® for treatment of KCS and dry eye, and to refer to its ability to restore tears. (Ex. 6, Advertisement AGN_RES0585435-441 at AGN_RES0585435, AGN_RES0585437, AGN_RES0585441; Ex. 7, FAQ AGN_RES1103931-32 at AGN_RES1103931.) There is nothing about the history of the approval process for Restasis® to suggest that use of the product to treat dry eye or KCS, or to restore tearing, are distinct, off-label uses.

D. Defendants' Labels Induce Infringement of Claims to KCS, Dry Eye, and Restoring Tearing, and there Are No Substantial Non-Infringing Uses

Finally, Defendants' arguments concerning lack of intent to induce and substantial non-infringing uses are all built on the faulty premise that uses of the product for treatment of KCS and dry eye and for restoring tear production are "off-label" and non-infringing. But, as discussed in detail above, there is at least a factual dispute on those arguments.

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