

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS**

TEVA PHARMACEUTICALS  
INTERNATIONAL GMBH and  
TEVA PHARMACEUTICALS  
USA, INC.,

*Plaintiffs,*

v.

ELI LILLY AND COMPANY,

*Defendant.*

Civil Action No.  
1:18-cv-12029-ADB

**TEVA'S OPPOSITION TO LILLY'S MOTION *IN LIMINE* NO. 6 TO PRECLUDE  
PLAINTIFFS FROM PRESENTING ARGUMENTS AND EVIDENCE REGARDING  
THE PREVALENCE OF MIGRAINE ENCOUNTERED IN CLINICAL PRACTICE  
AND WHETHER MIGRAINE IS REPRESENTATIVE OF THE HEADACHES THAT A  
POSA WOULD ENCOUNTER IN CLINICAL PRACTICE**

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## I. INTRODUCTION

The Court should deny Lilly's Motion *in Limine* No. 6 (ECF No. 479, "Mot.") because granting it would require the Court to resolve competing expert testimony about how a person of ordinary skill in the art ("POSA") would understand the scope of the term "headache." That would be improper. The relevance of the evidence in dispute is unquestionable, and Lilly has not and cannot articulate any unfair prejudice. While Lilly argues that a POSA would understand the scope of "headaches" referred to in the asserted claims to be dictated by a 2004 publication by the International Classification of Headache Disorders ("ICHD"), Teva's experts, Drs. Blumenfeld and Hill, disagree because the person of ordinary skill in the art is someone who, among other things, "treat[s] patients with a CGRP-related disease, such as migraine headaches." ECF No. 368, Ex. O ¶ 73. Teva's experts explain that the proper perspective for determining the scope of "headaches" is that of practicing physicians who actually treat headache patients in clinical practice. This dispute between the experts is one that should be resolved by the jury.

The particular evidence Lilly attempts to exclude—including two academic articles, Lipton 2001 and Tepper 2004—is probative of factual disputes underlying the § 112 written description and enablement inquiries and is directly responsive to Lilly's own arguments about how a POSA would understand the scope of headaches covered by the asserted claims. Moreover, Lilly has failed to identify how such information would be unfairly prejudicial. The Court should therefore deny Lilly's Motion to exclude under Rules 401, 402, and 403.

## II. ARGUMENT

### A. A POSA's Understanding of the Prevalence and Representativeness of Migraine and Other CGRP-Related Headaches is Relevant to the 112 Inquiry

A POSA's understanding of the prevalence and representativeness of migraine and other CGRP-related headaches in a clinical setting is probative of the parties' dispute regarding Lilly's

§ 112 defenses. In its Motion, Lilly assumes the correctness of its expert's position that "headache" in the asserted claims refers to specific diagnostic criteria adopted in 2004 by the ICHD and contends that Teva's contrary evidence is irrelevant or unfairly prejudicial. But Teva's contrary evidence is relevant and does not pose any undue prejudice or risk of jury confusion.

Teva's experts disagree that the "full scope" of headaches in the asserted claims is determined by the ICHD for several factual reasons. First, Teva's experts explain that the ICHD was principally used for clinical trials and not widely deployed by treating physicians in ordinary clinical practice. ECF No. 368, Ex. L ¶ 102; ECF No. 368, Ex. V ¶ 410. Second, Teva's experts explain that a POSA would assess the full scope of headache disorders through the lens of what is treated in a clinical setting, before citing empirical evidence (including Lipton 2001 and Tepper 2004) showing that the vast majority of headaches encountered in clinical practice are migraine. ECF No. 368, Ex. L ¶ 103. Third, Teva's experts explain that the ICHD had been criticized and had limited utility for treating physicians as of 2006. *Id.* ¶ 104. The studies in Lipton 2001 and Tepper 2004 stand for the more general proposition that, when a patient complains to his or her doctor about headache, that "headache" is a migraine upwards of 90% of the time.<sup>1</sup> Lipton 2001, in particular, looked at other common terms used by physicians such as "sick headache," "sinus headache," and "tension headache" and then evaluated whether those diagnoses were, in fact, migraines. ECF No. 486, Ex. AA at 639. To the extent Lilly believes Lipton 2001 and Tepper 2004 are less probative because those studies were mostly (but not entirely) surveys of primary care physicians, Lilly can explore that on cross examination.

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<sup>1</sup> Lipton 2001 included, but was not limited to diagnosis in "primary care settings." ECF No. 486, Ex. AA at 643. Lipton 2001 was a prevalence study that surveyed 20,000 household and asked, among other things, "Have you ever been diagnosed by a physician as suffering from migraine?" *Id.* at 639.

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