

UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD

ELI LILLY AND COMPANY
v.
TEVA PHARMACEUTICALS INTERNATIONAL GMBH

Case IPR2018-01422 (Patent No. 9,340,614)
Case IPR2018-01423 (Patent No. 9,266,951)
Case IPR2018-01424 (Patent No. 9,346,881)
Case IPR2018-01425 (Patent No. 9,890,210)
Case IPR2018-01426 (Patent No. 9,890,211)
Case IPR2018-01427 (Patent No. 8,597,649)*

ELI LILLY TRIAL DEMONSTRATIVES

November 22, 2019

Eli Lilly Trial Demonstratives

- I. Summary of Case_____
- II. Overview of Challenged Patent Claims_____
- III. Overview of Asserted References_____
- IV. Additional Motivation from Prior Art_____
- V. Teva Failed to Rebut Motivation_____
- VI. Reasonable Expectation of Success_____
- VII. Alleged Secondary Considerations _____
- VIII. Teva's Affinity Claims Are Obvious_____
- IX. Detailed Analysis_____
- X. Motion to Strike_____
- XI. Motion to Exclude_____

Summary of Case

- Teva's patents broadly claim *any* humanized anti-CGRP antagonist antibody with known or routinely achievable features
- Tan 1995 describes an anti-CGRP antagonist antibody effective *in vivo* and provides guidance to improve immunoblockade
- Wimalawansa expressly teaches that humanized anti-CGRP antibodies "should be explored" to treat human diseases
- The prior art is replete with reports providing additional motivation to make a humanized anti-CGRP antagonist antibody
- Teva conceded it was routine to make a humanized antibody
- Neither Tan 1995 nor Teva's purported safety concerns teach away from the claimed subject matter
- Teva's purported secondary considerations lack nexus and are insufficient to overcome obviousness

The Breadth of Teva's Claims

We claim:

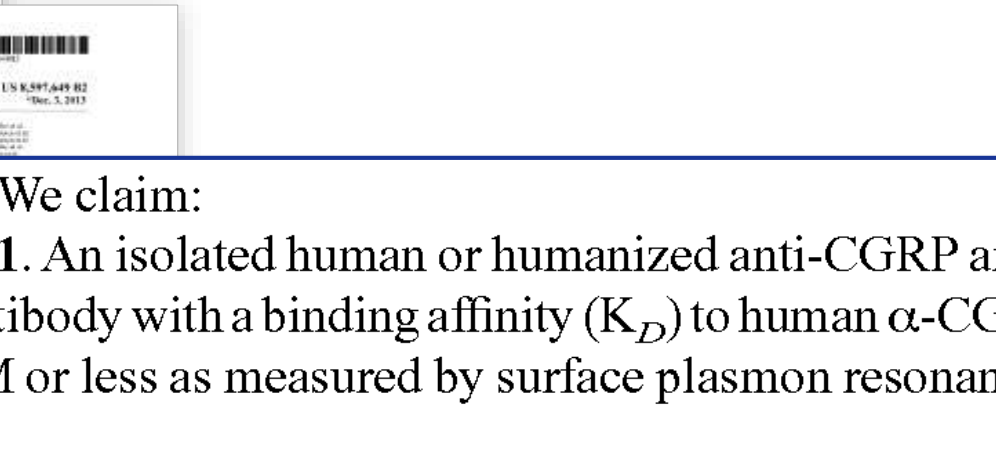
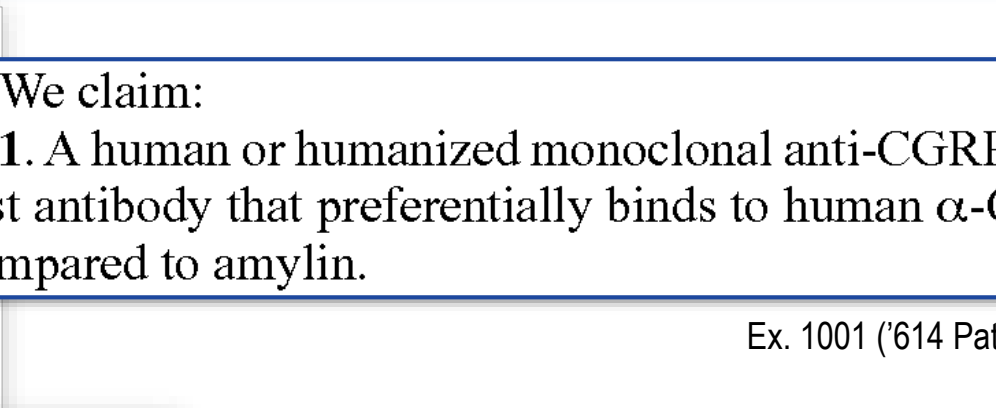
1. A human or humanized monoclonal anti-CGRP antagonist antibody that preferentially binds to human α -CGRP compared to amylin.

Ex. 1001 ('614 Pat)

We claim:

1. An isolated human or humanized anti-CGRP antibody with a binding affinity (K_D) to human α -CGRP of 100 nM or less as measured by surface plasmon resonance.

Ex. 1001 ('649 Pat)



Tan 1995 (Ex. 1022) Shows MAb C4.19 Was Effective /



This study has clearly demonstrated the MAb C4.19 IgG and its Fab' fragment to block the hypotensive effects of exogenous α CGRP

Ex. 1022, 570; Ex. 1000

to CGRP. MAb C4.19 does not cross-react with amylin *in vitro* but the potential of MAb C

Ex. 1022, 572; Ex. 1000

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