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

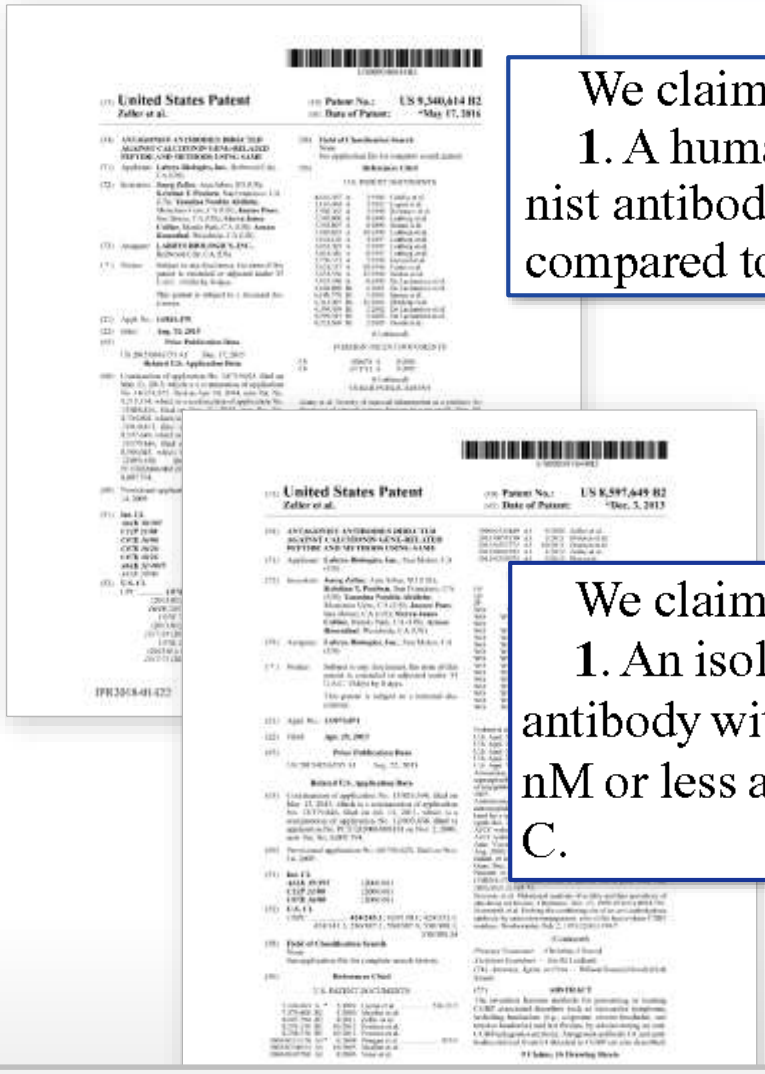
November 22, 2019

Eli Lilly Trial Demonstratives

Summary of Case

- Teva's patents broadly claim *any* humanized anti-CGRP antagonist an with known or routinely achievable features
- Tan 1995 describes an anti-CGRP antagonist antibody effective *in viv* provides guidance to improve immunoblockade
- Wimalawansa expressly teaches that humanized anti-CGRP antibodie "should be explored" to treat human diseases
- The prior art is replete with reports providing additional motivation t 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 fr claimed subject matter
- Teva's purported secondary considerations lack nexus and are insuffi overcome obviousness

The Breadth of Teva's Claims


United States Patent

Zeller et al.

US 8,540,614 B2

May 17, 2016

We claim:

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

Ex. 1001 ('614 Pat

United States Patent

Zeller et al.

US 8,597,649 B2

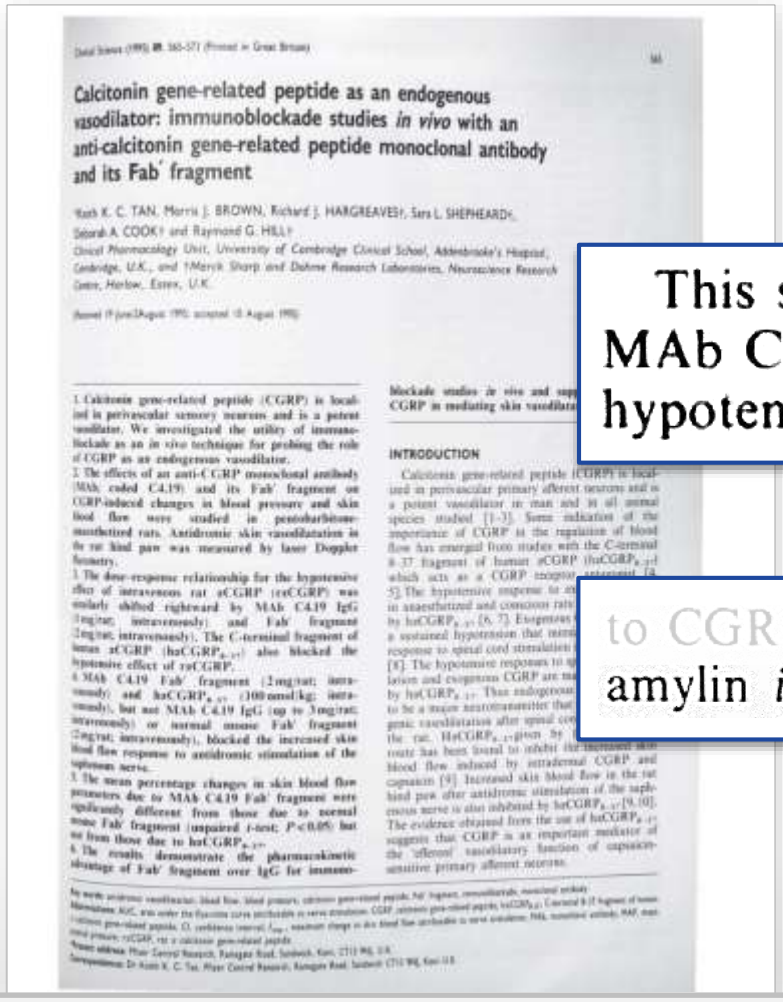
Dec. 3, 2013

We claim:

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

Ex. 1001 ('649 Pate

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



Calcitonin gene-related peptide as an endogenous vasodilator: immunoblockade studies *in vivo* with an anti-calcitonin gene-related peptide monoclonal antibody and its Fab′ fragment

Keith K. C. TAN, Morris J. BROWN, Richard J. HARGREAVES†, Sara L. SHEPHEARD†, Deborah A. COOK† and Raymond G. HILL†

Clinical Pharmacology Unit, University of Cambridge Clinical School, Addenbrooke's Hospital, Cambridge, U.K., and †Merck Sharp and Dohme Research Laboratories, Neuroscience Research Centre, Harlow, Essex, U.K.

INTRODUCTION

This study has clearly demonstrated the
MAb C4.19 IgG and its Fab′ fragment to
hypotensive effects of exogenous rαCGR

Ex. 1022, 570; Ex. 1008

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

Ex. 1022, 572; Ex. 1009

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