

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

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**ELI LILLY AND COMPANY**  
**v.**  
**TEVA PHARMACEUTICALS INTERNATIONAL GMBH**

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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

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## 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:

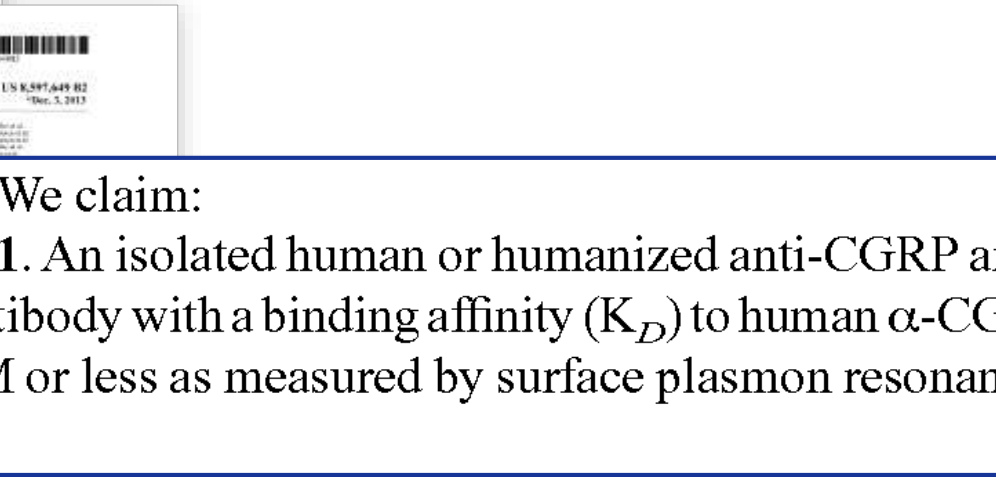
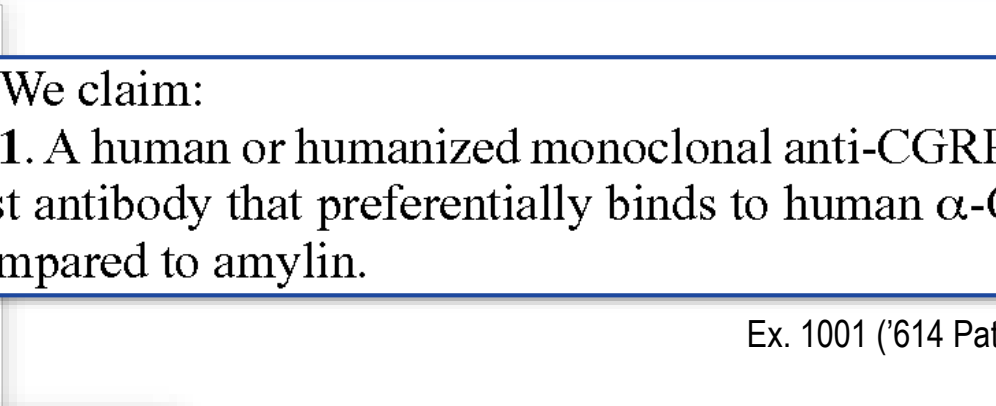
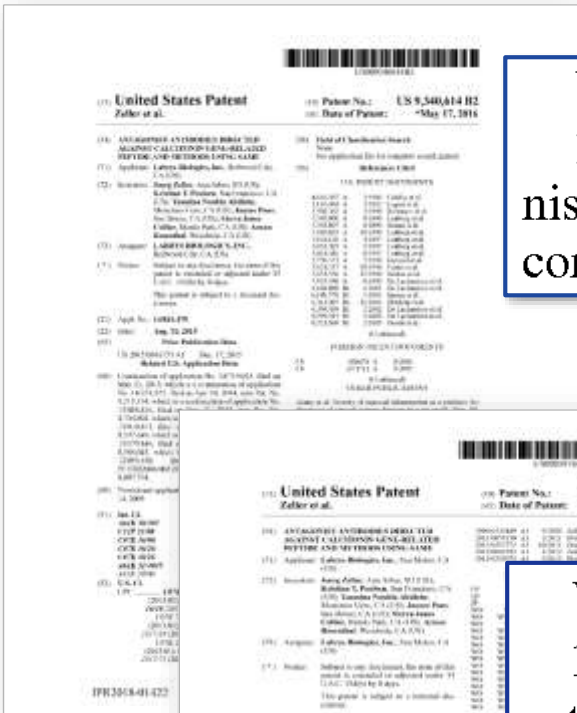
1. A human or humanized monoclonal anti-CGRP antagonist antibody that preferentially binds to human  $\alpha$ -CGRP compared to amylin.

Ex. 1001 ('614 Pat)

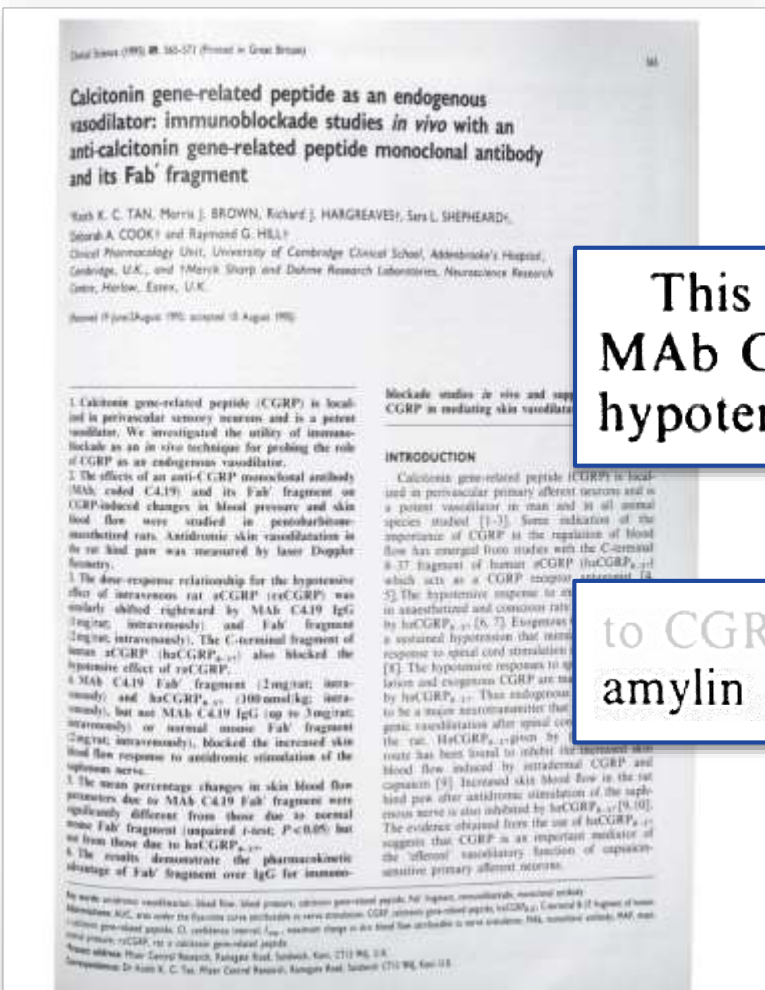
We claim:

1. An isolated human or humanized anti-CGRP antibody with a binding affinity ( $K_D$ ) to human  $\alpha$ -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  $\alpha$ 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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