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### UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

# GRÜNENTHAL GMBH,

Petitioner

v.

## ANTECIP BIOVENTURES II LLC,

Patent Owner.

Case PGR2017-00022 U.S. Patent No. 9,408,862

### PETITIONER'S OPPOSITION TO PATENT OWNER'S CORRECTED CONTINGENT MOTION TO AMEND

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### Cases

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### I. <u>INTRODUCTION</u>

In an attempt to avoid the prior art asserted in the Petition, Patent Owner contingently seeks to substitute original claims 2-30 with proposed claims 31-56, which, *inter alia*, narrow the claimed bioavailability ranges. But all the newly proposed claims are still unpatentable under 35 U.S.C. §112 and/or §103.

The proposed claims' narrower bioavailability ranges are nowhere disclosed in the '241 application (Exh. 2027, the application leading to the '862 patent). Therefore, these new claims, like the original claims, are invalid for lack of written description. Dependent claims 36-38 and 48-50 further lack adequate written description because their respective dosage amount limitations are also not described in the '241 application.

Also, like the original claims, the proposed claims are not enabled. The specification does not disclose a single example of a pharmaceutical formulation having the newly claimed bioavailability, and does not report any bioavailability data associated with any dosage form. Patent Owner's expert, Dr. William Wargin, and Petitioner's expert, Dr. Clive Wilson, agree that a POSA in May 2014 would have been skeptical that different zoledronic acid salt forms would have bioavailabilities within the claimed ranges. They further agree that the '862 patent provides no information that would cure that skepticism.

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