Filed on behalf of: Celltrion, Inc.
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CELLTRION, INC.,
Petitioner,

v.

REGENERON PHARMACEUTICALS, INC.,
Patent Owner.

Case No. IPR2022-00258
Patent No. 9,254,338

PETITION FOR INTER PARTES REVIEW OF U.S. PATENT NO. 9,254,338

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Celltrion, Inc. ("Petitioner") petitions for *inter partes* review ("IPR") under 35 U.S.C. §§ 311-319 and 37 C.F.R. §§ 42 *et seq.*, seeking cancellation of claims 1, 3-11, 13-14, 16-24, and 26 (the "Challenged Claims") of U.S. Patent No. 9,254,338 ("'338 patent") (EX1001), currently assigned to Regeneron Pharmaceuticals, Inc. ("Regeneron" or "Patent Owner").

I. INTRODUCTION

The Challenged Claims should have never issued. They are drawn to "VEGF Trap-Eye" dosing regimens known to persons of ordinary skill in the art (hereafter, "skilled artisans") long before the patent's alleged 2011 priority date. Regeneron's age-related macular degeneration ("AMD") clinical trials (VIEW1/VIEW2) with EYLEA® (a/k/a VEGF Trap-Eye or aflibercept) were designed to use the precise dosing regimens now covered by the Challenged Claims. The problem: Regeneron publicly disclosed these exact dosing regimens to skilled artisans as early as 2008, three years prior to filing its patent application. Regeneron then withheld those publications from the Examiner, allowing the '338 patent to issue. For at least these reasons, the Challenged Claims are unpatentable.

Petitioner thus files this Petition, supported by expert declarations from Dr. Thomas Albini—a renowned ophthalmologist (EX1002), and Dr. Mary Gerritsen—a pharmacologist with over thirty years' experience (EX1003).

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