UNITED STATES PATENT AND TRADEMARK OFFICE

_____

BEFORE THE PATENT TRIAL AND APPEAL BOARD

_____

CHARLES RIVER LABORATORIES, INC.,
Petitioner,

v.

SEIKAGAKU CORPORATION,
Patent Owner.

Case No. PGR2025-00023 and IPR2025-00440

Patent Nos. 11,959,109 and 11,236,318

PATENT OWNER'S SUPPLEMENTAL BRIEF

Patent Owner Seikagaku Corp. ("PO") submits this Supplemental Brief concerning the relevance of the Federal Circuit's April 16, 2026 decision in *Teva Pharmaceuticals Int'l GmbH v. Eli Lilly & Co*. ("*Teva*"), No. 2024-1094 to issues in PGR2025-00023 and IPR2025-00440, as authorized by the Board on May 20, 2026. The claims at issue in *Teva* related to a method of using ***humanized*** anti-CGRP antagonist antibodies to treat headache. *Teva,* at 3-4.[1] The specification explained that anti-CGRP antibodies were known in the art, citing prior art regarding ***murine*** antibodies, and described prior art methods for humanization. *Id*. at 3. Despite the specification only disclosing one example of a humanized anti-CGRP antagonist antibody, the Court determined that the claims had adequate written description support and were enabled.

IPR2025-00440

Although *Teva* involved a method claim, the Court's findings are applicable to pending issues in IPR2025-00440. Specifically, in the IPR, Petitioner has repeatedly pointed to the lack of specific examples in the specification of a recombinant Factor C protein derived from *L. polyphemus* with the claimed residual activity to support its arguments. *See, e.g.*, Paper 1 at 25. But as the Court in *Teva* reiterated, actual reduction to practice and examples are ***not*** required. *Teva*, at 14.

[1] Citations to *Teva* are to the slip opinion.

Indeed, in *Teva,* the Court noted the lack of humanized antibodies known in the prior art but nonetheless found written description support existed by pointing to ***murine*** antibodies being known and it being "routine" to humanize them. *Id*. This discussion is relevant to one of PO's arguments in support of written description that relies on publicly available deposit information and the ***routine*** procedures a POSA could employ to generate the full Factor C coding sequence for *L. polyphemus* Factor C and then recover the remaining sequence. Paper 26 at 16-17.

PGR2025-00023

Written Description. The dispute in *Teva* concerned whether the specification disclosed a representative number of species of the genus of humanized antibodies. *Teva* at 8-9. The specification disclosed one humanized anti-CGRP antagonist antibody, several such murine antibodies, and that humanization of antibodies was a routine technique. *Id.* at 13. Because the claims "pertain[] to a well-known genus" of anti-CGRP antagonist antibodies "that is not, itself, the claimed invention" the Court found that these disclosures satisfied the representative number of species test and constituted adequate written description of the claimed method. *Id.* at 8-9.

The *Teva* panel cited three prior decisions as "particularly instructive" to claims directed to a known genus. *Id.* at 9-11 (citing *Ajinomoto v. ITC,* 9832 F.3d 1342 (Fed. Cir. 2019), *In re Herschler,* 591 F.2d 693 (CCPA 1979), and the plurality

opinion in *In re Fuetterer,* 319 F.2d 259 (CCPA 1963)). This line of precedent is also instructive as to the Challenged Claims. The specification describes the discovery as being able to express functional Factor C in human or hamster cells, despite the known issues with using monkey cells. EX1001 at 2:44-53, 3:25-31. The claimed invention requires combining Factor C expressed by specified host cells, with Factor B, and Pro-clotting enzyme expressed by a mammalian cell to make an endotoxin assay agent—not the proteins' sequences. EX1001, claim 1. It is undisputed the recited proteins were well-known and widely available. EX1001, claim 1; EX2062 ¶¶ 18-34, 38-41, 45-51, 108-112, 165; PO Sur-Reply at 9, 11-12.

In Reply, Petitioner focused on the lack of disclosure of coding sequences in the specification and the prior art, arguing that the disclosed *T. tridentatus* sequences and proteins cannot be representative. *See* Reply (Paper 30) at 14, 16-17, 21. Lilly (the patentee) advanced a similar argument in *Teva*: that "because humanizing an antibody requires knowing its amino acid sequence, and because no such sequences were disclosed in the specification or prior art, adequate written description is lacking." *Teva,* at 15. The Federal Circuit ***rejected*** this argument because "[s]ubstantial evidence showed that if a skilled artisan possessed an anti-CGRP antagonist antibody, he or she could determin[e] its amino acid sequence through known sequencing techniques" therefore the "specification demonstrates that the

inventors possessed sequences necessary to humanize" murine antibodies. *Id.* at 15-16 (cleaned up).

Here, substantial evidence—including arguments and evidence advanced by Petitioner before the European Patent Office—similarly shows that as of the priority date, the Factor C, Factor B and Pro-clotting enzyme proteins were known and accessible and determining their sequences would have been routine for a skilled artisan. *See* PO Response at 34-36, 81-87; Sur-Reply at 12-14; EX2062 ¶ 66. The Board should follow *Teva* and conclude the specification demonstrates the inventors possessed sequences necessary to make the recited recombinant proteins. And, just as *Teva* found that murine antibodies could be representative of humanized antibodies in a well-known genus, the Board should find that the *T. tridentatus* sequences and examples are representative of proteins from other crab species.

Enablement. As Petitioner does here (*see* Pet. at 40, 46-47), Lilly argued the specification "left to others the 'research assignment' of screening and testing" candidate antibodies to determine which would antagonize CGRP, constituting undue experimentation. *Teva v. Lilly,* slip op. at 21. The Federal Circuit rejected these arguments as unpersuasive because the asserted claims "do not claim humanized anti-CGRP antagonist antibodies *themselves*; instead they claim only the use of such antibodies for the different, limited purpose of treating headache." *Id.* at 22-23 (, which Petitioner relies on). Thus, the relevant degree of experimentation

was not the work required to make, screen, and humanize antibodies, but rather determining which would work to treat headache. *Id.* at 23. The specification disclosed that all such antibodies would work for that purpose, thus the work that Lilly focused on was "more akin to extra credit than a necessary research assignment left to others to complete." *Id.*

Here, Petitioner focused its undue experimentation arguments on the work involved in assembling sequences and designing and expressing proteins. Reply at 23. However, in view of the specification's disclosures, that work is "more akin to extra credit" than a research assignment. Indeed, the evidence reflects that such work is routine for recombinant protein expression—not even extra credit, much less a research assignment. *See* Sur-Reply at 11-12. Petitioner did not dispute PO's evidence that the recited proteins have robust functions individually or that a POSA would believe each of the recited proteins would be functional when expressed by the recited mammalian cells. EX2062 ¶¶ 108-112, 116, 120-128, 130-135, 163, 165.

Finally, that the Challenged Claims are directed to a method of using a well-known genus also distinguishes Petitioner's written description case and enablement case law. *See Teva,* at 16-17 (distinguishing *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916 (Fed. Cir. 2004)); *id.* at 22-24 (distinguishing *Amgen v. Sanofi,* 598 U.S. 594 (2023) and *Idenix Pharms. LLC v. Gilead Scis. Inc*., 941 F.3d 1149 (Fed. Cir. 2019)).

Respectfully Submitted,

Dated: May 26, 2026

/s/ Alexander B. Stein
Alexander B. Stein, Reg. No. 71,397

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e)(4), lead counsel for Patent Owner hereby certifies that on May 26, 2026, a copy of this PATENT OWNER'S SUPPLEMENTAL BRIEF was served via the email correspondence address of record for Petitioner's counsel of record:

Scott A. McKeown (SMcKeown-PTAB@wolfgreenfield.com)

Flora Luo (FLuo-PTAB@wolfgreenfield.com)

Chelsea A. Loughran (CLoughran-PTAB@wolfgreenfield.com)

Respectfully Submitted,

Dated: May 26, 2026

/ Alexander B. Stein /
Alexander B. Stein, Reg. No. 71,397