

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CHARLES RIVER LABORATORIES, INC.,
Petitioner,

v.

SEIKAGAKU CORPORATION,
Patent Owner.

IPR2025-00440
Patent No. 11,236,318

SECOND DECLARATION OF SIDDHARTHA JAIN, PH.D.

CRL Exhibit 1071 CRL v. Seikagaku IPR2025-00440

I, Dr. Siddhartha Jain, declare as follows:

I. INTRODUCTION

1. I am over the age of eighteen and otherwise competent to make this declaration.

2. As discussed in my prior declaration (EX1002), based on my education and experience, I believe I have a detailed understanding of the state of the art relating to claim 21 of the '318 Patent during the relevant time period (as of December 10, 2013 and also as of April 30, 2019) as well as a sound basis for opining on how persons of skill in the art at that time would understand the technical issues in this case.

3. I have been asked to provide this second declaration in the IPR2025-00440. The purpose of this declaration is to provide information relevant to the patentability of a certain proposed substitute claim submitted as part of Patent Owner's Contingent Motion to Amend ("Motion").

4. I have reviewed Patent Owner's Motion and the proposed substitute claim 22 and provide the following opinions.

5. Proposed claim 22 is reproduced as annotated in Appendix A of the Motion.

Claim 22. [Proposed substitute for claim 21] A horseshoe crab Factor C protein having activity of Factor C,

wherein the horseshoe crab is *Limulus polyphemus*, and wherein the horseshoe crab Factor C protein is produced through being recombinantly expressed from a Human Embryonic Kidney (HEK) 293 cell, and

wherein the Factor C protein exhibits a higher residual activity [[of at least one selected from the group consisting of:]]

[[(1) 10% or higher in the presence of 21 mM sodium citrate; and]]

[[(2) 15% or higher in the presence of 16 mM magnesium sulfate]] in the presence of 21 mM sodium citrate and 16 mM magnesium sulfate, as compared with the corresponding *Limulus polyphemus* Factor C protein expressed in a Sf9 cell or a native *Limulus polyphemus* Factor C protein.

6. As shown in this annotation, proposed claim 22 deletes the 10% and 15% lower range bounds associated with residual activity in the presence of 21 mM sodium citrate and 16 mM magnesium sulfate, respectively (as represented by the double brackets).

7. Whereas original claim 21 required that the claimed recombinant Factor C protein exhibited a residual activity “of at least one selected from the group consisting of” [two ranges], claim 22 now requires the claimed Factor C protein to have a higher residual activity “in the presence of 21 mM sodium citrate *and* 16 mM magnesium sulfate.”

8. A POSA would interpret the meaning of the word “and” in this phrase in one of two ways. First, this phrase could mean that the claimed Factor C has a required higher residual activity in the presence of 21 mM sodium citrate and also has the required higher residual activity in the presence of 16 mM magnesium sulfate, when the Factor C is in each of those two ionic solutions separately.

9. A POSA could also interpret this phrase to mean that the claimed Factor C has the required higher residual activity in the presence of 21 mM sodium citrate and 16 mM magnesium sulfate, when those two ionic concentrations are present together in the same solution.

10. The specification of the '318 Patent includes data in Figure 7 showing the results of testing of recombinantly produced *Tachypleus tridentatus* Factor C in separate ionic solutions (i.e., in the presence of 21 mM sodium citrate and separately in the presence of 16 mM magnesium sulfate). This would suggest that the phrase used in proposed substitute claim 22 means that the claimed Factor C has the required higher residual activity in the presence of 21 mM sodium citrate and also has the required higher residual activity in the presence of 16 mM magnesium sulfate when the Factor C is in each of those two ionic solutions separately.

11. However, original claim 21 used the language “at least one selected from the group consisting of” which clearly delineated the two required ranges of

claim 21 as separately measurable requirements. The amended claim language of claim 22 now adds “*in the presence of* 21 mM sodium citrate and 16 mM magnesium sulfate” which, to a POSA, could signal that the requirement as to the residual activity of Factor C is to Factor C in a single solution containing both ionic concentrations. The removal of the language “at least one selected from the group consisting of” to now insert “in the presence of” only amplifies this ambiguity.

12. A POSA, faced with this new claim language, would be unable to determine its scope with reasonable clarity. The claim fails to clearly delineate to a POSA what the required test is for the claimed Factor C protein: is it a particular residual activity in the presence of two separate solutions, each with distinct ionic concentrations? Or is it a particular residual activity in the presence of a single solution defined by two ionic concentrations? Depending on which test is the one intended, a given Factor C protein may satisfy one version of the claim and not the other.

I declare that all statements made herein of my own knowledge are true, that all statements made on information and belief are believed to be true, and that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: 02 March 2026

/Siddhartha Jain/
Siddhartha Jain, Ph.D.