

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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CHARLES RIVER LABORATORIES, INC.,  
Petitioner,

v.

SEIKAGAKU CORPORATION,  
Patent Owner.

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Case No. IPR2025-00440  
Patent No. 11,236,318

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**PETITIONER'S NOTICE OF FILING REVISED  
DEMONSTRATIVE EXHIBITS**

## LISTING OF EXHIBITS

| Exhibit | Description                                                                                                                                                                                                                                                      |
|---------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1001    | U.S. Patent No. 11,236,318 (“the ’318 patent”)                                                                                                                                                                                                                   |
| 1002    | Declaration of Siddhartha Jain, Ph.D., PMP (“Jain”)                                                                                                                                                                                                              |
| 1003    | Curriculum Vitae of Dr. Siddhartha Jain, Ph.D., PMP                                                                                                                                                                                                              |
| 1004    | Prosecution History for U.S. Application No. 16/399,386                                                                                                                                                                                                          |
| 1005    | International Patent Publication No. WO 2018/074498 A1                                                                                                                                                                                                           |
| 1006    | U.S. Patent Application No. 14/650,767, as filed June 9, 2015                                                                                                                                                                                                    |
| 1007    | Muta et al., “Limulus Factor C. An endotoxin-sensitive serine protease zymogen with a mosaic structure of complement-like, epidermal growth factor-like, and lectin-like domains,” <i>J Biol Chem.</i> 1991 Apr 5; 266(10):6554-61.                              |
| 1008    | Gan et al., “Analysis of Protein Sequence/Structure Similarity Relationships,” <i>Biophys J.</i> 2002 Nov; 83(5):2781-91.                                                                                                                                        |
| 1009    | U.S. Patent Application Publication No. 2015/0307864                                                                                                                                                                                                             |
| 1010    | Karen McClymont, Ph.D. Thesis, submitted in fulfilment of the requirements for the Degree of Doctor of Philosophy from the University of Glasgow, Institute of Molecular, Cell and Systems Biology College of Medical, Veterinary and Life Sciences, March 2017. |
| 1011    | Transition Certification for U.S. Patent Application No. 15/983,725, filed May 31, 2019.                                                                                                                                                                         |
| 1012    | U.S. Patent No. 5,716,834                                                                                                                                                                                                                                        |
| 1013    | Declaration of Dr. Mary K. Bolin                                                                                                                                                                                                                                 |
| 1014    | U.S. Patent No. 5,858,706                                                                                                                                                                                                                                        |
| 1015    | International Patent Publication No. WO 2000/026366 A1                                                                                                                                                                                                           |
| 1016    | Iwanaga, Sadaaki, “Biochemical principle of <i>Limulus</i> test for detecting bacterial endotoxins,” <i>Proc. Jpn. Acad., Ser. B. Phys Biol Sci.</i> 2007 May; 83(4):110-9.                                                                                      |
| 1017    | RESERVED                                                                                                                                                                                                                                                         |
| 1018    | RESERVED                                                                                                                                                                                                                                                         |
| 1019    | Japanese Priority Document JP2012-269840 (certified translation, plus original)                                                                                                                                                                                  |
| 1020    | U.S. Application No. 14/650,767, addition to PCT specification                                                                                                                                                                                                   |
| 1021    | Higdon, R. et al., “Modeling sequence and function similarity between proteins for protein functional annotation,” <i>Proc Int Symp High Perform Distrib Comput</i> ; 2010: 499–502.                                                                             |

| Exhibit | Description                                                                                                                                                                                                                                                                                                      |
|---------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1022    | Tokunaga, F., et al. "Further studies on lipopolysaccharide-sensitive serine protease zymogen (Factor C): Its isolation from <i>Limulus polyphemus</i> hemocytes and identification as an intracellular zymogen activated by $\alpha$ -chymotrypsin, not by trypsin," <i>J. Biochem.</i> 1991 Jan; 109(1):150-7. |
| 1023    | Levin, J., Bang, F., "The role of endotoxin in the extracellular coagulation of <i>Limulus</i> blood," <i>Bulletin of John's Hopkins Hospital.</i> 1964 Sep: 115:265-74.                                                                                                                                         |
| 1024    | Walls, E. et al, The Horseshoe Crab, <i>Limulus polyphemus</i> : 200 Million Years of Existence, 100 Years of Study, <i>Reviews in Fisheries Science.</i> 2002; 10(1):39-73.                                                                                                                                     |
| 1025    | Carmichael, R., et al., "Changing Global Perspectives on Horseshoe Crab Biology, Conservation, and Management," Springer, Ch. 29: "Biotechnology Efforts to Conserve Horseshoe Crabs Through the Development of Recombinant Factor C-Based Endotoxin Test" pp. 501-512 (2015).                                   |
| 1026    | Dwarakanath et al., "Recombinant COS-1 cells express <i>Carcinoscorpius rotundicauda</i> Factor C," <i>Biotechnology Letters.</i> 1997 April; 19(4):357-361.                                                                                                                                                     |
| 1027    | Wang, J. et al., "Functional expression of full length <i>Limulus</i> Factor C in stably transformed Sf9 cells," <i>Biotechnology Letters.</i> 2001; 23:71-76.                                                                                                                                                   |
| 1028    | Ding et al, "A new era in pyrogen testing," <i>Trends in Biotechnology.</i> 2001 Aug; 19(8):277-81.                                                                                                                                                                                                              |
| 1029    | U.S. Appln. No.: 14/650,767, "Novel Recombination Factor C and Method for Producing the Same, and Method for Measuring Endotoxin," Declaration Under 37 C.F.R. § 1.132, Feb. 22, 2018.                                                                                                                           |
| 1030    | Barrabes, S. et al., "Effect of sialic acid content on glycoprotein p/ analyzed by two-dimensional electrophoresis," <i>Electrophoresis.</i> 2010 Sep; 31(17):2903-12.                                                                                                                                           |
| 1031    | Palomares, L.A., "Production of Recombinant Proteins: Challenges and Solutions," From: <i>Methods in Molecular Biology</i> , vol. 267: <i>Recombinant Gene Expression: Reviews and Protocols</i> , Second Edition Edited by: P. Balbás and A. Lorence © 2004 Humana Press Inc., Totowa, NJ, pp. 15-51.           |
| 1032    | U.S. Patent No. 6,645,724                                                                                                                                                                                                                                                                                        |
| 1033    | Mizumura, H., et al., "Genetic engineering approach to develop next-generation reagents for endotoxin quantification," <i>Innate Immunity.</i> 2017 Feb; 23(2):136-146.                                                                                                                                          |

| Exhibit | Description                                                                                                                                                                                                                                             |
|---------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1034    | Ding et al., “Expression of full length and deletion homologues of <i>Carcinoscorpius rotundicauda</i> Factor C in <i>Saccharomyces cerevisiae</i> : immunoreactivity and endotoxin binding,” <i>Journal of Endotoxin Research</i> . 1997; 4(1): 33-43. |
| 1035    | International Patent Publication No. WO 2014/092079 A1 (“the ‘082 PCT”)                                                                                                                                                                                 |
| 1036    | Wang et al., “Modular Arrangement and Secretion of a Multidomain Serine Protease,” <i>J Biol Chem</i> . 2002 Sep 27; 277(39):36363-72.                                                                                                                  |
| 1037    | Marengo-Rowe, Alain, J., “Structure-function relations of human hemoglobins,” <i>Proc (Bayl Univ Med Cent)</i> 2006 Jul; 19(3):239–245.                                                                                                                 |
| 1038    | Sekiguchi, K. and Shuster, C.N., “Limits on the Global Distribution of Horseshoe Crabs (Limulacea): Lessons Learned from Two Lifetimes of Observations: Asia and America,” <i>Biology and Conservation of Horseshoe Crabs</i> , 2009.                   |
| 1039    | Hossler et al., “Optimal and consistent protein glycosylation in mammalian cell culture,” <i>Glycobiology</i> . 2009 Sep; 19(9):936-4.                                                                                                                  |
| 1040    | RESERVED                                                                                                                                                                                                                                                |
| 1041    | RESERVED                                                                                                                                                                                                                                                |
| 1042    | U.S. Appln. No.: 17/554,128, “Novel Recombinant Factor C And Method for Producing the Same, and Method for Measuring Endotoxin” Non-Final Office Action, Mar. 20, 2025 (“128 App. NFR”)                                                                 |
| 1043    | European Patent No. 3530670, “Method for producing endotoxin detecting agent comprising recombinant limulus factor c and use thereof,” Response to Opposition, May 9, 2025                                                                              |
| 1044    | European Patent No. 3441466, “Method for Producing a Novel Recombinant Factor C, Method for Mitigating Reaction Inhibition In Endotoxin Assays, And Method for Measuring Endotoxin,” Decision on Opposition, Oct. 26, 2022                              |
| 1045    | USP, General Chapter Prospectus: Use of Recombinant Reagents in Bacterial Endotoxins Test. May 29, 2020                                                                                                                                                 |
| 1046    | Stewart, C.M., “Interim Processes for PTAB Workload Management,” Memorandum dated March 26, 2025                                                                                                                                                        |
| 1047    | U.S. Appln. No.: 17/554,128, “Novel Recombinant Factor C And Method for Producing the Same, and Method for Measuring Endotoxin” Amendment under 37 C.F.R. § 1.111 , Jan. 28, 2025                                                                       |
| 1048    | European Patent No. 3530670, “Method for producing endotoxin detecting agent comprising recombinant limulus factor c and use thereof,” Notice of Opposition, Nov. 22, 2024                                                                              |

| <b>Exhibit</b> | <b>Description</b>                                                                                                                                                                   |
|----------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1049           | RESERVED                                                                                                                                                                             |
| 1050           | U.S. Appln. No.: 16/331,810, “Recombinant Proteins Derived From Genus <i>Limulus</i> , and DNA Molecules Encoding Same,” Notice of Abandonment, Mar. 14, 2023                        |
| 1051           | Press Release, “USP Provides Guidance on the Use of Recombinant Reagents for the Bacterial Endotoxin Test” May 29, 2020                                                              |
| 1052           | U.S. Patent Application Publication No. 2019/0241629 (“629 publication”)                                                                                                             |
| 1053           | U.S. Appln. No.: 14/650,767, “Novel Recombination Factor C and Method for Producing the Same, and Method for Measuring Endotoxin,” Non-Final Office Action, Sept. 16, 2016           |
| 1054           | U.S. Appln. No.: 14/650,767, “Novel Recombination Factor C and Method for Producing the Same, and Method for Measuring Endotoxin,” Final Office Action, Apr. 13, 2017                |
| 1055           | U.S. Appln. No.: 14/650,767, “Novel Recombination Factor C and Method for Producing the Same, and Method for Measuring Endotoxin,” Amendment under 37 C.F.R. § 1.111 , Mar. 16, 2017 |
| 1056           | RESERVED                                                                                                                                                                             |
| 1057           | RESERVED                                                                                                                                                                             |
| 1058           | RESERVED                                                                                                                                                                             |
| 1059           | RESERVED                                                                                                                                                                             |
| 1060           | RESERVED                                                                                                                                                                             |
| 1061           | RESERVED                                                                                                                                                                             |
| 1062           | Transcript of August 1, 2025 Conference Call                                                                                                                                         |
| 1063           | Email from McKeown, Scott, RE: PGR2025-00023 and IPR2025-00440: Request for Position on Motions to Compel Routine Discovery (Jun. 25, 2025)                                          |
| 1064           | Declaration of Chelsea A. Loughran in Support of Admission <i>Pro Hac Vice</i>                                                                                                       |
| 1065           | Transcript of November 4, 2025 Deposition of Siddhartha Jain, Ph.D., PMP                                                                                                             |
| 1066           | Huaman et al., “Genomic Serveillance of Rabies Virus in Georgian Canines,” <i>Viruses</i> . 2023 Aug 24;15(9):1797.                                                                  |
| 1067           | Transcript of February 12, 2026 Deposition of Brain Schaefer, Ph.D.                                                                                                                  |
| 1068           | Transcript of February 13, 2026 Deposition of Brain Schaefer, Ph.D.                                                                                                                  |
| 1069           | Transcript of January 28, 2026 Deposition of Tina Morris, Ph.D.                                                                                                                      |
| 1070           | RESERVED                                                                                                                                                                             |
| 1071           | Second Declaration of Siddhartha Jain, Ph.D., PMP                                                                                                                                    |

| <b>Exhibit</b> | <b>Description</b>                                                                                                                                                                                                                           |
|----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1072           | European Patent No. 3530670 B1 [ <b>SERVED ONLY – NOT FILED</b> ]                                                                                                                                                                            |
| 1073           | Certified Translation of Japanese Patent Application Publication No. 2016-204729 A [ <b>SERVED ONLY – NOT FILED</b> ]                                                                                                                        |
| 1074           | European Patent No. 3530670, “Method for producing endotoxin detecting agent comprising recombinant limulus factor c and use thereof,” Information about the result of oral proceedings, January 21, 2026 [ <b>SERVED ONLY – NOT FILED</b> ] |
| 1075           | Transcript of April 29, 2026 Conference Call                                                                                                                                                                                                 |
| 1076           | Petitioner’s Demonstrative Exhibits                                                                                                                                                                                                          |
| 1077           | Petitioner’s Revised Demonstrative Exhibits                                                                                                                                                                                                  |

Pursuant to 37 CFR § 42.6(e)(4)(ii), and the Board's Hearing Order (Paper 43), Petitioner herewith submits the following Exhibit:

| <u>Exhibit</u> | <u>Description</u>                          |
|----------------|---------------------------------------------|
| 1077           | Petitioner's Revised Demonstrative Exhibits |

Respectfully submitted  
*Charles River Laboratories, Inc.*

Date: June 8, 2026

/Chelsea A. Loughran/  
Scott A. McKeown, Reg. No. 42,866  
Flora Luo, Reg. No. 78,667  
Chelsea A. Loughran, admitted *pro hac vice*  
WOLF, GREENFIELD & SACKS, P.C.

**CERTIFICATE OF SERVICE UNDER 37 C.F.R. § 42.6 (E)(4)**

I certify that on June 8, 2026, a copy of the foregoing document, including any exhibits filed therewith, is being served via electronic mail, as previously consented to by Patent Owner, upon the following:

|                      |                                                                                                |
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Date: June 8, 2026

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