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

NOTICE OF FILING TRANSCRIPT OF AUGUST 1, 2025 CONFERENCE CALL

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," *J Biol Chem.* 1991 Apr 5; 266(10):6554-61.
1008	Gan et al., "Analysis of Protein Sequence/Structure Similarity Relationships," *Biophys J.* 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 *Limulus* test for detecting bacterial endotoxins," *Proc. Jpn. Acad., Ser. B. Phys Biol Sci.* 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," *Proc Int Symp High Perform Distrib Comput*; 2010: 499–502.

Exhibit	Description
1022	Tokunaga, F., et al. "Further studies on lipopolysaccharide-sensitive serine protease zymogen (Factor C): Its isolation from *Limulus polyphemus* hemocytes and identification as an intracellular zymogen activated by α-chymotrypsin, not by trypsin," *J. Biochem.* 1991 Jan; 109(1):150-7.
1023	Levin, J., Bang, F., "The role of endotoxin in the extracellular coagulation of *Limulus* blood," *Bulletin of John's Hopkins Hospital.* 1964 Sep: 115:265-74.
1024	Walls, E. et al, The Horseshoe Crab, Limulus polyphemus: 200 Million Years of Existence, 100 Years of Study, *Reviews in Fisheries Science*. 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 Carcinoscorpius rotundicauda Factor C," *Biotechnology Letters*. 1997 April; 19(4):357-361.
1027	Wang, J. et al., "Functional expression of full length *Limulus* Factor C in stably transformed Sf9 cells," *Biotechnology Letters*. 2001; 23:71-76.
1028	Ding et al, "A new era in pyrogen testing," *Trends in Biotechnology*. 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," *Electrophoresis.* 2010 Sep; 31(17):2903-12.
1031	Palomares, L.A., "Production of Recombinant Proteins: Challenges and Solutions," From: Methods in Molecular Biology, vol. 267: Recombinant Gene Expression: Reviews and Protocols, 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," *Innate Immunity.* 2017 Feb; 23(2):136-146.

Exhibit	Description
1034	Ding et al., "Expression of full length and deletion homologues of *Carcinoscorpius rotundicauda* Factor C in *Saccharomyces cerevisiae:* immunoreactivity and endotoxin binding," *Journal of Endotoxin Research.* 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," *J Biol Chem.* 2002 Sep 27; 277(39):36363-72.
1037	Marengo-Rowe, Alain, J., "Structure-function relations of human hemoglobins," *Proc (Bayl Univ Med Cent)* 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," *Biology and Conservation of Horseshoe Crabs,* 2009.
1039	Hossler et al., "Optimal and consistent protein glycosylation in mammalian cell culture," *Glycobiology*. 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

Exhibit	Description
1049	RESERVED
1050	U.S. Appln. No.: 16/331,810, "Recombinant Proteins Derived From Genus Limulus, 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

Pursuant to 37 CFR § 42.6(e)(4)(ii), and the Board's Trial Practice Guide, Petitioner herewith submits the following Exhibit:

Exhibit	**Description**
1062	Transcript of August 1, 2025 Conference Call

Respectfully submitted
Charles River Laboratories, Inc.

Date: August 4, 2025

/Scott A. McKeown/
Scott A. McKeown, Reg. No. 42,866
WOLF, GREENFIELD & SACKS, P.C.

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

I certify that on August 4, 2025, 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:

Alexander B. Stein	alexander.stein@morganlewis.com
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Date: August 4, 2025

/MacAulay Rush/
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