

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
Patent No. 11,959,109

**NOTICE OF INTENT TO DESIGNATE CHELSEA A. LOUGHRAN,
A PROVISIONALLY RECOGNIZED PATENT TRIAL
AND APPEAL BOARD ATTORNEY, AS BACK-UP COUNSEL**

LISTING OF EXHIBITS

Exhibit	Description
1001	U.S. Patent No. 11,959,109
1002	Prosecution History of U.S. Patent No. 11,959,109 (Application No. 18/346,420)
1003	Declaration of Siddhartha Jain, Ph.D., PMP (“Jain”)
1004	Curriculum Vitae of Dr. Siddhartha Jain, Ph.D., PMP
1005	International Patent Publication No. WO 2018/074498 A1
1006	Higdon 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.
1007	Kobayashi et al., “Factor B Is the Second Lipopolysaccharide-binding Protease Zymogen in the Horseshoe Crab Coagulation Cascade,” <i>J Biol Chem.</i> 2015 Jun 24; 290(31):19379–19386.
1008	Japanese Priority Application No. JP2012-269840 (certified translation)
1009	U.S. Patent No. 5,716,834
1010	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.
1011	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
1012	U.S. Patent Application Publication No. 2021/0363564
1013	Declaration of Dr. Mary K. Bolin
1014	RESERVED
1015	U.S. Patent Application Publication No. 2019/0241629
1016	U.S. Patent Application Publication No. 2015/0307864
1017	U.S. Patent Application No. 14/650,767, as filed June 9, 2015
1018	RESERVED
1019	Shi et al., “Protein N-Glycosylation in the Baculovirus-Insect Cell System,” <i>Curr Drug Targets.</i> 2007 Oct; 8(10): 1116–1125.
1020	RESERVED
1021	RESERVED
1022	Transition Certification for U.S. Patent Application No. 15/983,725, filed May 31, 2019.

1023	RESERVED
1024	RESERVED
1025	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 α -chymotrypsin, not by trypsin,” <i>J. Biochem.</i> 1991 Jan; 109(1):150-7.
1026	Dwarakanath, R.S. et al., “Recombinant COS-1 cells express <i>Carcinoscorpius rotundicauda</i> Factor C,” <i>Biotechnology Letters</i> . 1997 April; 19(4):357-61.
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	RESERVED
1029	RESERVED
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: 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	RESERVED
1033	RESERVED
1034	RESERVED
1035	RESERVED
1036	RESERVED
1037	RESERVED
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	File History of United States Application No. 16/399,386
1041	ExpiCHO™ Expression System - USER GUIDE – For transfection of ExpiCHO-S™ in a defined, serum-free medium. Catalog Number A29133, Publication Number MAN0014337 Revision D.0 (May 25, 2018).

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
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	RESERVED
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	RESERVED
1055	RESERVED
1056	U.S. Appln. No.: 18/346,420, “Novel Recombinant Factor C and Method for Producing the Same, and Method for Measuring Endotoxin,” Non-Final Office Action, Sept. 15, 2023
1057	R. Davis, Acting USPTO Leader Says New Policies Will Bolster Patents, Law360 (Apr. 1, 2025), https://www.law360.com/articles/2316863/ (accessed June 10, 2025)

1058	U.S. Appln. No.: 14/650,767, “Novel Recombination Factor C and Method for Producing the Same, and Method for Measuring Endotoxin,” Preliminary Amendment, Jun. 9, 2015
1059	U.S. Patent No. 10,144,923
1060	U.S. Patent No. 10,982,202
1061	U.S. Patent No. 6,391,570
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>

Pursuant to 37 C.F.R. § 42.10(c)(2), and the Board's authorization given in Paper 5, Petitioner Charles River Laboratories, Inc. hereby submits this Notice of Intent to Designate Chelsea A. Loughran, a Provisionally Recognized PTAB Attorney, as Back-up Counsel.

Registered practitioner Scott A. McKeown, Reg. No. 42,866, is serving as Lead Counsel for Petitioner in this proceeding. See Paper 2. The most recent prior proceeding in which Ms. Loughran was recognized *pro hac vice* by order of the Board, pursuant to a motion of the type described in 37 C.F.R. §42.10(c)(1), was IPR2017-00800 (Paper 20, October 17, 2017).

Filed herewith is a certification in the form of a declaration in which Ms. Loughran attests to satisfying all requirements set forth by the Board in Paper 5. *See* Ex. 1064. A power of attorney from the Petitioner appointing Ms. Loughran was previously filed in this proceeding on January 16, 2025. See Paper 1.

Respectfully submitted,
Charles River Laboratories, Inc.

Date: October 27, 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 October 27, 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
Christopher J. Betti

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Date: October 27, 2025

/MacAulay Rush/
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