

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

**PETITIONER’S OPPOSITION TO PATENT OWNER’S MOTION FOR
ADDITIONAL DISCOVERY UNDER 37 C.F.R. § 42.51(b)(2)(i)¹**

¹ Sections I-III of this Opposition provide specific responses to PO’s characterizations of inconsistency and evidence refuting the same and so are different than the corresponding sections in the Opposition in PGR2025-00023. Section IV in both briefs are nearly identical.

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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.

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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 α -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.

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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
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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
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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

I. INTRODUCTION

PO bases its request for additional discovery (Mot.)—just as it did its request for routine discovery—on excerpted statements in an EP Opposition (EPO) challenging the inventive step of sequencing and recombinantly producing *L. polyphemus* Factor C proteins as of Oct. 18, 2016. Studiously avoiding any discussion of necessary context or the fact that Petitioner here challenges the sufficiency of written description and enablement of the full scope of a broader claim functionally defining such proteins operating in a cascade before their gene sequence was even known, PO concludes there is an inconsistency between proceedings. But the panel already told PO: *“the claims...at issue in the Opposition are different and both broader and narrower than the challenged claim in this proceeding in different respects. Neither has [PO] explained why the grounds on which the Opposition is based are necessarily inconsistent with positions advanced by Petitioner in this proceeding.”* Paper 17, 4-5 (internal citations omitted).

PO’s withholding of necessary context and available information continues here. A week prior to filing its Motion, PO deposed Petitioner’s declarant, Dr. Siddhartha Jain, which PO conspicuously says nothing at all about. Dr. Jain unequivocally explained why—in his scientific opinion—there is no inconsistency between the Declaration of Dr. Frohman (filed in the EPO) and the arguments of Petitioner in this IPR:

Q Do you disagree that the cDNA sequence of *Limulus polyphemus* Factor C is very similar to the other known horseshoe crabs?

A ...I think this paragraph [EX2004 (Frohman Decl.), ¶45] needs to be read in context with the subsequent paragraphs....[I]t would not be scientifically accurate for anyone to claim similarity without looking at the context, because we know that cDNA codes for -- will lead to a protein sequence, and even one amino acid difference can change the function of the protein. So if you are looking at it from the context of protein function, I would say the answer is no. But that's not what [Dr. Frohman is] talking about in his declaration in paragraphs 45 and 46, but that is why I'm saying that I don't think any POSA would give a straightforward yes or no answer, because just looking at the similarity of cDNA and resulting amino acid similarity would [not (tr. error)] be conclusive to say without knowing the context and the specific level of similarity.

Q ...Do you disagree with Professor Frohman's opinion in paragraph 46?

A No. And if you see my declaration, it's aligned with my own statement that once the sequence was available in 2017-2018, through the two references, a person skilled in art would have a reasonable expectation of being able to express using the listed mammalian cells. So my statement even in declaration is not in conflict with his statement.

EX1065 (Jain Depo.), 73:2-75:14, *see also, id.*, 86:18-87:20, 185:12-186:15. As Dr. Jain explained, his analysis as to lack of possession of (and amount of experimentation required to complete the sequencing and development of)

recombinant *L. polyphemus* Factor C proteins across the full scope of claim 21 in 2013 is not inconsistent with the fact that obtaining an exemplary protein would have been reasonably expected and obvious to a POSA several years later. *Id.*, 75:3-14; *see also id.*, 73:2-75:1.

Even setting aside PO's withholding of necessary scientific context and week-old testimony directly on point, PO has not explained why the discovery it seeks is ***relevant*** to its claimed invention, which lacks written description and enablement, as of 2013. That is, even accepting PO's ostensible argument that somehow the EPO acknowledges a possible later priority date for the claim at issue there (which is hypothetical since the EPO is only considering the question of inventive step (***obviousness***) of a recombinant *L. polyphemus* Factor C protein as of 2016), PO has made clear in its own words— it ***is not arguing for such an intervening date in this IPR***. EX1062, 25:6-14.

PO's Motion abuses the additional discovery mechanism for the sole purpose of injecting conspiratorial distraction into the record and should be denied.

II. PO HAS FAILED TO SHOW THE RELEVANCE OF THE REQUESTED DISCOVERY

PO's request for additional discovery does not demonstrate how the requested information—confirming whether Petitioner initiated the EPO—is relevant to this IPR. PO has pointed to no affirmative evidence supporting such relevance, and has ignored new evidence explaining why no inconsistency exists.

A. Dr. Jain Explained Why There Is No Inconsistency

PO claims that “[i]t is immaterial that the claims involved in the Opposition are different than those at issue here.” Mot. 4. But Dr. Jain explained why this difference in scope accounts for the difference in opinions and arguments advanced in the EPO and before this Board. When asked: “And so you don’t see any inconsistency between this opinion in paragraph 82 [of Dr. Jain’s IPR Declaration] and Professor Frohman’s opinion that he would not anticipate experiencing any difficulties expressing *Limulus polyphemus* Factor C?”, Dr. Jain explained:

So I think you have to look at it in full context. I have said that a POSA would have a reasonable expectation of expressing *Limulus* Factor C in CHO and HEK293 cells, which I see as being aligned with Dr. Frohman’s statement....[A] [POSA] would not and should not ***assume by default*** that different proteins, different sequence would necessarily express in a secreted and ***functional state*** by following the protocol that was successful for another protein. And this is simply coming from the complexity, unpredictability and the diversity that exists in the field of biology. ***You can’t just assume something that has been done for one protein to occur likewise for another protein.***

EX1065, 86:18-87:20. Dr. Jain’s admonishment against extrapolating function of one protein based on results of a different protein explains why Dr. Frohman’s opinions regarding the obviousness of sequencing and expressing *L. polyphemus* Factor C are not inconsistent with Dr. Jain’s testimony regarding the full scope of functional proteins encompassed by claim 21. *See Arkema Inc. v. Honeywell Int’l*

Inc., PGR2016-00012, Paper No. 13, at 35 (P.T.A.B. Sept. 2, 2016) (granting institution—“[PO] contends that Petitioner has presented inconsistent arguments concerning enablement as Petitioner has stated that [a POSA] had a reasonable expectation of success of achieving the limitation of claim 13....A reasonable expectation of success of achieving one composition within the scope of the claim, however, differs from reasonably enabling the full scope of the claim.”); *Liquidia Techs., Inc. v. United Therapeutics*, IPR2021-00406, Paper No. 78, 32-33 (P.T.A.B. July 19, 2022) (“Reasonable expectation of success is a separate inquiry from enablement....[T]hat [the expert] testifies to a lack of enablement in one forum and to the presence of a reasonable expectation of success in a second forum does not render unreliable the testimony in either.”).

B. PO Saddles Petitioner With The Inventors’ Inconsistencies

Even beyond Dr. Jain’s deposition, PO knows that any inconsistency in this proceeding flows from the *inventors’ own statements*. PO points to the ’498 PCT and purportedly inconsistent “characterizations” of that reference. Mot. 2. That the inventors made these admissions is a fact, and their significance has different relevance to different legal questions at different points in time. In the ’498 PCT, the inventors of claim 21 stated that “*it has not been possible* to accurately determine the full-length sequence structure, expression, and function of [*L. polyphemus* zymogen] proteins and genes using conventional methods.” EX1005,

¶12 (emphasis added). In the context of whether such inventors described and enabled the full scope of a claim to recombinantly produced *L. polyphemus* Factor C proteins with a functional residual activity across multiple characteristics (ion resistances) and across a broad range of residual activities for each characteristic, the inventors’ statements that *L. polyphemus* Factor C had **not** been identified “structurally and functionally” (*id.*, ¶10) is highly relevant. Such statements may be less relevant to whether such proteins were obvious several years later. In any case, this Board can assess and weigh the fact of the inventors’ statements.

PO also twists citation of its own arguments into manufactured evidence of inconsistency. In the EPO, Opponent argued—pointing to Dr. Mizumura’s **February 22, 2018** declaration—that with the knowledge of the *L. polyphemus* sequence, and in the context of an obviousness rejection, sequence homology would support the expectation that *L. polyphemus* Factor C would have similar ion resistance as that exhibited by Factor C of *T. tridentatus*. EX1048, 14. This is **precisely** what Petitioner argues in this IPR. Pet., 58. There is no inconsistency.

Finally, PO excerpts and misconstrues Petitioner’s arguments in painting them as inconsistent. The argument at Pet., 38, that “[r]eaching the full scope of claim 21 therefore requires an extensive amount of experimentation across multiple fronts” is supported by the **inventors’** abandonment of a structural explanation for the broad scope of functional properties of the purportedly

inventive proteins. *Id.* (citing Jain, ¶¶130-135). Dr. Frohman provided no testimony on residual activity and, as Dr. Jain explained, Dr. Frohman’s theoretical opinion on obtaining the sequence of *L. polyphemus* Factor C—while relevant to the obviousness of trying to make such protein—does not show that the inventors possessed and enabled the full scope of claim 21 by 2013. EX1065, 73:2-75:14.

The inventors admitted to a struggle in sequencing *L. polyphemus* Factor C well after 2013. Mot. 4 (citing Pet. 38-39, which cites ’498 PCT). Highlighting that admission in this IPR does not prove inconsistency on the part of Petitioner. If anything, the veracity of PO—now claiming to have invented recombinant proteins of such type across a broad functional range in 2013—should be questioned.

III. PO HAS NOT DEMONSTRATED THAT THE REQUESTED DISCOVERY IS IN THE INTEREST OF JUSTICE.

A. *Garmin* Factor 1

Factor 1 supports denial as the alleged inconsistency is already in the record via EPO filings, and, as discussed in Sections I and II, *supra*, the arguments in the EPO are ***not*** inconsistent with Petitioner’s arguments in this IPR. Petitioner’s expert explained in detail at his deposition how the various statements and arguments cited in the Board’s order (Paper 17, 7-8) are scientifically consistent. *See* §§ I-II, *supra*. PO has not explained why its requested “confirmation” is useful to any disputed issue in the IPR. The Board is fully capable of weighing the facts and relevant expert testimony on the science.

B. *Garmin* Factor 2

The EPO affords an Opponent anonymity for several reasons including that he should not be “obliged to reveal to the patent proprietor why a patent disturbs him.” G 0004/97, 15-17 (Jan. 21, 1999). PO’s cursory statement that the requested information does not seek Petitioner’s litigation positions (Mot. 5) is incorrect as revelation of the identity of an anonymous EP Opponent is tantamount to revealing litigation strategy. *See* § III, *infra*. PO cites no authority to the contrary.

C. *Garmin* Factor 3

PO argues: “PO cannot generate the information without the requested discovery.” Mot. 5. This is untrue. PO wants this Board to associate the EPO with Petitioner, which the Board may or may not do without forcing Petitioner to waive its privileges. The requested discovery is unnecessary.

D. *Garmin* Factor 4

PO did not attach any formal discovery request or define any terms, so as to render its discovery request “easily understandable.”

E. *Garmin* Factor 5

PO says it is seeking a “simple answer.” Mot. 5. However, PO is asking Petitioner to reveal its attorney-client privileged and work product legal strategy and such forced revelation could be leveraged to argue for a broader waiver.

IV. PO CANNOT COMPEL A WAIVER OF ATTORNEY-CLIENT PRIVILEGE OR ATTORNEY WORK PRODUCT IMMUNITY.

PO copies its privilege argument (Mot., 6-10) almost verbatim from its prior failed motion (Paper 12, 3-7) without addressing Petitioner's prior Opposition. Paper 13, 6-7. Again, PO cites zero authority permitting the Board to compel a party to confirm/deny anonymity (and attorney-client privilege and work product immunity arising from its EPO litigation strategy). While there is no question that Charles River is the client of Wolf Greenfield, any disclosure by either entity confirming or denying involvement (Petitioner's or any other entity's) in the anonymous EPO (*i.e.*, legal strategy and whether to employ the same in a confidential proceeding) in a very small competitive space, would reveal confidential attorney-client communications and risk waiver of the same.

Moreover, work-product immunity covers documents and communications created in anticipation of post-issuance patent challenges. Fed. R. Civ. P. 26(b)(3); *see Applied Telematics, Inc. v. Sprint Commc 'ns. Co., L.P.*, 1996 WL 539595, *3-6 (E.D. Pa. Sept. 18, 1996). And in the analogous context of anonymous *ex parte* reexaminations, multiple Courts have ***declined*** to compel the identification of a requesting party where, as here, such identity is only "marginally relevant" and so "protecting the confidentiality of the requester outweighs [POs] interest in discovery the identity of the requester." *Davco Mfg. Corp. v. Peninsular Diesel, Inc.*, 128 F.R.D. 91, 92 (N.D. Ohio 1989); *TQ Delta, LLC v. DISH Network Corp.*,

No. 1:15-cv-00614-GBW, ECF No. 407, at 6-8 (D. Del. Mar. 1, 2022) (declining to compel discovery relating to *ex parte* reexam where movant failed to show relevance and interest in discovery was “outweighed by...safeguards imposed to ensure confidentiality of the requester’s identity”).

Petitioner has more than met its burden to show that the requested discovery, *which has no useful relevance to the IPR grounds at issue here*, does not outweigh the significant confidentiality interests protecting Petitioner’s work product developed in anticipation of litigation. Any inconsistency between this IPR and the EPO arises from *the inventors’ own duplicitous strategy* of claiming to have invented a broad scope of functional *L. polyphemus* recombinant Factor C proteins as of 2013, while telling the world several years later — to secure an additional patent — that *only then* had they finally “succeeded in obtaining full-length cDNAs encoding all of the protein factors...of *Limulus polyphemus* something that no one had succeeded in doing for many years, and in expressing all of the recombinant proteins.” EX1005, ¶17. PO’s request for additional discovery should be denied.

Date: November 21, 2025

Respectfully submitted,
/Scott A. McKeown/

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

I certify that on November 21, 2025, a copy of the foregoing document, including any exhibits filed therewith, is being served via electronic mail, as previously consented to by PO, upon the following:

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