

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 TO
COMPEL ROUTINE DISCOVERY UNDER 37 C.F.R. § 42.51(b)(1)(iii)¹**

¹ Sections I and II of this Opposition provide specific responses to PO's general characterizations of alleged inconsistency and so are different than the corresponding sections in the Opposition in PGR2025-00023. Sections III in both briefs are identical.

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LISTING OF EXHIBITS

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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 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
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
1063	Email from McKeown, Scott, RE: PGR2025-00023 and IPR2025-00440: Request for Position on Motions to Compel Routine Discovery (Jun. 25, 2025)

I. INTRODUCTION

PO has argued before the USPTO *both* that (1) it was *finally* able to complete the invention of recombinantly producing *Limulus polyphemus* Factor C as of 2017 (EX1052), *and* (2) it should be entitled to a claim directed to that invention with a priority date of 2013 (EX1001). Pet. 31-35. Both cannot be true. Faced with no reasonable explanation for its own contradictory positions,² PO seeks to manufacture a false narrative that Petitioner is somehow duplicitous for bringing this blatant gamesmanship to the attention of the agency.

The discovery PO seeks must be “narrowly directed to specific information known to the responding party to be inconsistent with a position advanced by that party.” *Garmin v. Cuozzo*, IPR2012-00001, Paper 26, 4 (PTAB Mar. 5, 2013).

PO’s requested discovery is neither narrow nor directed to *specific information known to Petitioner to be inconsistent* with a position advanced by Petitioner, and should therefore be denied. Tellingly, PO does not even attempt to explain its alleged theory of “inconsistency” in any meaningful detail. Rather, PO simply cites to the fact that in an anonymously filed EP Opposition (“the EP670 Opposition”), the Opponent argued that *as of 2016*, there would have been no “inventive step”

² PO should be producing all relevant discovery to Petitioner regarding these inconsistencies. 37 C.F.R. § 42.51(b)(1)(iii).

involved in producing recombinant *Limulus polyphemus* Factor C, where almost the entire genome for said species of horseshoe crab was by-then publicly available. EX2004, ¶¶17-19. Opponent's declarant said nothing about what a POSA would have known or expected about this recombinant production ***before such genomic information was available***, and certainly said nothing about the experimentation required to produce the claimed proteins ***with the full scope of residual activity function of challenged claim 21***. There is no inconsistency between statements that explicitly refer to what was known or routine as of different points in time, and PO does not and cannot explain the relevance of this to the actual arguments made in the Petition depriving the '318 Patent of its priority claim based on inadequate written description and lack of enablement. As emphasized during the teleconference with the Board, PO is confusing issues of priority with European "inventive step," which PO does not dispute are different.

Regardless of the identity of the anonymous EP Opponent, there is simply no inconsistency. 37 C.F.R. § 42.51(b)(1)(iii); EX1063. As PO has not proven this prerequisite, the Board need go no further. In any event, routine discovery does not "make discoverable anything otherwise protected by legally recognized privileges such as attorney-client or attorney work product," which is precisely what PO seeks. § 42.51(b)(1)(iii). The Motion should be denied.

II. PATENT OWNER FAILS TO IDENTIFY ANY INCONSISTENCY BETWEEN THE EP670 OPPOSITION AND THIS IPR

The Petition argues that the inventors did not describe or enable the claimed *Limulus polyphemus* Factor C recombinant proteins with the claimed, exceedingly broad scope of residual activity function, as of a claimed 2013³ priority date, years before the gene and amino acid sequence for such proteins were even discovered. Pet. 20-42. As confirmed on the August 1, 2025 Teleconference, PO is arguing entitlement to its earliest claimed priority date. EX1062, 25:6-14; Paper 7. Without this priority date, however, claim 21 is obvious over intervening art. Pet. 45-64. The same Examiner who allowed the '318 Patent recently rejected at least one related application based on §112 flaws highlighted in the Petition. EX1042, 2-6.

In view of the Petition's arguments, PO fails to explain why anything stated in the EP670 Opposition is contradictory. PO excerpts a convenient portion of page 38 of the Petition (Mot. 2), however, the full statement is that "reaching the full scope of claim 21...requires an extensive amount of experimentation across multiple fronts: (1) to discover and characterize the gene and amino acid sequence for *Limulus polyphemus* Factor C itself, ***which was not known as of 2013***...[and]

³ The Petition explains that claim 21 was neither described nor enabled by the 12/10/2013 disclosure, and so if that disclosure is insufficient, the more cursory 12/10/2012 priority document is equally insufficient. Pet. 21-22.

(2) to use this as-yet undiscovered genetic information to recombinantly generate Factor C protein ***across the full scope of residual activity function*** characteristic as defined by claim 21.” Pet. 38. Petitioner’s position regarding the lack of possession and experimentation required to discover and characterize the gene and amino acid sequence for *Limulus polyphemus* Factor C is tied to both the ***unknown*** status of the *Limulus polyphemus* Factor C gene and amino acid sequence information as of 2013, and to the ***function*** of the resulting protein as recited in the challenged claim. It is also consistent with PO’s own admission years after the ’767 Application was filed that the field had struggled to sequence *Limulus polyphemus* Factor C protein and ***could not make accurate predictions as to its structural and functional properties in view of the biodiversity between horseshoe crab species***. EX1005, ¶¶0012-17; EX1038, 6-7, 10-15, Jain, ¶136.

Dr. Frohman’s declaration, by contrast, explains that the gene and amino acid sequence information for the *Limulus polyphemus* genome was almost fully known by 2016⁴ and opines about the experimentation required ***from that point on***

⁴ As the Petition explains, McClymont (EX1010) provides a public disclosure of the full gene and amino acid sequence of *L. polyphemus* Factor C as of April 7, 2017 (which then also appears in PO’s April 26, 2018 ’498 PCT (EX1005)). Pet. 43-45. In combination with the October 29, 2015 publication of the specification of

to generate recombinant Factor C protein (via the RACE procedure). EX2004, ¶18-19. While Dr. Frohman cites to earlier publications and earlier-known background information from the 1980's and 1990's, for example, about RACE, this is in the context of what a skilled person would have done with such teachings after 2016 (i.e., after the vast majority of the *Limulus polyphemus* coding sequence was public). Dr. Frohman's testimony about the "inventive step" of completing the *Limulus polyphemus* sequence by 2016 sufficient to generate recombinant proteins is in no way inconsistent with the fact that in 2013, ***before any such information was known***, the '318 Patent priority documents failed to describe or enable such recombinant proteins with the claimed residual activity function. PO ***agrees*** and is "[not] going to argue that there are different doctrines around obviousness or invented steps and then enablement" (EX1062, 25:19-23) but still points to no

the '318 Patent, challenged claim 21 was obvious at least by April 7, 2017 (Pet. 45-64). Being obvious, however, is insufficient to demonstrate that the full scope of a claimed invention was described or enabled at that time. *Parus Holdings, Inc. v. Google LLC*, 70 F.4th 1365, 1374 (Fed. Cir. 2023) (precedential) (affirming PTAB finding of no written description and no entitlement to priority date and affirming obviousness based on intervening prior-art (identical publication of challenged patent)). *In re Mraz*, 455 F.2d 1069, 1072-73 (C.C.P.A. 1972).

other relevant inconsistency warranting its overly general discovery request, which should be denied. *Synaptive Med. Inc. v. Karl Storz Endoscopy-Am., Inc.*, IPR2018-00462, Paper No. 14, 2-3 (PTAB Oct. 11, 2017).

III. CONFIDENTIAL LITIGATION STRATEGY IS PROTECTED BY THE ATTORNEY-CLIENT PRIVILEGE AND WORK PRODUCT

Beyond its overly general and therefore improper request for “any other inconsistent information [] that is inconsistent with a position it advanced in IPR2025-00440”, PO seeks to know *specifically* whether or not Petitioner directed the filing of the EP670 Opposition. Mot. 2. But PO cites no authority permitting the PTAB to compel a party to forfeit a privilege conferred by the EPO.

The EPO affords patent opponents in Europe anonymity and confidentiality (*see* G 4/97; T 953/21) and, from these guarantees, creates a scope of privilege and work product protection around the question of *whether or not* a particular entity afforded itself the strategic benefits of such a challenge in Europe based on advice of counsel. Petitioner cannot comply with PO’s unjustified discovery request without violating at least the attorney-client privilege and the work product doctrine, nor can it produce a privilege log “without revealing information itself privileged or protected.” Fed. R. Civ. P. 26(b)(5).

PO makes the unremarkable point that the “attorney-client privilege does not protect the identity of a client.” Mot. 4. But that point and the cases cited in support are inapposite to the argument of privilege here. There is no question that

Petitioner is the client of Wolf Greenfield. But any disclosure by Petitioner or Wolf Greenfield confirming or denying involvement (Petitioner's or any other entity's) in an anonymous EP opposition proceeding (*i.e.*, the details of a legal strategy and whether to employ the same in a legal proceeding that is confidential, **by definition**) in a very small competitive space, would reveal confidential attorney-client communications and the substance of attorney work-product, and risk waiver of the same. The work-product privilege protects documents and communications created in anticipation of litigation, including in anticipation of post-issuance patent challenges. Fed. R. Civ. P. 26(b)(3); *see Applied Telematics, Inc. v. Sprint Communications Co., L.P.*, 1996 WL 539595, *3-6 (E.D. Pa. 1996) (work-product immunity applied to documents generated in anticipation of reexamination).

Moreover because there are no inconsistent positions between this IPR and the EP670 Opposition (*see* Section II, *supra*), the identity of the EP Opponent is at most "marginally relevant" and so "protecting the confidentiality of the requester outweighs [PO's] interest in discovering the identity of the requester." *Davco Mfg. Corp. v. Peninsular Diesel, Inc.*, 128 F.R.D. 91, 92 (N.D. Ohio 1989) (declining to compel identification of requester of anonymous reexam). PO has failed to reveal any inconsistency justifying piercing the EPO's afforded confidentiality and the resulting privilege waiver. Such extraordinary relief should be denied.

Respectfully submitted,

Date: August 15, 2025

/Scott A. McKeown/

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

I certify that on August 15, 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:

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