

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

**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 IPR2025-00440. Sections III in both briefs are identical.

TABLE OF CONTENTS

I.	INTRODUCTION	1
II.	PATENT OWNER FAILS TO IDENTIFY ANY INCONSISTENCY BETWEEN THE EP670 OPPOSITION AND THIS PGR.....	3
III.	CONFIDENTIAL LITIGATION STRATEGY IS PROTECTED BY THE ATTORNEY-CLIENT PRIVILEGE AND WORK PRODUCT	6

TABLE OF AUTHORITIES

CASES

<i>Ariad Pharms., Inc. v. Eli Lilly and Co.</i> , 598 F.3d 1336 (Fed. Cir. 2010) (<i>en banc</i>).....	4
<i>Biogen Int’l GMBH v. Mylan Pharms. Inc.</i> , 18 F.4th 1333, 1342–44 (Fed. Cir. 2021).....	4
<i>Biogen Int’l GmbH v. Mylan Pharms. Inc.</i> , 28 F.4th 1194 (Fed. Cir. 2022).....	4
<i>Davco Mfg. Corp. v. Peninsular Diesel, Inc.</i> , 128 F.R.D. 91 (N.D. Ohio 1989).....	7
<i>Garmin International, Inc. et al. v. Cuozzo Speed Technologies LLC</i> , IPR2012-00001, Paper 26 (PTAB Mar. 5, 2013).....	1
<i>Hercules, Inc. v. Exxon Corp.</i> , 434 F. Supp. 136 (D. Del. 1977)	7
<i>Nuvo Pharm. (Ireland) Designated Activity Co. v. Dr. Reddy’s Laby’s Ltd.</i> , 923 F.3d 1368 (Fed. Cir. 2019)	4
<i>Plant Genetic Systems, N.V. v. DeKalb Genetics Corp.</i> , 315 F.3d 1335 (Fed. Cir. 2003)	4
<i>Vas–Cath Inc. v. Mahurkar</i> , 935 F.2d 1555 (Fed. Cir. 1991)	4

STATUTES

35 U.S.C. § 112	2
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REGULATIONS

37 C.F.R. § 42.51(b)(1)(iii).....	1, 2
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RULES

Fed. R. Civ. P. 26(b)(3).....	7
Fed. R. Civ. P. 26(b)(5).....	6

OTHER AUTHORITIES

G 4/97, Decision of the Enlarged Board of Appeal, 21 Jan. 1999	6
T 953/21, Decision of Technical Board of Appeal, 5 Feb 2024.....	6

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)

I. INTRODUCTION

PO has argued before the USPTO *both* that (1) it was *finally* able to complete the invention of recombinantly producing *Limulus polyphemus* zymogen proteins as of 2017 (EX1015), *and* (2) it should be entitled to a claim broadly covering that invention with a priority date of 2013 (EX1001). Pet. 31-32. 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).

Patent Owner’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

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

“inventive step” involved in producing recombinant *Limulus polyphemus* Factor C, since by that time almost the entire genome for said species of horseshoe crab was publicly available. EX2004, ¶¶17-19. Opponent’s declarant said nothing about what a POSA would have known or expected about such recombinant production *before such information was available*, and certainly said nothing linking this to the significant *experimentation required to produce the full scope of the thousands of claimed combinations of zymogen proteins with the claimed function* that the Petition argues lack a written description and enabling disclosure. There is no inconsistency between arguments and 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 of failure to satisfy 35 U.S.C. § 112 made in the Petition. As emphasized during the teleconference with the Board, PO is confusing issues of description and enablement 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 PGR

The Petition argues that the challenged claims are unpatentable for lack of written description, lack of enablement, and anticipation based on intervening art, because those claims cover an extraordinarily broad scope of recombinant horseshoe crab proteins, configured in over at least 3,456 combinations, as a working assay for endotoxin detection, *without disclosing or describing how to make or use a single example of any such assay*. As confirmed on the August 1, 2025 Teleconference, PO is arguing that it is entitled to its earliest claimed priority date of December 10, 2012 (though Ground 3 argues unpatentability even if such were otherwise).³ EX1062, 25:6-14); *see generally* Paper 7. The Petition makes clear that the inventors did not possess the claimed combination of recombinant proteins and a POSA would have had to engage in undue experimentation to identify and execute all of the possible recombinant proteins, in the possible expression systems, with the possible gene sequences for the various species of horseshoe crab (while, for example, such information for *Limulus polyphemus* was not even then known). Pet. 23-60. The Petition explains that as of 2013, such

³ The Petition explains that the challenged claims were 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. 24, n. 6.

POSA would have had to work to express such proteins in all claimed varieties of mammalian expression systems (at minimum, CHO and HEK), would have had to implement a methodology to demonstrate that each protein was functionally active, and then would have had to ensure that each protein worked with the various other required proteins (from the same or different species of horseshoe crabs and expressed via the same or different host cell types) to detect endotoxin. Pet. 46-60. As Petitioner's expert explains, based on the disclosure of the sought after 2013 priority date (which is the same disclosure found in the '109 Patent application, as filed) "such experimentation would have been undue and unreasonable for a POSA as of 2013 (and even today)." EX1003, ¶112. *Ariad Pharms., Inc. v. Eli Lilly and Co.*, 598 F.3d 1336, 1355–57 (Fed. Cir. 2010) (*en banc*); *Biogen Int'l GMBH v. Mylan Pharms. Inc.*, 18 F.4th 1333, 1342–44 (Fed. Cir. 2021), *reh'g denied* 28 F.4th 1194 (Fed. Cir. 2022)); *Nuvo Pharm. (Ireland) Designated Activity Co. v. Dr. Reddy's Laby's Ltd.*, 923 F.3d 1368, 1376–77 (Fed. Cir. 2019); *Plant Genetic Systems, N.V. v. DeKalb Genetics Corp.*, 315 F.3d 1335, 1339 (Fed. Cir. 2003). The same Examiner who allowed the '109 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 points to pages 39-41 of its POPR, however, these pages cite to paragraphs in the EP Notice of Opposition discussing

the declaration of Professor Frohman whose opinions were based on the fact that a POSA would start with the known partial genomic data for *Limulus polyphemus* horseshoe crabs ***that was publicly available, for example, by 2016***. EX2004, ¶¶18-19. Such statements (including citation to general background publications on cDNA amplification protocols and horseshoe crabs from the 1980's and 1990's) are not inconsistent with the Petition's argument that ***the full scope*** of the challenged claims—whose scope encompasses an exceedingly broad and complex combination of recombinant proteins for detecting endotoxin—were neither described nor enabled as of 2013, or even today.

PO also cites statements made in the EP670 Opposition about the related '767 Application, however these statements merely echo ***Patent Owner's own arguments*** in U.S. Prosecution ***which were submitted on February 22, 2018*** and were accompanied by an inventor declaration where Dr. Mizumura had, ***by that point in 2018***, learned the specific sequence information for *Limulus polyphemus* Factor C (presumably prompting the filing of PO's '498 PCT where it claimed to have “finally” invented such recombinant proteins). Mot. 2. Again, the spotlighting of PO's own shifting positions before the USPTO does not contradict the Petition's argument that the '109 Patent inventors were not in possession of—and did not enable—the at least 3,456 combinations of recombinant proteins (encompassing recombinant *Limulus polyphemus* zymogen proteins but extending well beyond

such scope) encompassed by the challenged assay claims as of 2013, or even today. PO's own inconsistencies do not warrant discovery of Petitioner.

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 PGR2025-00023”, 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 Patent Owner'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 any 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 immunity, 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 PGR 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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WOLF, GREENFIELD & SACKS, P.C.

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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