



Notice of opposition to a European patent

I. Patent opposed

Patent No.

EP3530670

Application No.

EP17862926.7

Date of mention of the grant in the European Patent Bulletin
(Art. 97(3), Art. 99(1) EPC)

28 February 2024

Title of the invention

METHOD FOR PRODUCING ENDOTOXIN
DETECTING AGENT COMPRISING RECOMBINANT
LIMULUS FACTOR C AND USE THEREOF

II. Proprietor of the patent

first named in the patent specification

Seikagaku Corporation

Opponent's or representative's reference

SP27447OP

III. Opponent

Name

Pohlman, Ms Sandra

Company:

df-mp Dörries Frank-Molnia & Pohlman

Department

Patentanwälte Rechtsanwälte PartG mbB

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Multiple opponents (see additional sheet)

☐

IV. Authorisation

1. Representative

Pohlman, Ms Sandra

Company: df-mp Dörries Frank-Molnia & Pohlman
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Additional representative(s) on additional sheet/see
authorisation

☐

Authorisation(s)

is/are enclosed

☐

has/have been registered under No.

☐

V. Opposition is filed against

the patent as a whole

☒

claim(s) No(s).

VI. Grounds for opposition:

Opposition is based on the following grounds:

(a) the subject-matter of the European patent opposed is not
patentable (Art. 100(a) EPC) because:

• it is not new (Art. 52(1); Art. 54 EPC)

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• it does not involve an inventive step (Art. 52(1);
Art. 56 EPC)

☒

• patentability is excluded on other grounds, namely
articles

☐

(b) the patent opposed does not disclose the invention in a
manner sufficiently clear and complete for it to be carried
out by a person skilled in the art (Art. 100(b) EPC; see Art.
83 EPC).

☒

(c) the subject-matter of the patent opposed extends beyond
the content of the application/of the earlier application as
filed (Art. 100(c) EPC, see Art. 123(2) EPC).

☒

VII. Facts (Rule 76(2)(c) EPC)

presented in support of the opposition are submitted herewith
on an attached document

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VIII. Other requests:

- Oral proceedings are hereby requested auxiliarily.

IX. Evidence presented

AI	Other evidence	DNA Sequence Alignments original file name: Annex I_DNA Sequence Alignments.PDF attached as: Other-evidence-11.pdf
AI1	Other evidence	Protein Sequence Alignment original file name: Annex II_Protein Sequence Alignment.PDF attached as: Other-evidence-12.pdf
APA	Other evidence	NCBI Blast Protein Sequence original file name: Appendix A - NCBI Blast Protein Sequence.pdf attached as: Other-evidence-39.pdf
APB	Other evidence	Limulus polyphemus coverage original file name: Appendix B_Limulus polyphemus coverage.PDF attached as: Other-evidence-14.pdf
APC	Other evidence	tBlastN search of Tokunaga LP peptides original file name: Appendix C_tBlastN search of Tokunaga LP peptides.PDF attached as: Other-evidence-15.pdf
APD	Other evidence	Tachypleus sequence original file name: Appendix D_tachypleus sequence.PDF attached as: Other-evidence-16.pdf
D1	Patent document	EP2930241 (A1) , 14.10.2015 original file name: D1_EP2930241.PDF attached as: Published-Evidence-3.pdf
D10	Other evidence	Wimbish, L. "Advantages of recombinant Factor C based endotoxin testing", 2015, European Pharmaceutical Manufacturer original file name: D10_Wimbish 2015.PDF attached as: Other-evidence-27.pdf
D11	Other evidence	Yeku and Frohman, "Rapid Amplification of cDNA Ends (RACE)", Methods Mol. Biol., Chapter 8, 107-122, 2010 original file name: D11_Yeku 2010.PDF attached as: Other-evidence-28.pdf
D12	Other evidence	Frohman, M. et al., "Rapid production of full-length cDNAs ...", 1988, Proc. Natl. Acad. Sci. 85:8998-9002 original file name: D12_Frohman 1988.PDF attached as: Other-evidence-29.pdf
D13	Other evidence	Dorit and Ohara, "cDNA Amplification Using One-Sided (Anchored) PCR", Curr. Protoc. Mol. Biol., 15.6.1-15.6.10, 2000 original file name: D13_Dorit 2000.PDF attached as: Other-evidence-30.pdf
D14	Other evidence	Frohman, M., "On Beyond Classic RACE (Rapid Amplification of cDNA Ends)", PCR Methods Appl., 4(1):S40-S58, 1994 original file name: D14_Frohman 1994.PDF attached as: Other-evidence-31.pdf
D15	Other evidence	Partial screenshot of search results for "cDNA RACE kits" before Oct. 18, 2016 original file name: D15_Screenshot of search results for kits.PDF

		attached as: Other-evidence-32.pdf
D16	Other evidence	Manual accompanying the 5' RACE kit from Invitrogen, 2004 original file name: D16_TFS-Assets_LSG_manuals_5prime_race_man.PDF attached as: Other-evidence-33.pdf
D17	Other evidence	Manual accompanying the 3' RACE kit from Invitrogen, 2004 original file name: D17_TFS-Assets_LSG_manuals_3prime_race_man.PDF attached as: Other-evidence-34.pdf
D18	Other evidence	NCBI entry regarding the genome assembly of Limulus polyphemus-2.1.2, accessed from: https://www.ncbi.nlm.nih.gov/datasets/... original file name: D18_Limulus_polyphemus-2.1.2 - NCBI - NLM.PDF attached as: Other-evidence-35.pdf
D19	Other evidence	Nossa, C. W. et al., "Joint assembly and genetic mapping of the Atlantic horseshoe crab genome reveals ancient whole genome ..." original file name: D19_Nossa 2014.PDF attached as: Other-evidence-36.pdf
D2	Other evidence	Technical Bulletin for "pCI-neo Mammalian Expression Vector" from Promega, 2009 original file name: D2_pCI-neo Mammalian Expression Vector TB215-4.PDF attached as: Other-evidence-18.pdf
D20	Other evidence	NCBI entry for the predicted sequence of Limulus polyphemus clotting factor C-like mRNA (accession number XM_013937646.1) original file name: D20_PREDICTED LOC10647 - Nucleotide - NCBI.PDF attached as: Other-evidence-37.pdf
D21	Other evidence	NCBI Release Information for the Limulus polyphemus Annotation Release, corresponding to D20 original file name: D21_Limulus polyphemus Annotation Report_Release 100.PDF attached as: Other-evidence-38.pdf
D22	Other evidence	Tokunaga et al., "Further Studies on Lipopolysaccharide-Sensitive Serine Protease Zymogen (Factor C):..." original file name: D22_Tokunaga.PDF attached as: Other-evidence-1.pdf
D23	Patent document	US5,176,834 (B1) , 10.02.1998 original file name: D23_US5716834.PDF attached as: Published-Evidence-1.pdf
D24	Other evidence	Ding, JL and Navas, AA, "Molecular cloning and sequence analysis of Factor C cDNA from the Singapore horseshoe crab, ..." original file name: D24_Ding 1995.PDF attached as: Other-evidence-2.pdf
D25	Other evidence	Wikipedia page related to "Tandem mass spectrometry" captured by the WayBack Machine on August 11, 2016 original file name: D25_Tandem mass spectrometry - Wikipedia.PDF attached as: Other-evidence-3.pdf
D26	Other evidence	Proprietor's response to the communication pursuant to Rules 70(2) and 70a(2) dated Oct. 16, 2020 original file name: D26_Reply ro rules 70.PDF attached as: Other-evidence-4.pdf

D26a	Other evidence	Annex to the Communication in response to the Proprietor's reply of Oct. 16, 2020, dated Oct 21, 2022 original file name: D26a_Annex to Communication of 21Oct2022.PDF attached as: Other-evidence-5.pdf
D27	Other evidence	Miura, Y. et al., "Preparation and Properties of Monoclonal Antibodies against Lipopolysaccharide-Sensitive Serine Protease..." original file name: D27_Miura 1992.PDF attached as: Other-evidence-6.pdf
D28	Patent document	WO 2012/118226 (A1) , 07.09.2012 original file name: D28_WO2012118226.PDF attached as: Published-Evidence-2.pdf
D29	Other evidence	A copy of the Annex to the Communication pursuant to Rule 71(3) EPC original file name: D29_Annex to the communication pursuant to R.71(3).PDF attached as: Other-evidence-7.pdf
D3	Other evidence	Proprietor's submission in US Application No. 14/650,767 dated Feb. 22, 2018 original file name: D3_remarks 2018Feb22_US14650767.PDF attached as: Other-evidence-19.pdf
D30	Other evidence	Chong, S., "Overview of Cell-Free Protein Synthesis: Historic Landmarks, Commercial Systems, and Expanding Applications", 2014, original file name: D30_Chong 2014.PDF attached as: Other-evidence-8.pdf
D31	Other evidence	Dwarakanath, RS et al., "Recombinant COS-1 cells express Carcinoscopus rotundicauda Factor C", 1997, Biotechnol. Lett. 19 original file name: D31_Dwarakanath 1997.PDF attached as: Other-evidence-9.pdf
D32	Other evidence	Alwis & Milton, "Recombinant factor C assay for measuring endotoxin in house dust: Comparison with LAL, and (1???)?-D-glucans" original file name: D32_Alwis & Milton 2006.PDF attached as: Other-evidence-10.pdf
D3a	Other evidence	Inventor's declaration accompanying the Proprietor's submission original file name: D3a_Declaration of 2018Feb22.PDF attached as: Other-evidence-20.pdf
D3b	Other evidence	Claims accompanying the Proprietor's submission original file name: D3b_claims remarks 2018Feb22_US14650767.PDF attached as: Other-evidence-21.pdf
D3c	Other evidence	US 10,144,923 B2 original file name: D3c_US10144923B2.PDF attached as: Other-evidence-22.pdf
D4	Other evidence	Ding and Ho, "Endotoxin Detection- from Limulus Amebocyte Lysate to Recombinant ...", C. Subcell. Biochem., 2010:53, 187-208 original file name: D4_Ding 2010.PDF attached as: Other-evidence-23.pdf
D5	Patent document	USUS 6,645,724 (B1) , 11.11.2003 original file name: D5_US 6645724.PDF attached as: Published-Evidence-4.pdf

D6	Patent document	WO 2003/002976 (A2) , 09.01.2003 original file name: D6_WO2003002976.PDF attached as: Published-Evidence-5.pdf
D7	Other evidence	A copy of the ESO original file name: D7_ESO.PDF attached as: Other-evidence-24.pdf
D8	Other evidence	Declaration of Professor Frohman original file name: D8_Frohman Declaration executed.PDF attached as: Other-evidence-25.pdf
D8a	Other evidence	CV Prof. Frohman original file name: CV_Prof. Frohman.PDF attached as: Other-evidence-17.pdf
D9	Other evidence	Sandle, T. "FDA guidance on pyrogens and endotoxin testing", 2013, GMP Review 12(2): 7-9; original file name: D9_Sandle 2013.pdf attached as: Other-evidence-26.pdf

X. Payment

Method of payment

Debit from deposit account

The European Patent Office is hereby authorised, to debit from the deposit account with the EPO any fees and costs indicated in the fees section below.

Currency:

EUR

Deposit account number:

28001000

Account holder:

df-mp Dörries Frank-Molnia & Pohlman

Refunds

Any refunds should be made to EPO deposit account:

28001000

Account holder:

df-mp Dörries Frank-Molnia & Pohlman

Fees

	Factor applied	Fee schedule	Amount to be paid
010 Opposition fee	1	880.00	880.00
Total:		EUR	880.00

A Forms

Details:

System file name:

A-1

Form for notice of opposition

ep-oppo.pdf

B Attached document files

Original file name:

System file name:

B-1

1. Facts and arguments

SP27447OP_Notice of opposition - final_.pdfOPPO.pdf

C Attached evidence files

Original file name:

System file name:

C-1

1. Patent document

D5_US 6645724.PDF

Published-Evidence-4.pdf

C-2

2. Patent document

D6_WO2003002976.PDF

Published-Evidence-5.pdf

C-3

3. Patent document

D23_US5716834.PDF

Published-Evidence-1.pdf

C-4

4. Patent document

D28_WO2012118226.PDF

Published-Evidence-2.pdf

C-5

5. Patent document

D1_EP2930241.PDF

Published-Evidence-3.pdf

C-6

1. Other evidence

D3c_US10144923B2.PDF

Other-evidence-22.pdf

C-7

2. Other evidence

D4_Ding 2010.PDF

Other-evidence-23.pdf

C-8	3. Other evidence	D7_ESO.PDF	Other-evidence-24.pdf
C-9	4. Other evidence	D8_Frohman Declaration executed.PDF	Other-evidence-25.pdf
C-10	5. Other evidence	D10_Wimbish 2015.PDF	Other-evidence-27.pdf
C-11	6. Other evidence	D11_Yeku 2010.PDF	Other-evidence-28.pdf
C-12	7. Other evidence	D3b_claims remarks 2018Feb22_US14650767.PDF	Other-evidence-21.pdf
C-13	8. Other evidence	D12_Frohman 1988.PDF	Other-evidence-29.pdf
C-14	9. Other evidence	D14_Frohman 1994.PDF	Other-evidence-31.pdf
C-15	10. Other evidence	D15_Screenshot of search results for kits.PDF	Other-evidence-32.pdf
C-16	11. Other evidence	D16_TFS-Assets_LSG_manuals_5prime_rac e_man.PDF	Other-evidence-33.pdf
C-17	12. Other evidence	D17_TFS-Assets_LSG_manuals_3prime_rac e_man.PDF	Other-evidence-34.pdf
C-18	13. Other evidence	D18_Limulus_polyphemus-2.1.2 - NCBI - NLM.PDF	Other-evidence-35.pdf
C-19	14. Other evidence	D19_Nossa 2014.PDF	Other-evidence-36.pdf
C-20	15. Other evidence	D20_PREDICTED LOC10647 - Nucleotide - NCBI.PDF	Other-evidence-37.pdf
C-21	16. Other evidence	D21_Limulus polyphemus Annotation Report_Release 100.PDF	Other-evidence-38.pdf
C-22	17. Other evidence	D13_Dorit 2000.PDF	Other-evidence-30.pdf
C-23	18. Other evidence	D3a_Declaration of 2018Feb22.PDF	Other-evidence-20.pdf
C-24	19. Other evidence	D2_pCI-neo Mammalian Expression Vector TB215-4.PDF	Other-evidence-18.pdf
C-25	20. Other evidence	D22_Tokunaga.PDF	Other-evidence-1.pdf
C-26	21. Other evidence	D24_Ding 1995.PDF	Other-evidence-2.pdf
C-27	22. Other evidence	D25_Tandem mass spectrometry - Wikipedia.PDF	Other-evidence-3.pdf
C-28	23. Other evidence	D26_Reply ro rules 70.PDF	Other-evidence-4.pdf
C-29	24. Other evidence	D26a_Annex to Communication of 21Oct2022.PDF	Other-evidence-5.pdf

C-30	25. Other evidence	D27_Miura 1992.PDF	Other-evidence-6.pdf
C-31	26. Other evidence	D29_Annex to the communication pursuant to R.71(3).PDF	Other-evidence-7.pdf
C-32	27. Other evidence	D3_remarks 2018Feb22_US14650767.PDF	Other-evidence-19.pdf
C-33	28. Other evidence	D30_Chong 2014.PDF	Other-evidence-8.pdf
C-34	29. Other evidence	D32_Alwis & Milton 2006.PDF	Other-evidence-10.pdf
C-35	30. Other evidence	Annex I_DNA Sequence Alignments.PDF	Other-evidence-11.pdf
C-36	31. Other evidence	Annex II_Protein Sequence Alignment.PDF	Other-evidence-12.pdf
C-37	32. Other evidence	Appendix B_Limulus polyphemus coverage.PDF	Other-evidence-14.pdf
C-38	33. Other evidence	Appendix C_tBlastN search of Tokunaga LP peptides.PDF	Other-evidence-15.pdf
C-39	34. Other evidence	Appendix D_tachypleus sequence.PDF	Other-evidence-16.pdf
C-40	35. Other evidence	CV_Prof. Frohman.PDF	Other-evidence-17.pdf
C-41	36. Other evidence	D31_Dwarakanath 1997.PDF	Other-evidence-9.pdf
C-42	37. Other evidence	D9_Sandle 2013.pdf	Other-evidence-26.pdf
C-43	38. Other evidence	Appendix A - NCBI Blast Protein Sequence.pdf	Other-evidence-39.pdf

Signature of opponent or representative

Place: Munich Germany

Date: 22 November 2024

Signed by: Sandra Pohlman 13690

Representative name: Sandra Pohlman

Capacity: (Representative)