



Notice of opposition to a European patent

I. Patent opposed

Patent No.

EP3441466

Application No.

EP18190686.8

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

05 February 2020

Title of the invention

METHOD FOR PRODUCING A NOVEL
RECOMBINANT FACTOR C, METHOD FOR
MITIGATING REACTION INHIBITION IN ENDOTOXIN
ASSAYS, AND METHOD FOR MEASURING
ENDOTOXIN

II. Proprietor of the patent

first named in the patent specification

Seikagaku Corporation

Opponent's or representative's reference

SP23737OP

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

Company:

Department:

Address of place of business

Pohlman, Ms Sandra

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

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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

D1	Other evidence	A copy of the European Search Opinion; original file name: D1 ESO.PDF attached as: Other-evidence-1.pdf
D10	Other evidence	Tomiya, N. et al., "Comparing N-glycan processing in mammalian cell lines to native and engineered lepidopteran insect cell line original file name: D10 Tomiya 2004.PDF attached as: Other-evidence-8.pdf
D11	Other evidence	Nettleship, Joanne E., "Structural Biology of Glycoproteins", Glycosylation, 2012, p. 41-62. original file name: D11 Structural biology.PDF attached as: Other-evidence-9.pdf
D12	Other evidence	Hossler, P. et al., "Optimal and consistent protein glycosylation in mammalian cell culture", Gycobiol. 19(9): 936-949 original file name: D12 Hossler 2009.PDF attached as: Other-evidence-10.pdf
D13	Other evidence	Thomas, P. and Smart, T.G., "HEK293 cell line: A vehicle for the expression of recombinant proteins", J. Pharmacol. And Toxicol. original file name: D13 Thomas 2005.PDF attached as: Other-evidence-11.pdf
D14	Other evidence	Koshiba, T. et al., "A Structural Perspective on the Interaction between Lipopolysaccharide and Factor C original file name: D14 Koshiba 2007.PDF attached as: Other-evidence-12.pdf
D15	Other evidence	Kingston, R. E. et al., "Protein Expression", Current Protocols in Molecular Biology, 1993, 60: 16.23.1-16.23.13 original file name: D15 current protocols in molec.PDF attached as: Other-evidence-13.pdf
D16	Other evidence	Declaration by Dr. Hikaru Mizumura submitted to the USPTO, signed Oct. 11, 2017 original file name: D16 Mizumura declaration 2017.PDF attached as: Other-evidence-14.pdf
D17	Other evidence	Excerpt from Essential Cell Biology (2nd Edition), Alberts et al., Taylor and Francis Group, New York and London, 2004 original file name: D17 Cell biol_ excerpt.PDF attached as: Other-evidence-15.pdf
D18	Other evidence	Declaration by Dr. Hikaru Mizumura signed submitted to the USPTO, signed Feb. 22, 2018; original file name: D18 Mizumura declaration 2018.PDF attached as: Other-evidence-16.pdf
D19	Other evidence	Inhibition data performed using a Limulus Factor C expressed in HEK 293 cells and HEK 293 GnTI- cells. original file name: D19 Inhibition experiments.PDF attached as: Other-evidence-17.pdf
D2	Patent document	US6,645,724 (B) , 11.11.2003 original file name: D2 US6645724.PDF

		attached as: Published-Evidence-1.pdf
D3	Other evidence	Wang, Jing et al., "Modular Arrangement and Secretion of a Multidomain Serine Protease- Evidence for involvement of proline-rich original file name: D3 Wang 2002.PDF attached as: Other-evidence-2.pdf
D4	Other evidence	Carlesso, E. et al., "The rule regulating pH changes during crystalloid infusion", Intensive Care Med., 2011, 37(3): 461-468; original file name: D4 Carlesso 2011.PDF attached as: Other-evidence-3.pdf
D5	Other evidence	The Wikipedia site relating to "Blood Plasma" as of Nov. 19, 2012, provided by the WayBack Machine; original file name: D5 Blood plasma - Wikipedia.PDF attached as: Other-evidence-4.pdf
D6	Other evidence	The Wikipedia site relating to "Horseshoe Crab" as of Nov. 23, 2011, provided by the WayBack Machine; original file name: D6 Horseshoe crab - Wikipedia.PDF attached as: Other-evidence-5.pdf
D7	Other evidence	Ding, Jeak L. and Ho, Bow, "A new era in pyrogen testing", TRENDS in Biotech., 2001, 19(8): 277-281; original file name: D7 A new era.PDF attached as: Other-evidence-6.pdf
D8	Patent document	US5,858,706 (B) , 12.01.1999 original file name: D8 US5858706.PDF attached as: Published-Evidence-2.pdf
D9	Other evidence	Harada-Suzuki, T. et al., "Further Studies on the Chromogenic Substrate Assay Method for Bacterial Endotoxins Using Horseshoe Cr original file name: D9 Suzuki 1982.PDF attached as: Other-evidence-7.pdf
P1	Other evidence	A certified translation of the priority document JP 2012269840 original file name: P1 translated priority Doc-with certificate.PDF attached as: Other-evidence-18.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	815.00	815.00
Total:		EUR	815.00

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

SP_Notice of opposition-Nov5_.pdf

OPPO.pdf

C Attached evidence files

Original file name:

System file name:

C-1

1. Patent document

D8 US5858706.PDF

Published-Evidence-2.pdf

C-2

2. Patent document

D2 US6645724.PDF

Published-Evidence-1.pdf

C-3

1. Other evidence

D1 ESO.PDF

Other-evidence-1.pdf

C-4

2. Other evidence

P1 translated priority Doc-with
certificate.PDF

Other-evidence-18.pdf

C-5

3. Other evidence

D19 Inhibition experiments.PDF

Other-evidence-17.pdf

C-6

4. Other evidence

D18 Mizumura declaration 2018.PDF

Other-evidence-16.pdf

C-7	5. Other evidence	D17 Cell biol_ excerpt.PDF	Other-evidence-15.pdf
C-8	6. Other evidence	D16 Mizumura declaration 2017.PDF	Other-evidence-14.pdf
C-9	7. Other evidence	D15 current protocols in molec.PDF	Other-evidence-13.pdf
C-10	8. Other evidence	D14 Koshiba 2007.PDF	Other-evidence-12.pdf
C-11	9. Other evidence	D13 Thomas 2005.PDF	Other-evidence-11.pdf
C-12	10. Other evidence	D12 Hossler 2009.PDF	Other-evidence-10.pdf
C-13	11. Other evidence	D11 Structural biology.PDF	Other-evidence-9.pdf
C-14	12. Other evidence	D10 Tomiya 2004.PDF	Other-evidence-8.pdf
C-15	13. Other evidence	D9 Suzuki 1982.PDF	Other-evidence-7.pdf
C-16	14. Other evidence	D7 A new era.PDF	Other-evidence-6.pdf
C-17	15. Other evidence	D6 Horseshoe crab - Wikipedia.PDF	Other-evidence-5.pdf
C-18	16. Other evidence	D5 Blood plasma - Wikipedia.PDF	Other-evidence-4.pdf
C-19	17. Other evidence	D4 Carlesso 2011.PDF	Other-evidence-3.pdf
C-20	18. Other evidence	D3 Wang 2002.PDF	Other-evidence-2.pdf

Signature of opponent or representative

Place: **Munich Germany**

Date: **05 November 2020**

Signed by: **Sandra Pohlman 13690**

Representative name: **Sandra Pohlman**

Capacity: **(Representative)**