

European Patent Office

Bob-van-Benthem-Platz 1
80469 München

EPO - Munich
51
10.2. Aug. 2016

Ihr Zeichen / Your Ref.

Unser Zeichen / Our Ref.

Datum / Date

EP101800FZRPpau

August 2, 2016

European Patent Application No. 14 781 729.0
Applicant: REG Life Sciences, LLC

In response to the Official Communication pursuant to Article 94(3) EPC dated
March 24, 2016:

Submitted herewith are new claims 1-11, which should form the basis for further examination. Also submitted herewith is an adapted description, which has been brought into conformity with the new set of claims.

1. Amendments to the claims

New claims 1-11 correspond to previous claims 1-7, 9, and 13-15, with the exception that redundant sequence identifiers have been omitted from new claims 1 and 3.

Furthermore, new claim 7 has been amended so as to specify the "*at least one mutation in the N-terminal region*" of the biotin carboxyl carrier protein (BCCP) of SEQ ID NO: 2 as "*an amino acid substitution at position 2 of SEQ ID NO: 2*". Support for this amendment can be found, *inter alia*, in lines 6-7 of paragraph [0017] on page 6 of the application as filed.

MÜNCHEN

Patentanwälte
European Patent Attorneys
Hans Hilgers
Thomas Schuster
Dr. Klara Goldbach
Martin Aufenanger, LL.M., MM.¹
Gottfried Klitzsch
Dr. Heike Vogelsang-Wenke
Reinhard Knauer
Dietmar Kuhl
Dr. Franz-Josef Zimmer
Bettina K. Reichelt
Dr. Anton K. Pfau
Dr. Udo Weigelt, LL.M.
Rainer Bertram
Jens C. Koch, M.S. (U of PA)
Bernd Rothaemel
Thomas W. Laubenthal, LL.M.
Dr. Andreas Kayser
Dr. Jens Hammer
Dr. Thomas Eickelkamp
Dr. Peter Miltényi²
Dr. Moritz Höffe, LL.M.
Gero Maatz-Jansen
Michael Heise
Christian Meisinger
Dr. Martin Ahr
Dr. Wolfgang Neubeck
Steven M. Zeman, Ph.D.
André Nickel
Felix Kahr
Dr. Alexander Stumvoll, LL.M.
Dr. Stefano Marchini³
Dr. Thomas Kronberger
Yilin Jin
Dr. Georg Seisenberger
Amir Nemetzade
Dr. Olivia Nemethova, LL.M.
Dr. Rainer Plaggenborg
Victor Lopes Aguiar

Rechtsanwälte
Attorneys-at-Law
Dr. Helmut Eichmann
Gerhard Barth
Dr. Ulrich Blumenröder, LL.M.
Prof. Dr. Maximilian Kinkeldey, LL.M.⁴
Dr. Karsten Brandt
Anja Franke, LL.M.
Ute Stephani
Dr. Bernd Allekotte, LL.M.⁵
Dr. Elvira Bertram, LL.M.
Babett Ertle
Christine Neuhierl
Sabine Brandstätter
Cornelia Schmitt
Petra Lübke
Dr. Holger Gauss
Dr. Nicolás Schmitz
Marina Schlumberger
Kirsten Hammerstingl
Sebastian Clotten, LL.M.
Jennifer Rosenhäger, LL.M.
Ina Schwerter-Strumpf
Mark Peters, LL.M.
Julia Bittner, LL.M.
Sebastian Ochs
Christian Werkmeister, LL.M.

BERLIN

Patentanwälte
European Patent Attorneys
Dr. Patrick P. Erk, M.S. (MIT)
Dr. Svenja Sethmann
Tino Rumpold

KÖLN

Patentanwälte
European Patent Attorneys
Dr. Martin Drogmann

PARIS⁶

Conseil en Propriété Industrielle
European Patent Attorney
Dr. Wolfgang Neubeck

- 1.2 Previous claims 8 and 10-12 have been omitted from the new set of claims without prejudice.
- 1.3 The amendments made to the claims do not introduce subject matter, which extends beyond the disclosure content of the application as originally filed. The requirements of Article 123(2) EPC are thus fulfilled.

2. Clarity (Article 84 EPC)

- 2.1 It is believed that the clarity objections raised in sections 4.1, 4.2 and 4.3 of the Communication have been overcome with the amendments made to the claims.

New claims 1-11 submitted herewith are clear to the skilled person in the sense of Article 84 EPC.

- 2.2 Furthermore, with regard to the Examiner's comment in section 4.4 of the Communication, it is submitted that Fig. 1 refers to "Acyl-ACP" while Fig. 3 refers to "Acyl-CoA".

3. Novelty (Article 54 EPC)

While the Examining Division has acknowledged novelty of previous claims 1-6 and 9-15, it is held in section 5.3 of the Communication that claim 7 lacks novelty over cited reference D2 (Choi-Rhee *et al.*, 2003), which is said to describe deletions of four-residue stretches in the N-terminal region of the BCCP.

In response, it is submitted that claim 7 has been amended to specify the mutation in the N-terminal region of the BCCP of SEQ ID NO: 2, as explained herein above. It is respectfully submitted that reference D2 does not describe a mutation specifically at position 2 of the BCCP, let alone an amino acid substitution at position 2 of the BCCP.

It is therefore respectfully submitted that new claim 7 is novel over D2 in accordance with Article 54 EPC.

4. Inventive Step (Article 56 EPC)

The Examining Division has acknowledged the presence of an inventive step for the subject matter of previous claims 1-6 and 9-15 (sections 6.3 and 6.4 of the Communication). It is respectfully submitted that new claim 7 also involves an

inventive step for the same reasons because new claim 7 also describes a mutation (an amino acid substitution) specifically at position 2 of the BCCP protein.

Therefore, it is respectfully submitted that new claim 7 submitted herewith meets the requirements of Article 56 EPC.

5. Adaptation of the description

As requested by the Examining Division, the description has been brought into conformity with the new set of claims. The amendments made to the description become evident from the marked-up version of the description.

References D1 and D2 discussed in the Communication have been identified and the relevant background art disclosed therein has been briefly discussed on page 3 of the adapted description. Reference D3 discussed in the Communication has been identified and discussed in paragraph [0008] on page 3 and in paragraph [0032] on page 36 of the application as originally filed.

It is respectfully submitted that the amendments made to the description do not introduce subject matter, which extends beyond the disclosure content of the application as originally filed. The requirements of Article 123(2) EPC are thus fulfilled.

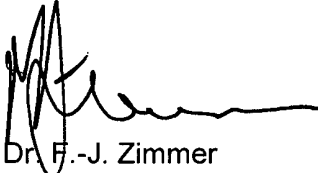
6. Requests

It is requested that as a next step a Communication pursuant to Article 94(3) EPC be issued based on the following application documents:

- (i) Adapted description pages 1-71 submitted herewith;
- (ii) Sequence listing (SEQ ID NOs: 1 – 109) as published;
- (iii) New claims 1-11 submitted herewith;
- (iv) Drawings (Sheets 1/5 – 5/5) as published.

If, however, the Examining Division cannot agree with the above, it is requested that a further Communication pursuant to Article 94(3) EPC be issued. Oral proceedings pursuant to Article 116(1) EPC are requested as an auxiliary measure.

If only minor matters remain to be resolved, then the Primary Examiner is welcome to contact the undersigned over the telephone in order to allow them to be resolved in an efficient manner.

A handwritten signature in black ink, appearing to read 'F. Zimmer', with a long horizontal flourish extending to the right.

Dr. F.-J. Zimmer
- Patent Attorney -

Enc.

New claims 1-11 (marked-up and clean version)

Adapted description (pages 1-71; marked-up and clean version)