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UNITED STATES PATENT AND TRADEMARK OFFICE

Filed: June 24, 2019

BEFORE THE PATENT TRIAL AND APPEAL BOARD

THE REGENTS OF THE UNIVERSITY OF CALIFORNIA, UNIVERSITY OF VIENNA, AND EMMANUELLE CHARPENTIER
Junior Party

(Applications 15/947,680; 15/947,700; 15/947,718; 15/981,807; 15/981,808; 15/981,809; 16/136,159; 16/136,165; 16/136,168; and 16/136,175),

v.

THE BROAD INSTITUTE, INC., MASSACHUSETTS INSTITUTE OF TECHNOLOGY, and PRESIDENT AND FELLOWS OF HARVARD COLLEGE, Senior Party

(Patents 8,697,359; 8,771,945; 8,795,965; 8,865,406; 8,871,445; 8,889,356; 8,895,308; 8,906,616; 8,932,814; 8,945,839; 8,993,233; 8,999,641; 9,840,713; and Application 14/704,551).

Patent Interference No. 106,115 (DK) (Technology Center 1600)

DECLARATION – 37 C.F.R. § 41.203(b)¹

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¹ It is noted that "Bd.R. x" may be used as shorthand for "37 C.F.R. § 41.x". 69 Fed. Reg. 49960, 49961 (12 Aug. 2004).

Part A. Declaration of interference

An interference is declared (35 U.S.C. § 135(a)²) between the above-identified parties. Details of the applications, patents, count and claims designated as corresponding or as not corresponding to the count appear in Parts E and F of this DECLARATION.

Part B. Judge managing the interference

Administrative Patent Judge Deborah Katz has been designated to manage the interference. 37 C.F.R. § 41.104(a).

Part C. Standing order

A Trial Section STANDING ORDER ("SO") (Paper 2) accompanies this DECLARATION. The STANDING ORDER applies to this interference.

Part D. Initial conference call

A telephone conference call to discuss the interference is set for **5 August 2019** at **2:00 p.m.** (the Board will provide call-in information).

No later than **four business days** prior to the conference call, each party shall file and serve (SO ¶¶ 10.1 & 105) a list of the motions (37 C.F.R. § 41.120; 37 C.F.R. § 41.204; SO ¶¶ 104.2.1, 120 & 204) the party intends to file.

A sample schedule for taking action during the motion phase appears as Form 2 in the STANDING ORDER. Counsel are encouraged to discuss the schedule prior to the conference call and to agree on dates for taking action.

² Patent interferences continue under the relevant statutes in effect on 15 March 2013. *See* Pub. L. 112-29, § 3(n), 125 Stat. 284, 293 (2011).

A typical motion period lasts approximately eight (8) months. Counsel should be prepared to justify any request for a shorter or longer period.

Part E. Identification and order of the parties

Junior Party ("University of California")

Application: **15/947,680**, filed 6 April 2018

Application: **15/947,700**, filed 6 April 2018

Application: **15/947,718**, filed 6 April 2018

Application: **15/981,807**, filed 16 May 2018

Application: **15/981,808**, filed 16 May 2018

Application: **15/981,809**, filed 16 May 2018

Application: **16/136,159**, filed 19 September 2018

Application: **16/136,165**, filed 19 September 2018

Application: **16/136,168**, filed 19 September 2018

Application: **16/136,175**, filed 19 September 2018

The named inventors on each of the involved UC applications are:

Jennifer A. Doudna Berkeley, CA

Martin Jinek Berkeley, CA

Emmanuelle Charpentier Braunschweig, GERMANY

Krzysztof Chylinski Vienna, AUSTRIA

The assignees of each of the involved UC applications are:

The Regents of the University of California and University of Vienna

According to the assignment records of the Office, Emmanuelle Charpentier has not assigned rights to the application to another entity.

The title of each of the involved UC applications is:

Methods and Compositions for RNA-Directed Target DNA Modification and for RNA-Directed Modulation of Transcription

Senior Party ("Broad Institute")

Patent: **8,697,359**

Named Inventors: Feng Zhang

Cambridge, MA

Issue Date: 15 April 2014

Application: 14/054,414, filed 15 October 2013

Title: CRISPR-Cas Systems and Methods for Altering

Expression of Gene Products

Assignees: The Broad Institute, Inc. and Massachusetts Institute of

Technology

Patent: **8,771,945**

Named Inventors: Feng Zhang

Cambridge, MA

Issue Date: 8 July 2014

Application: 14/183,429, filed 18 February 2014

Title: CRISPR-Cas Systems and Methods for Altering

Expression of Gene Products

Assignees: The Broad Institute, Inc. and Massachusetts Institute of

Technology

Patent: **8,795,965**

Named Inventors: Feng Zhang

Cambridge, MA

Issue Date: 5 August 2014

Application: 14/183,486, filed 18 February 2014

Title: CRISPR-Cas Component Systems, Methods, and

Compositions for Sequence Manipulation

Assignees: The Broad Institute, Inc. and Massachusetts Institute of

Technology

Patent: **8,865,406**

Named Inventors: Feng Zhang

Cambridge, MA

Fei Ran

Boston, MA

Issue Date: 21 October 2014

Application: 14/222,930, filed 24 March 2014

Title: Engineering and Optimization of Improved Systems,

Methods and Enzyme Compositions for Sequence

Manipulation

Assignees: The Broad Institute, Inc., Massachusetts Institute of

Technology, and President and Fellows of Harvard

College

Patent: **8,871,445**

Named Inventors: Le Cong

Cambridge, MA

Feng Zhang Cambridge, MA

Issue Date: 28 October 2014

Application: 14/259,420, filed 23 April 2014

Title: CRISPR-Cas Component Systems, Methods, and

Compositions for Sequence Manipulation

Assignees: The Broad Institute, Inc., Massachusetts Institute of

Technology, and President and Fellows of Harvard

College

Patent: **8,889,356**

Named Inventors: Feng Zhang

Cambridge, MA

Issue Date: 18 November 2014

Application: 14/183,471, filed 18 February 2014

Title: CRISPR-Cas Nickase Systems, Methods, and

Compositions for Sequence Manipulation in Eukaryotes

Assignees: The Broad Institute, Inc. and Massachusetts Institute of

Technology

Patent: **8,895,308**

Named Inventors: Feng Zhang

Cambridge, MA

Fei Ran

Boston, MA

Issue Date: 25 November 2014

Application: 14/293,498, filed 2 June 2014

Title: Engineering and Optimization of Improved Systems,

Methods and Enzyme Compositions for Sequence

Manipulation

Assignees: The Broad Institute, Inc., Massachusetts Institute of

Technology, and President and Fellows of Harvard

College

Patent: **8,906,616**

Named Inventors: Feng Zhang

Cambridge, MA

Le Cong

Cambridge, MA

Patrick Hsu

Cambridge, MA

Fei Ran

Boston, MA

Issue Date: 9 December 2014

Application: 14/290,575, filed 29 May 2014

Title: Engineering of Systems, Methods and Optimized Guide

Compositions for Sequence Manipulation

Assignees: The Broad Institute, Inc., Massachusetts Institute of

Technology, and President and Fellows of Harvard

College

Patent: **8,932,814**

Named Inventors: Le Cong

Cambridge, MA

Feng Zhang Cambridge, MA

Issue Date: 13 January 2015

Application: 14/258,458, filed 22 April 2014

Title: CRISPR-Cas Nickase Systems, Methods and

Compositions for Sequence Manipulation in Eukaryotes

Assignees: The Broad Institute, Inc., Massachusetts Institute of

Technology, and President and Fellows of Harvard

College

Patent: **8,945,839**

Named Inventors: Feng Zhang

Cambridge, MA

Issue Date: 3 February 2015

Application: 14/256,912, filed 18 April 2014

Title: CRISPR-Cas Systems and Methods for Altering

Expression of Gene Products

Assignees: The Broad Institute, Inc. and Massachusetts Institute of

Technology

Patent: **8,993,233**

Named Inventors: Feng Zhang

Cambridge, MA

Le Cong

Cambridge, MA

Randall Jeffrey Platt

Cambridge, MA

Neville Espi Sanjana Cambridge, MA

Fei Ran

Boston, MA

Issue Date: 31 March 2015

Application: 14/105,017, filed 12 December 2013

Title: Engineering and Optimization of Systems, Methods and

Compositions for Sequence Manipulation with

Functional Domains

Assignees: The Broad Institute, Inc., Massachusetts Institute of

Technology, and President and Fellows of Harvard

College

Patent: **8,999,641**

Named Inventors: Feng Zhang

Cambridge, MA

Le Cong

Cambridge, MA

Randall Jeffrey Platt Cambridge, MA

Neville Espi Sanjana Cambridge, MA

Issue Date: 7 April 2015

Application: 14/226,274, filed 26 March 2014

Title: Engineering and Optimization of Systems, Methods and

Compositions for Sequence Manipulation with

Functional Domains

Assignees: The Broad Institute, Inc., Massachusetts Institute of

Technology, and President and Fellows of Harvard

College

Patent: 9,840,713

Named Inventors: Feng Zhang

Cambridge, MA

Issue Date: 12 December 2017

Application: 14/523,799, filed 24 October 2014

Title: Crispr-Cas Component Systems, Methods and

Compositions for Sequence Manipulation

Assignees: The Broad Institute, Inc. and Massachusetts Institute of

Technology

Application: **14/704,551**, filed 5 May 2015

Named Inventors: Feng Zhang

Cambridge, MA

Le Cong

Cambridge, MA

Patrick Hsu

Cambridge, MA

Fei Ran

Boston, MA

Title: Engineering of Systems, Methods and Optimized Guide

Compositions for Sequence Manipulation

Assignees: The Broad Institute, Inc., Massachusetts Institute of

Technology, and President and Fellows of Harvard

College

The senior party is assigned exhibit numbers 1001-1999. The junior party is assigned exhibit numbers 2001-2999. 37 C.F.R. § 41.154(c)(1); SO ¶ 154.2.1. The senior party is responsible for initiating settlement discussions. SO ¶ 126.1.

Part F. Count and claims of the parties

Count 1

Broad Institute patent 8,697,359, claim 18

OI

University of California application 15/981,807, claim 156

Broad Institute 8,697,359, claim 18 recites:

The CRISPR-Cas system of claim 15, wherein the guide RNAs comprise a guide sequence fused to a tracr sequence.

Broad Institute 8,697,359, claim 15 recites:

An engineered, programmable, non-naturally occurring Type II CRISPR-Cas system comprising a Cas9 protein and at least one guide RNA that targets and hybridizes to a target sequence of a DNA molecule in a eukaryotic cell, wherein the DNA molecule encodes and the eukaryotic cell expresses at least one gene product and the Cas9 protein cleaves the DNA molecules, whereby expression of the at least one gene product is altered; and, wherein the Cas9 protein and the guide RNA do not naturally occur together.

University of California application 15/981,807, claim 156 recites:

A eukaryotic cell comprising a target DNA molecule and an engineered and/or non-naturally occurring Type II Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR)—CRISPR associated (Cas) (CRISPR-Cas) system comprising

- a) a Cas9 protein, or a nucleic acid comprising a nucleotide sequence encoding said Cas9 protein; and
- b) a single molecule DNA-targeting RNA, or a nucleic acid comprising a nucleotide sequence encoding said single molecule DNA-targeting RNA; wherein the single molecule DNA-targeting RNA comprises:
- i) a targeter-RNA that is capable of hybridizing with a target sequence in the target DNA molecule, and
- ii) an activator-RNA that is capable of hybridizing with the targeter-RNA to form a double-stranded RNA duplex of a protein-binding segment,

wherein the activator-RNA and the targeter-RNA are covalently linked to one another with intervening nucleotides; and

wherein the single molecule DNA-targeting RNA is capable of forming a complex with the Cas9 protein, thereby targeting the Cas9 protein to the target DNA molecule, whereby said system is capable of cleaving or editing the target DNA molecule or modulating transcription of at least one gene encoded by the target DNA molecule.

The claims of the parties are:

University of California

Application 15/947,680 – Claims 156–185

Application 15/947,700 – Claims 156–185

Application 15/947,718 – Claims 156–185

Application 15/981,807 – Claims 156–185

Application 15/981,808 - Claims 156-170 and 172-185

Application 15/981,809 – Claims 156–170 and 172–185

Application 16/136,159 – Claims 156–184

Application 16/136,165 – Claims 156–184

Application 16/136,168 - Claims 156-184

Application 16/136,175 - Claims 156-184

Broad Institute

Patent 8,697,359 - Claims 1-20

Patent 8,771,945 - Claims 1-29

Patent 8,795,965 - Claims 1-30

Patent 8,865,406 – Claims 1-30

Patent 8,871,445 – Claims 1-30

Patent 8,889,356 – Claims 1-30

Patent 8,895,308 - Claims 1-30

Patent 8,906,616 – Claims 1-30

Patent 8,932,814 – Claims 1-30

Patent 8,945,839 - Claims 1-28

Patent 8,993,233 - Claims 1-43

Patent 8,999,641 – Claims 1-28

Patent 9,840,713 - Claims 1-41

Application 14/704,551 – Claims 2 and 4–18

The claims of the parties that correspond to Count 1 are:

<u>University of California</u>

Application 15/947,680 – Claims 156–185

Application 15/947,700 – Claims 156–185

Application 15/947,718 - Claims 156-185

Application 15/981,807 – Claims 156–185

Application 15/981,808 - Claims 156-170 and 172-185

Application 15/981,809 - Claims 156-170 and 172-185

Application 16/136,159 – Claims 156–184

Application 16/136,165 - Claims 156-184

Application 16/136,168 - Claims 156-184

Application 16/136,175 - Claims 156-184

Broad Institute

Patent 8,697,359 – Claims 1-20

Patent 8,771,945 – Claims 1-29

Patent 8,795,965 – Claims 1-30

Patent 8,865,406 – Claims 1-30

Patent 8,871,445 – Claims 1-30

Patent 8,889,356 – Claims 1-30

Patent 8,895,308 - Claims 1-30

Patent 8,906,616 - Claims 1-30

Patent 8,932,814 – Claims 1-30

Patent 8,945,839 – Claims 1-28

Patent 8,993,233 - Claims 1-43

Patent 8,999,641 – Claims 1-28

Patent 9,840,713 - Claims 1-41

Application 14/704,551 – Claims 2 and 4–18

The claims of the parties that do not correspond to Count 1 and therefore are not involved in the interference, are:

University of California

None

Broad Institute

None

The parties are accorded the following benefit for Count 1:

University of California

None

Broad Institute

None

Part G. Heading to be used on papers

The following heading must be used on all papers filed in this interference, see SO \P 106.1.1:

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

THE REGENTS OF THE UNIVERSITY OF CALIFORNIA, UNIVERSITY OF VIENNA, AND EMMANUELLE CHARPENTIER Junior Party

(Applications 15/947,680; 15/947,700; 15/947,718; 15/981,807; 15/981,808; 15/981,809; 16/136,159; 16/136,165; 16/136,168; and 16/136,175),

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Patent Interference No. 106,115 (DK)

Part H. Order form for requesting file copies

When requesting copies of files, use of SO Form 4 will greatly expedite processing of the request. Please attach a copy of Parts E and F of this DECLARATION with a hand-drawn circle around the patents and applications for which a copy of a file wrapper is requested.

Part I. Electronic filing

The web portal for interferences < https://acts.uspto.gov/ifiling/Login.jsp can no longer accept a document larger than 25MB. If you need to file a document larger than 25MB, unless otherwise instructed by order, please contact the board at 571-272-INTF (571-272-4683) to make alternate arrangements, such as sending a CD-ROM by Express Mail.

Because the administrative patent judges now work from the electronic record, SO \P 154.3.2 notwithstanding, exceptions to electronic filing should be very rare. SO \P 104.1.

/Deborah Katz/
Administrative Patent Judge

Enc:

Copy of STANDING ORDER³

³ For a United States patent or published application listed in this paper, *see* http://patft.uspto.gov/; *see also* http://portal.uspto.gov/external/portal/pair for prosecution histories available to the public.

cc (via overnight delivery):

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