

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

THE BROAD INSTITUTE, INC., MASSACHUSETTS INSTITUTE OF TECHNOLOGY, and PRESIDENT AND FELLOWS OF HARVARD COLLEGE,
(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; and 8,999,641),

Junior Party,

v.

THE REGENTS OF THE UNIVERSITY OF CALIFORNIA, UNIVERSITY OF VIENNA, AND EMMANUELLE CHARPENTIER
(Application 13/842,859),

Senior Party.

Patent Interference No. 106,048 (DK)
(Technology Center 1600)

DECLARATION – 37 C.F.R. § 41.203(b)

Before DEBORAH KATZ, *Administrative Patent Judge.*

Part A. Declaration of interference

An interference is declared (35 U.S.C. § 135(a)¹) between the above-identified parties. Interferences are conducted under the provisions of 37 C.F.R. Part 41.² Details of the application, patents, count and claims designated as corresponding or as not corresponding to the count appear in Parts E and F of this DECLARATION. Subparts D and E are of particular relevance.

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 **9 March 2016 at 3:00 p.m.** (the Board will initiate the call).

No later than **3 March 2016**, 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

¹ 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).

² 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).

schedule prior to the conference call and to agree on dates for taking action. 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 (“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

Senior Party (“University of California”)

Application: **13/842,859**, filed 15 March 2013

Named Inventors: Jennifer A. Doudna
Berkeley, CA

Martin Jinek
Berkeley, CA

Emmanuelle Charpentier
Braunschweig, GERMANY

Krzysztof Chylinski
Vienna, AUSTRIA

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

Assignees³: The Regents of the University of California and University of Vienna

The senior party is assigned exhibit numbers 1001-1999. The junior party is assigned exhibit numbers 2001-2999. 37 C.F.R. § 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

A method, in a eukaryotic cell, of cleaving or editing a target DNA molecule or modulating transcription of at least one gene encoded thereon, the method comprising:

contacting, in a eukaryotic cell, a target DNA molecule having a target sequence with an engineered and/or non-naturally-occurring Type II Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR)-CRISPR associated (Cas) (CRISPR-Cas) system comprising:

³ According to the assignment records of the Office, Emmanuelle Charpentier has not assigned rights to the application to another entity.

a) a DNA-targeting RNA comprising

i) a targeter-RNA or guide sequence that hybridizes with the target sequence, and

ii) an activator-RNA or tracr sequence that hybridizes with the targeter-RNA to form a double-stranded RNA duplex of a protein-binding segment,

and

b) a Cas9 protein,

wherein the DNA-targeting RNA forms a complex with the Cas9 protein, thereby targeting the Cas9 protein to the target DNA molecule, whereby said target DNA molecule is cleaved or edited or transcription of at least one gene encoded by the target DNA molecule is modulated.

The claims of the parties are:

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

University of California

Application 13/842,859 – claims 165-200, 202-218, 220-222 and 224-247

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

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

University of California

Application 13/842,859 – claims 165, 200, 202-218, 220-222 and
224-247

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

Broad Institute

None

University of California

None

The parties are accorded the following benefit for Count 1:

Broad Institute

None

University of California

None

Part G. Heading to be used on papers

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

**THE BROAD INSTITUTE, INC., MASSACHUSETTS INSTITUTE OF
TECHNOLOGY, and PRESIDENT AND FELLOWS OF HARVARD COLLEGE,**
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; and 8,999,641,

Junior Party,

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**THE REGENTS OF THE UNIVERSITY OF CALIFORNIA, UNIVERSITY
OF VIENNA and EMMANUELLE CHARPENTIER**
Application 13/842,859.

Senior Party

Patent Interference No. 106,048 (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 ¶ 154.3.2 notwithstanding, exceptions to electronic filing should be very rare. SO ¶ 104.1.

Part J. Other matters

On 5 and 6 January 2016 Broad Institute filed two papers styled as petitions in, *inter alia*, application 14/054,414, which became Broad Institute involved patent 8,697,359.⁴ Those papers are directed to the Chief Administrative Patent

⁴ The papers are entitled “Emergency Petition Under 37 C.F.R. §§ 41.3, 1.181-1,183 for PTAB to Dismiss Interference Memorandum in USSN 13/842,859 with Remand of USSN 13/842,859 for Full, Proper Examination Thereof Which Has to Date Been Lacking,” which was filed 5 January 2016, and “Supplemental and Renewed Emergency Petition Under 37 C.F.R. §§ 41.3, 1.181-1,183 for PTAB to Dismiss Interference Memorandum in USSN 13/842,859 with Remand of USSN 13/842,859 for Full, Proper Examination Thereof Which Has to Date Been Lacking,” which was filed 6 January 2016.

Judge, who has delegated authority to review these papers to the administrative patent judge assigned to manage this interference. *See* 37 C.F.R. § 41.3(a).

The papers request that an interference memorandum filed in University of California's application 13/842,859 be dismissed and that the examiner be directed to cancel the pending claims. The papers appear to be more akin to a protest against pending application 13/842,859 rather than petitions because they relate to prosecution of University of California's application. *See* 37 C.F.R. §1.291. Accordingly, it is ORDERED that these papers be matched with the file of application 13/842,859, for such consideration that the Examiner may deem appropriate when the application returns to the jurisdiction of the Examiner. *See* 37 C.F.R. §1.291(a) ("A protest may be filed by a member of the public against a pending application, and it will be matched with the application file if it adequately identifies the patent application."); *see also* §41.103 ("The Board acquires jurisdiction over any involved file when the Board initiates a contested case."); and §41.104(a) ("The Board may determine a proper course of conduct in a proceeding for any situation not specifically covered by this part and may enter non-final orders to administer the proceeding.") No substantive communication relating to the papers will be issued by the Board. *Cf.* 37 C.F.R. § 1.291(d) ("A member of the public filing a protest in an application under this section will not receive any communication from the Office relating to the protest")

This interference was declared under 37 C.F.R. § 41.203 after consideration of the parties' claims and University of California's suggestion for an interference filed in accordance with 37 C.F.R. § 41.202(a) (providing for the suggestion of an interference by an applicant). Accordingly, an *inter partes* proceeding has been initiated between the parties regarding their claims. While no substantive communication relating to Broad Institute's papers will be issued by the Board, it

appears that the matters argued in those papers may be appropriately raised, in due course, as proposed motions during the interference. *See* 37 C.F.R. §§ 41.121 and 41.208; Standing Order at ¶104.2.1.

Enc:

Copy of STANDING ORDER⁵

cc (via United Parcel Service):

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⁵ 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.