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UNITED STATES PATENT AND TRADEMARK OFFICE

Filed: June 11, 2020

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SNIPR TECHNOLOGIES LIMITED

(Inventors: Jasper Clube, Morten Sommer, Christian Grøndahl, Eric Van Der Helm, Ruben Vazquez-Uribe)

Junior Party (Patents 10,463,049; 10,506,812; 10,561,148; 10,524,477; 10,582,712),

v.

The Rockefeller University

(Inventors: David Bikard and Luciano Marraffini)

Senior Party (Patent Application 15/159,929).

Patent Interference No. 106,123 (DK) (Technology Center 1600)

DECLARATION – 37 C.F.R. \S 41.203(b)¹

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 application, patent, 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 **22 July 2020** at **2:00 p.m.** (the Board will provide information for the call).

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

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).

Part E. Identification and order of the parties

Junior Party ("SNIPR")

Each of Junior Party's involved patents is entitled "ALTERING MICROBIAL POPULATIONS AND MODIFYING MICROBIOTA" and is assigned to SNIPR Technologies, Ltd. Individual patents are as follows.

Involved Patent: 10,463,049, issued 5 November 2019, from

application 15/817,135, filed 17 November 2017

Named inventors: Jasper Clube

London, GREAT BRITAIN

Morten Sommer

Hørsholm, DENMARK

Christian Grøndahl

London, GREAT BRITAIN

Eric Van Der Helm

Hørsholm, DENMARK

Ruben Vazquez-Uribe Hørsholm, DENMARK

Involved Patent: 10,506,812, issued 17 December 2019, from

application 15/817,125, filed 17 November 2017

Named inventor: Jasper Clube

London, GREAT BRITAIN

Involved Patent: 10,524,477, issued 7 January 2020, from

application 15/817,139, filed 17 November 2017

Named inventors: Jasper Clube

London, GREAT BRITAIN

Morten Sommer

Hørsholm, DENMARK

Christian Grøndahl

London, GREAT BRITAIN

Eric Van Der Helm Hørsholm, DENMARK

Ruben Vazquez-Uribe Hørsholm, DENMARK

Involved Patent: 10,561,148, issued 18 February 2020, from

application 16/192,746, filed 15 November 2018

Named inventors: Jasper Clube

London, GREAT BRITAIN

Involved Patent: 10,582,712, issued 10 March 2020, from

application 15/460,962, filed 16 March 2017

Named inventors: Jasper Clube

London, GREAT BRITAIN

Morten Sommer

Hørsholm, DENMARK

Christian Grøndahl

London, GREAT BRITAIN

Eric Van Der Helm Hørsholm, DENMARK Ruben Vazquez-Uribe Hørsholm, DENMARK

Senior Party ("Rockefeller")

Title: SEQUENCE SPECIFIC ANTIMICROBIALS

Assignee: The Rockefeller University

Named Inventors: David Bikard

New York, NY

Luciano Marraffini New York, NY

Involved Application: 15/159,929, filed 20 May 2016

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

Claim 1 of Patent 10,582,712 or Claim 24 of Application 15/159,929

Claim 1 of Patent 10,582,712 recites:

A method of modifying a mixed population of bacteria, wherein the mixed population comprises a first bacterial subpopulation and a second bacterial sub-population,

wherein the first bacterial sub-population comprises a first bacterial species and the second bacterial sub-population comprises host cells of a second bacterial species,

wherein the second bacterial species is a different species than the first bacterial species,

the method comprising

a. contacting the mixed population of an engineered nucleic acid sequence for producing a host modifying crRNA (HM-crRNA), and

b. producing the HM-crRNA in the host cells,

wherein the HM-crRNA is operable with a Cas nuclease in the host cells, wherein the engineered nucleic acid sequence and the Cas nuclease are comprised by an HM-CRISPR/Cas system, and

wherein the HM-crRNA comprises a nucleic acid sequence that is capable of hybridizing to a target sequence in the host cells to guide the Cas nuclease to modify the target sequence in the host cells;

whereby the host cells are killed or growth of the host cells is reduced, thereby reducing the proportion of the host cells and altering the relative ratio of the first and second bacterial sub-populations in the mixed population of bacteria; and

wherein the mixed population of bacteria comprises E. coli.

Claim 24 of Application 15/159,929 recites:

The method of claim 20, wherein the mixed bacterial population comprises one or a combination of bacterial species selected from the group consisting of *Staphylococcus*, *Clostridium*, *Bacillus*, *Salmonella*, *Helicobacter pylori*, *Neisseria gonorrhoeae*, *Neisseria meningitidis*, and *Escherichia coli*.

Claim 20 of Application 15/159,929 recites:

A method for killing targeted bacteria in a mixed bacterial population comprising:

providing a pharmaceutical composition comprising a pharmaceutically acceptable carrier and packaged,

recombinant phagemids that are packaged in phage capsids, wherein the packaged phagemids comprise a clustered regularly interspaced short palindromic repeats (CRISPR) system,

wherein the CRISPR system comprises DNA encoding: i) a type II CRISPR-associated enzyme; and ii) a targeting RNA that targets at least one bacterial chromosome at a target site; and contacting the bacterial population with the pharmaceutical composition,

wherein the contacting with the pharmaceutical composition introduces at least some of the phagemids into at least some of the bacteria in the bacterial population,

wherein subsequent to the introduction of the phagemids, the bacteria into which the phagemid is introduced expresses the targeting RNA and the type II CRISPR-associated enzyme,

wherein the expressed type II CRISPR-associated enzyme cleaves the bacterial chromosome at the target site of the targeting RNA, and

wherein the cleavage of the bacterial chromosome at the target site kills the bacteria.

The claims of the parties are:

SNIPR 10,463,049: 1–27

SNIPR 10,506,812: 1–23

SNIPR 10,524,477: 1–25

SNIPR 10,561,148: 1–16

SNIPR 10,582,712: 1–51

Rockefeller: 20–33

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

SNIPR 10,463,049: 1–27

SNIPR 10,506,812: 1–23

SNIPR 10,524,477: 1–25

SNIPR 10,561,148: 1–16

SNIPR 10,582,712: 1–51

Rockefeller: 20–33

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

SNIPR 10,463,049: None

SNIPR 10,506,812: None

SNIPR 10,524,477: None

SNIPR 10,561,148: None

SNIPR 10,582,712: None

Rockefeller: None

The parties are accorded the following benefit for Count 1:

SNIPR: 15/160,405, filed 20 March 2016, issued as patent

9,701,964, 11 July 2017;

PCT/EP2016/059803, filed 3 May 2016.

Rockefeller: 14/766,675, filed 7 August 2015, issued as patent

10,660,943 on 26 May 2020;

PCT/US2014/015252, filed 7 February 2014.

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

SNIPR TECHNOLOGIES LIMITED

(Inventors: Jasper Clube, Morten Sommer, Christian Grøndahl, Eric Van Der Helm, Ruben Vazquez-Uribe)

Junior Party (Patents 10,463,049; 10,506,812; 10,561,148; 10,524,477; 10,582,712),

V.

The Rockefeller University

(Inventors: David Bikard and Luciano Marraffini)

Senior Party (Patent Application 15/159,929).

Patent Interference No. 106,123 (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 U.S. Mail):

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Attorney for Senior Party Rockefeller

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UNITED STATES PATENT AND TRADEMARK OFFICE

Filed: July 21, 2020

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SNIPR TECHNOLOGIES LIMITED

(Inventors: Jasper Clube, Morten Sommer, Christian Grøndahl, Eric Van Der Helm, Ruben Vazquez-Uribe)

Junior Party

(Patents 10,463,049; 10,506,812; 10,561,148; 10,524,477; 10,582,712),

v.

The Rockefeller University

(Inventors: David Bikard and Luciano Marraffini) Senior Party (Patent Application 15/159,929).

Patent Interference No. 106,123 (DK)

REDECLARATION – 37 C.F.R. § 41.203(c)

Before DEBORAH KATZ, Adminstrative Patent Judge.

This interference is redeclared to correct an oversight in the original Declaration (Paper 1). It has become apparent that the interference should have been declared with benefit accorded for the filing date of Senior Party's provisional application, 61/761,971, on 7 February 2013. The changes to the declaration are indicated below.

In light of this change, it is ORDERED that the initial conference call scheduled for 22 July 2020 is canceled and rescheduled for 19 August 2020. The parties are provided with an opportunity to file revised motions lists based on the change in the accorded benefit of priority (*e.g.*, motions regarding benefit or termination of the interference based on benefit).

No other changes to the Declaration are made.

Part D. Initial conference call

A telephone conference call to discuss the interference is set for **19 August 2020** at **2:00 p.m.** (the Board will provide information for the call).

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

Part F. Count and claims of the parties

Count 1

Claim 1 of Patent 10,582,712 or Claim 24 of Application 15/159,929

Claim 1 of Patent 10,582,712 recites:

A method of modifying a mixed population of bacteria,

wherein the mixed population comprises a first bacterial subpopulation and a second bacterial sub-population,

wherein the first bacterial sub-population comprises a first bacterial species and the second bacterial sub-population comprises host cells of a second bacterial species,

wherein the second bacterial species is a different species than the first bacterial species,

the method comprising

a. contacting the mixed population of an engineered nucleic acid sequence for producing a host modifying crRNA (HM-crRNA), and

b. producing the HM-crRNA in the host cells,

wherein the HM-crRNA is operable with a Cas nuclease in the host cells, wherein the engineered nucleic acid sequence and the Cas nuclease are comprised by an HM-CRISPR/Cas system, and

wherein the HM-crRNA comprises a nucleic acid sequence that is capable of hybridizing to a target sequence in the host cells to guide the Cas nuclease to modify the target sequence in the host cells;

whereby the host cells are killed or growth of the host cells is reduced, thereby reducing the proportion of the host cells and altering the relative ratio of the first and second bacterial sub-populations in the mixed population of bacteria; and

wherein the mixed population of bacteria comprises *E. coli*.

Claim 24 of Application 15/159,292 recites:

The method of claim 20, wherein the mixed bacterial population comprises one or a combination of bacterial species selected from the group consisting of *Staphylococcus*, *Clostridium*, *Bacillus*, *Salmonella*, *Helicobacter pylori*, *Neisseria gonorrhoeae*, *Neisseria meningitidis*, and *Escherichia coli*.

Claim 20 of Application 15/159,929 recites:

A method for killing targeted bacteria in a mixed bacterial population comprising:

providing a pharmaceutical composition comprising a pharmaceutically acceptable carrier and packaged,

recombinant phagemids that are packaged in phage capsids, wherein the packaged phagemids comprise a clustered regularly interspaced short palindromic repeats (CRISPR) system,

wherein the CRISPR system comprises DNA encoding: i) a type II CRISPR-associated enzyme; and ii) a targeting RNA that targets at least one bacterial chromosome at a target site; and contacting the bacterial population with the pharmaceutical composition,

wherein the contacting with the pharmaceutical composition introduces at least some of the phagemids into at least some of the bacteria in the bacterial population,

wherein subsequent to the introduction of the phagemids, the bacteria into which the phagemid is introduced expresses the targeting RNA and the type II CRISPR-associated enzyme,

wherein the expressed type II CRISPR-associated enzyme cleaves the bacterial chromosome at the target site of the targeting RNA, and

wherein the cleavage of the bacterial chromosome at the target site kills the bacteria.

The claims of the parties are:

SNIPR 10,463,049: 1–27

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Rockefeller: 20–33

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SNIPR 10,582,712: 1–51

Rockefeller: 20–33

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

SNIPR 10,463,049: None

SNIPR 10,506,812: None

SNIPR 10,524,477: None

SNIPR 10,561,148: None

SNIPR 10,582,712: None

Rockefeller: None

The parties are accorded the following benefit for Count 1:

SNIPR: 15/160,405, filed 20 March 2016, issued as patent

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Rockefeller: 14/766,675, filed 7 August 2015, issued as patent

10,660,943 on 26 May 2020;

PCT/US2014/015252, filed 7 February 2014; and

61/761,971, filed **7 February 2013**.

cc (via e-mail):

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