

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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**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;  
8,889,418; 8,895,308; 8,906,616; 8,932,814; 8,945,839; 8,993,233; 8,999,641;  
9,840,713, and Applications 14/704,551 and 15/330,876

**Junior Party,**

v.

**TOOLGEN, INC.**  
Application 14/685,510

**Senior Party**  
Patent Interference No. 106,126 (DK)

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**ORDER – Authorizing Motions and Setting Times**  
**37 C.F.R. §§ 104(c) and 121**

Before SALLY GARDNER LANE, JAMES T. MOORE, and  
DEBORAH KATZ, *Administrative Patent Judges*.

KATZ, *Administrative Patent Judge*.

- 1 A conference call was held on 4 February 2021 at approximately 1:00 p.m.
- 2 to discuss the parties' proposed motions in the initial phase of this interference.

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1 Raymond Nimrod, Steven Trybus, and Danny Huntington were present for Junior  
2 Party The Broad Institute, Inc., Massachusetts Institute of Technology, and  
3 President and Fellows of Harvard College (“Broad”). Anthony Insogna, Timothy  
4 Heverin, Roger Rich, and Jennifer Hartjes were present for Senior Party ToolGen,  
5 Inc. (“ToolGen”). Judges Lane, Moore, and Katz were present for the Board. A  
6 court reporter transcribed the call. (*See* Transcript, Paper 19.)

7 The parties previously filed notices of the bases for requesting relief during  
8 the interference. *See* 37 C.F.R. § 204(b); Declaration, Paper 1, 2. Specifically,  
9 Broad filed Paper 17 (“CVC List”) and ToolGen Paper 18 (“ToolGen List”). All  
10 motions must be authorized before filing. *See* 37 C.F.R. § 41.121(a). Pre-  
11 authorization is consistent with the Board’s discretion to reach patentability issues:  
12 “The [Patent Trial and Appeal Board] shall determine priority and may determine  
13 questions of patentability.” 35 U.S.C. § 135(a) (2009). In this phase of the  
14 interference, we authorize substantive motions that may change the original status  
15 quo of the interference, in order to set up a priority contest in the second phase, if  
16 one is necessary.

17 *Broad Proposed Motions*

18 Broad requests authorization for a motion to substitute proposed Count 2 for  
19 Count 1, which Broad asserts is broad enough to encompass the “dual-molecule  
20 RNA” CRISPR-Cas9 system. (*See* Broad List, Paper 17, 1:8–4:12.) Proposed  
21 Count 2 recites:

22 A CRISPR-Cas9 system, for use in a eukaryotic cell, comprising:  
23 a) a Cas9 or a nucleic acid encoding the Cas9 and  
24 b) an RNA or a nucleic acid encoding the RNA, wherein the RNA is a  
25 dual RNA comprising a CRISPR RNA (crRNA) and a trans activating

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1 crRNA (tracrRNA) or wherein the RNA is a chimeric RNA comprising a  
2 crRNA fused to a tracrRNA,  
3 wherein the crRNA directs the Cas9 to a target sequence in a  
4 eukaryotic cell, whereb a site-specific, double-strand break is introduced, or  
5 the target sequence is edited.  
6

7 (*Id.* 3:10–17.) According to Broad, proposed Count 2 is broad enough to cover its  
8 best proofs. (*See id.* 3:1–3.) In the alternative, Broad requests that Count 1 be  
9 substituted with a count that recites both claim 85 of the currently involved  
10 ToolGen application (14/685,510) and “a claim from one of the two Broad  
11 applications that Broad seeks to add to the interference,” that is, claim 1 of Broad  
12 application 15/160,710 or claim 74 of Broad application 15/430,260. (*Id.* 4:1–12.)  
13 Authorization for this motion is GRANTED. Broad may present arguments to  
14 substitute Count 1 with one proposed Count 2. The motion shall be entitled  
15 “BROAD MOTION 1.”

16 Broad next requests authorization to file a motion, contingent on the grant of  
17 Broad proposed motion to substitute the count, to add claims of Broad applications  
18 as corresponding to the count. (*See* Broad List, Paper 17, 4:13–5:26.)  
19 Specifically, Broad requests to argue that claims 1, 40, and 41 of application  
20 15/160,710 and claims 74, 94, and 95 of application 15/430,260 be added to the  
21 interference. Broad asserts that these claims encompass both dual and single RNA  
22 embodiments of CRISPR-Cas9 systems in eukaryotic cells. (*See id.*) Broad  
23 asserts further that these claims will be determined to be allowable shortly. (*See*  
24 *id.* 5:21–26.) Authorization for this motion is GRANTED, to the extent that the  
25 claims argued to be designated as corresponding to the count are determined by the

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1 Examiner to be allowable by the time the motion is filed. The motion shall be  
2 entitled “BROAD MOTION 2.” If none of the recited claims has been determined  
3 to be allowable, authorization to file the motion is denied.

4 Broad requests authorization to file a motion arguing that many of its claims  
5 should be designated as not corresponding to Count 1 or proposed Count 2. (*See*  
6 Broad List, Paper 17, 5:27–9:21.) In general, Broad asserts that the listed claims  
7 are drawn to patentably distinct subject matter because they are limited to vectors  
8 for RNA expression, *S. aureus* Cas9 protein, chimeric Cas9 protein, two or more  
9 nuclear localization signals, mutated Cas9 proteins, or Cas9 protein fusions. (*See*  
10 *id.* 5:27–9:21.) Authorization for this motion is GRANTED. The motion shall be  
11 entitled “BROAD MOTION 3.”

12 Broad also requests authorization to file a motion to argue that ToolGen  
13 claims are unpatentable under 35 U.S.C. § 112 for lack of written description. (*See*  
14 Broad List, Paper 17, 10:10–21.) Broad asserts that ToolGen’s provisional  
15 application 61/717,324 does not provide an adequate written description of the  
16 claimed subject matter and does not establish a constructive reduction to practice  
17 of Count 1. (*See id.*) On the conference call, Broad confirmed that it is not  
18 seeking authorization to file a motion attacking the benefit accorded to ToolGen.  
19 (Transcript, Paper 19, 12:19–21.) Broad did not allege that this motion will  
20 present a threshold issue depriving ToolGen of standing. Specifically, Broad did  
21 not allege that ToolGen’s application claims were first made after the publication  
22 of Broad’s applications or the issuance of any of Broad’s involved patents. *See* 37  
23 C.F.R. § 41.201 (“*Threshold issue* means an issue that, if resolved in favor of the  
24 movant, would deprive the opponent of standing in the interference. Threshold

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1 issues may include . . . (2) In the case of an involved application claim first made  
2 after the publication of the movant's application or issuance of the movant's patent:  
3 . . . (ii) Unpatentability for lack of written description under 35 U.S.C. 112 of an  
4 involved application claim where the applicant suggested, or could have suggested,  
5 an interference under §41.202(a).”). Because the motion will not otherwise further  
6 the inquiry into priority of invention of the count, authorization for the motion is  
7 DENIED. *See* 35 U.S.C. § 135(a).

8         Broad requests authorization to file a motion arguing that ToolGen’s claims  
9 are unpatentable over the recited prior art under either 35 U.S.C. § 102 or  
10 35 U.S.C. § 103. (*See* Broad List, Paper 17, 11:1–20.) Broad lists a manuscript  
11 submitted by Cong et al., and published as *Science*, 339, 819–23 (2013), including  
12 supplemental papers, a manuscript submitted by Mali et al. and published as  
13 *Science*, 339:823–26 (2013), including supplemental papers, and patent  
14 application publication 2014/0342457 as prior art. (*See id.*) Consideration of  
15 authorization for this motion is DEFFERED until a priority phase, if one is  
16 necessary. The issues raised by this motion are not necessarily dispositive of the  
17 priority contest with ToolGen. The determination of patentability issues that do  
18 not impact the determination of priority during an interference is discretionary.  
19 *See* 35 U.S.C. § 135(a). We note that patentability over the prior art is not now,  
20 and never has been, a “threshold issue” and a holding during the course of  
21 interference that a party’s claims are unpatentable over prior art does not  
22 necessarily deprive that party of standing on the central issue of an interference—  
23 priority. *Cf.* 37C.F.R. § 41.201 (defining “threshold issue”). Furthermore, an

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1 interference is not a substitute for other patentability proceedings in the Office or  
2 elsewhere.

3 Broad requests authorization to file a motion arguing that ToolGen keep the  
4 PTAB and Broad timely apprised of the issuance of any notice of allowance for  
5 any claim in ToolGen applications 17/004,338, 17/004,355 or in applications  
6 claiming a common priority. (*See* Broad List, Paper 17, 12:1–8.) Both parties are  
7 ORDERED to provide notice of the allowance of claims related to the involved  
8 patents and applications in this interference both in the record of the interference  
9 and to the Examiner of its applications. *See* 37 C.F.R. § 1.56. Accordingly,  
10 Broad’s request for a motion is DISMISSED as moot.

11 Finally, Broad requests a motion to argue for judgment based on priority.

12 Consideration of whether to authorize this motion is DEFERRED until a  
13 priority phase of the interference, if one is necessary.

14 *ToolGen Proposed Motions*

15 ToolGen requests an expedited miscellaneous motion to argue that this  
16 interference should be stayed, pending a final judgment in Interference 106,115,  
17 which involves a priority contest on similar subject matter between Broad and The  
18 Regents of the University of California, University of Vienna, and Emmanuelle  
19 Charpentier. (*See* ToolGen List, Paper 18, 1:5–2:17.) On the conference call,  
20 Broad indicated it did not believe there is any reason to stay the proceeding.  
21 (Transcript, Paper 19, 18:11–19:6.) Authorization for this motion is DENIED.  
22 The motions authorized in this Order are directed to changing the status quo of the  
23 interference as declared in preparation for a priority phase, if one is necessary.  
24 Thus, deciding these issues will prepare the proceeding for judgment on priority.

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1 Motions on other issues have been denied or consideration on authorization has  
2 been deferred. Thus, even if some motions include issues that overlap those in  
3 dispute in Interference 106,115, deciding the issues unique to this proceeding will  
4 prepare the proceeding for a priority phase if one is necessary and will further our  
5 goal of pendency within two-years. *See* 37 C.F.R. § 41.200(c).

6 ToolGen also requests authorization for a motion to argue that it should be  
7 accorded the benefit of the filing date of its provisional application 61/837,481,  
8 which was filed 20 June 2013, and of its international application  
9 PCT/KR2013/009488, which was filed 2 October 2013. (*See* ToolGen List,  
10 Paper 18, 2:19–23.) On the conference call, ToolGen indicated that this motion  
11 would be contingent upon the grant of a motion by Broad to attack the benefit of  
12 the filing date of ToolGen’s earlier provisional application 61/717,324 accorded to  
13 ToolGen upon declaration. (Transcript, Paper 19, 19:22–20:9.) Authorization for  
14 this motion is GRANTED. The motion shall be entitled “TOOLGEN MOTION  
15 1.”

16 ToolGen requests authorization for a motion to argue that Broad should be  
17 denied the benefit of the filing date of provisional application 61/736,527. (*See*  
18 ToolGen List, Paper 18, 3:1–4.) Authorization for this motion is GRANTED. The  
19 motion shall be entitled “TOOLGEN MOTION 2.”

20 ToolGen requests a motion to argue that Broad’s claims are unpatentable  
21 under 35 U.S.C. § 112, for lack of written description and an enabling disclosure.  
22 (*See* ToolGen List, Paper 18, 3:6–12.) Because Broad is involved in the  
23 interference based on patented claims, and ToolGen did not assert that it would  
24 raise a threshold issue, authorization for this motion is DENIED as it will not

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1 further the inquiry into priority of invention of a count. *See* 37 C.F.R. § 41.201;  
2 *see* 35 U.S.C. § 135(a).

3 ToolGen also requests authorization for a motion to argue that Broad's  
4 claims are unpatentable due to improper inventorship under 35 U.S.C. § 102(f).  
5 (*See* ToolGen List, Paper 18, 3:14–4:13.) Consideration of whether to authorize  
6 this motion is DEFERRED until a priority phase, if one is necessary, because the  
7 facts of inventorship may overlap with the facts of priority. Thus, the most just,  
8 speedy, and inexpensive resolution of the interference is to address these issues at  
9 once, if at all.

10 ToolGen requests authorization for a motion to argue that it be allowed to  
11 obtain additional discovery, specifically the testimony of Dr. Luciano Marraffini.  
12 (*See* ToolGen List, Paper 18, 4:15–5:13.) Specifically, ToolGen requests that it  
13 receive copies of documents that Dr. Marraffini produces related to his testimony  
14 in Interference 106,115 and to participate in, including by examination or cross-  
15 examination, the deposition of Dr. Marraffini in that interference. ToolGen further  
16 requests authorization to serve its own document and/or deposition subpoenas on  
17 Dr. Marraffini in the present interference. (*See id.* 5:8–13.) Authorization for this  
18 motion is DENIED at this time as being premature. A priority phase of this  
19 interference has not yet been authorized. Therefore, ToolGen has not provided a  
20 basis on which it should be allowed to seek a subpoena of Dr. Marraffini's  
21 testimony or to participate in his deposition in the other proceeding. Furthermore,  
22 the deposition transcript and relevant documents will be in the public record of the  
23 proceeding before this interference progresses to a priority phase. If, at that time,

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1 ToolGen has a basis to seek a subpoena for the further testimony of Dr.  
2 Marrraffini, it may seek relief.

3 ToolGen requests authorization for a motion to argue that Broad's involved  
4 claims are unpatentable over the prior art under 35 U.S.C. § 102 and/or § 103.  
5 (*See* ToolGen List, Paper 18, 5:15–6:1.) ToolGen cites patent application  
6 publications 2016/0298138 and 2015/0322457 as the prior art basis for this motion.  
7 (*See id.*) Consideration of authorization for this motion is DEFFERED until a  
8 priority phase, if one is necessary. The issues raised by this motion are not  
9 necessarily dispositive of the priority contest with ToolGen. Furthermore, these  
10 challenges might be raised in another type of proceeding in the Office or  
11 elsewhere.

12 ToolGen seeks a motion to argue that Broad's claims are unpatentable  
13 because of inequitable conduct. (*See* ToolGen List, Paper 18, 6:3–21.) ToolGen  
14 notes that this motion is based a motion requested by Junior Party in Interference  
15 106,115. (*See id.* 6:6.) Authorizing the requested motion at this time would be  
16 premature and, thus, is DENIED. The issues that ToolGen represents it will argue  
17 may overlap with issues that are raised and decided during a priority phase of the  
18 interference.

19 ToolGen requests authorization for a miscellaneous motion to argue that  
20 there be a protective order to allow ToolGen to file its priority statement under seal  
21 until an order scheduling a priority phase of this interference is scheduled. (*See*  
22 ToolGen List, Paper 18, 7:1–10.) ToolGen asserts that third-party competitors,  
23 specifically Sigma-Aldrich, are pursuing claims with subject matter that may  
24 interfere with ToolGen's claims in this interference. (*See id.*) On the conference

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1 call, Broad indicated it opposes entry of a protective order in the public interest of  
2 being able to review the record. (Transcript, Paper 19, 28:25–29:23.) Because  
3 ToolGen is concerned about potentially interfering subject matter by a competitor  
4 and in light of our rule allowing priority statements to be maintained in confidence  
5 for a limited time, ToolGen’s arguments to seal its priority statement has merit.  
6 *See* 37 C.F. R. § 41.120(a) (“The Board may require a party to provide a notice  
7 stating the relief it requests and the basis for its entitlement to relief. The Board  
8 may provide for the notice to be maintained in confidence for a limited time.”).  
9 Accordingly, it is ORDERED that ToolGen may submit a proposed protective  
10 order to keep ToolGen’s priority statement under seal until a priority phase of this  
11 interference is scheduled. The protective order in Interference 106,115 may be  
12 used as a reference. (*See* Interference 106,115, Paper 452.) ToolGen’s request to  
13 file a motion is DISMISSED as moot.

14 ToolGen requests authorization to file a miscellaneous motion for the Board  
15 to order that this interference and related Interference 106,126 proceed on the same  
16 schedule. (*See* ToolGen List, Paper 18, 7:12–15.) In order to allow the parties to  
17 stipulate to changes in the schedule, as provided below, no other general order  
18 regarding the schedule will be issued. Nevertheless, ToolGen is free to agree or  
19 disagree with proposed changes in the schedule and the Board expects all parties to  
20 cooperate on scheduling issues. Accordingly, ToolGen’s request is DENIED.

21 ToolGen requests authorization to file a motion for judgment based on  
22 priority. (*See* ToolGen List, Paper 18, 7:17–19.) Consideration of whether to  
23 authorize this motion is DEFERRED until a priority phase, if one is necessary.

*Other Matters*

1  
2 The requirement for statements of material facts is *not* waived in this  
3 interference. *See* 37 C.F.R. § 41.121(d). Such statements are included in the page  
4 limits set for each brief. *See, e.g.*, SO ¶ 121.2. Where required or otherwise helpful  
5 to presenting a party’s case, claim charts may be included in the briefs. Claim  
6 charts do not count towards the page limits. The parties are encouraged to find  
7 ways to consolidate arguments when briefing the authorized motions. Detailed  
8 arguments about representative claims, with a note that the argument applies to the  
9 other claims, can replace repeated arguments. Such strategies should be fully  
10 considered before asking for an extension of the limits on pages in briefs. *See* SO  
11 ¶¶ 121.2, 122.2.

12 It is ORDERED that the requirement for consecutive exhibits numbers in  
13 paragraph (Standing Order ¶ 154.2.1) is waived.

14 It is further ORDERED that exhibits may be filed through the interference  
15 portal within two business days of the due date of the paper in which they are cited,  
16 although it is preferred that exhibits be filed when the paper citing them is filed.

*Schedule*

18 The schedule is set by the Board, with the following provisions.

19 A. Time Periods Associated with Motions

20 The TIME PERIODS described below are set out in an Appendix to this  
21 ORDER. Action specified for each TIME PERIOD must be completed by the date  
22 specified for the TIME PERIOD. The parties are authorized to stipulate different  
23 times (earlier or later, but not later than TIME PERIOD 7) for TIME PERIODS 1  
24 through 6. A notice of the stipulation must be promptly filed. The notice must be

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1 in the form of a copy of the Appendix attached to this ORDER with old dates  
2 crossed out and new dates inserted by hand. The parties may not stipulate an  
3 extension of TIME PERIOD 7 or the default date for oral argument. In stipulating  
4 different times, the parties should consider the effect of the stipulation on times:  
5 (1) to object to evidence (5 business days, 37 C.F.R. § 41.155(b)(1)), (2) to  
6 supplement evidence (10 business days, 37 C.F.R. § 41.155(b)(2)), (3) to begin  
7 cross examination (no earlier than 21 days after service, SO ¶ 157.3.1) and (4) to  
8 conclude cross examination (at least 10 days before the opposition or reply is due,  
9 SO ¶ 157.3.2).

10 The parties should note that exhibits are no longer filed at the end of the  
11 schedule, but should be filed when served on the other party. An exhibit, including  
12 an affidavit, cited in connection with a motion, opposition, reply, or affidavit, must  
13 be served and filed with the motion, opposition, reply or affidavit in which the  
14 exhibit is first mentioned. Exhibits should not be filed more than once. Parties  
15 Interference should also note that a single pdf file size greater than 25 MB will  
16 need to be divided into smaller pdf files.

17 Transcripts of cross examinations and depositions taken under 35 U.S.C.  
18 § 24 must be served and filed when the other exhibits in connection with a motion,  
19 opposition, or reply are filed.

20 TIME PERIOD 1

21 File all authorized motions.

22 If no party files a motion, the SENIOR PARTY must arrange a conference  
23 call with the parties and the Board so that appropriate adjustments to the schedule  
24 may be made.

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1 TIME PERIOD 2

2 File any responsive motions (37 C.F.R. § 41.121(a)(2)) in response to an  
3 opponent's motion filed during TIME PERIOD 1.

4 TIME PERIOD 3

5 File oppositions to all motions, including responsive motions.

6 TIME PERIOD 4

7 File replies to all oppositions.

8 TIME PERIOD 5

9 a. File any request for oral argument on motions,

10 b. File motions to exclude evidence (37 C.F.R. § 41.155(c); SO ¶ 155.2), and

11 c. File observations on cross examination (SO ¶ 157.7) of reply testimony.

12 TIME PERIOD 6

13 a. File oppositions to an opponent's motion to exclude evidence and

14 b. File any response to observations. Interference 106,120

15 TIME PERIOD 7

16 File replies to oppositions to motions to exclude evidence.

17 **B. Priority Statements**

18 1. At TIME PERIOD 1, file but do not serve a priority statement (37 C.F.R.  
19 § 41.120; 37 C.F.R. § 41.204(a)).

20 2. When filing the priority statement, the filer may use the “Confidential”  
21 setting for the Public Access status.

22 3. A junior party who does not file a priority statement shall not have access  
23 to the priority statement of any other party.

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1           4. **One (1) business day** after TIME PERIOD 1, serve a copy of the priority  
2 statement upon each opponent (except for a junior party barred under B.3 above).

3           **C. Filing Exhibits**

4           A document larger than 25 MB cannot be filed online. If a party needs to  
5 file a document larger than 25 MB, unless otherwise instructed by order, please  
6 contact the board at the telephone number above to make other arrangements, such  
7 as sending a CD-ROM by Express Mail.

8           **D. Default Oral Argument Date**

9           If a request for oral argument (37 C.F.R. § 41.124(a); TIME PERIOD 5) is  
10 granted, the default date for such argument is the date provided in the appendix  
11 below. No oral argument will occur if either no argument is requested or granted.

cc (via e-mail):

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APPENDIX--ORDER - RULE 123(a)  
(Times for substantive motions; priority deferred)  
Interference 106,126

TIME PERIOD 1 .....	9 April 2021
File motions	
File (but serve one business day later) priority statements	
TIME PERIOD 2 .....	14 May 2021
File responsive motions to motions filed in TIME PERIOD 1	
TIME PERIOD 3 .....	25 June 2021
File oppositions to all motions	
TIME PERIOD 4 .....	6 August 2021
File all replies	
TIME PERIOD 5 .....	17 September 2021
File request for oral argument	
File motions to exclude	
File observations	
TIME PERIOD 6 .....	8 October 2021
File oppositions to motions to exclude	
File response to observations	
TIME PERIOD 7 .....	15 October 2021
File replies to oppositions to motions to exclude	
DEFAULT ORAL ARGUMENT DATE .....	TBD