

Filed on behalf of: **Junior Party, Broad**

Paper No. _____

By: Raymond N. Nimrod
Quinn Emanuel Urquhart & Sullivan,
51 Madison Avenue
New York, NY 10010
Telephone: 212-849-7000
raynimrod@quinnemanuel.com

By: Steven R. Trybus
Locke Lord LLP
111 South Wacker Drive
Chicago, IL 60606
Telephone: 312-443-0699
Steven.Trybus@lockelord.com

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;
8,889,418; 8,895,308; 8,906,616; 8,932,814; 8,945,839; 8,993,233; 8,999,641; and
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)
(Technology Center 1600)

BROAD REPLY 2

TABLE OF CONTENTS

I. Precise Relief Requested.....1

II. Description of Appendices.....1

III. Argument1

 A. Broad Has Met Its Burden to Show the Relief It Seeks Is Justified1

 B. Broad Addressed the Requirements of SO ¶ 203.2(4).....3

 C. Broad’s Motion 2 Was Authorized.....3

IV. Conclusion5

Appendix A (Statement of Material Facts)..... A-1

TABLE OF AUTHORITIES

Page(s)

Cases

Louis v. Okada,
59 U.S.P.Q.2d 1073, 2001 WL 775529 (B.P.A.I. 2009) 1-2

1 **I. PRECISE RELIEF REQUESTED**

2 Broad has moved, contingent upon the grant of Broad Motion 1, to add Broad Application
3 Nos. 15/160,710 (“710 Application”) (allowable claims 1, 40, and 41) and 15/430,260 (“260
4 Application”) (allowable claims 74, 94, and 95) to the Interference and to designate the allowable
5 claims as corresponding to Proposed Count 2. Allowable claim 1 of the 710 Application and
6 allowable claim 74 of the 260 Application are generic as to the RNA configuration and, thus,
7 should be added to the Interference if the PTAB adopts Proposed Count 2, along with their
8 dependent claims that specify either dual-molecule RNA or single-molecule RNA.

9 **II. DESCRIPTION OF APPENDICES**

10 Appendix A is the Statement of Material Facts and Broad’s Response to ToolGen’s
11 Statement of Material Facts.

12 **III. ARGUMENT**

13 **A. Broad Has Met Its Burden to Show the Relief It Seeks Is Justified**

14 At 1:19-4:5, ToolGen makes a series of arguments claiming Broad did not address the
15 requirements under SO ¶ 203.2 to add an application to an interference. Opp. 2. The response is
16 that ToolGen is misinterpreting Broad’s motion and the rules.

17 At 2:15-4:2, ToolGen argues that Broad must offer “a compelling reason” or explain “*why*
18 the claims should be added” to the Interference beyond the fact that they correspond to Proposed
19 Count 2 (a fact not disputed by ToolGen). Opp. 2. ToolGen is incorrect. SO ¶ 203.2 sets out four
20 requirements, none of which require showing a “compelling reason” for claims being added to an
21 Interference. That is because the fact that claims correspond to the Count—a required showing
22 under SO ¶ 203.2(3)—is enough to answer “why,” along with a showing that other remedies are
23 not sufficient under SO ¶ 203.2(4). ToolGen’s attempt to add an additional requirement beyond
24 those set out in the Standing Order finds no support in either SO ¶ 203.2, nor in *Louis v. Okada*,

1 59 U.S.P.Q.2d 1073, 2001 WL 775529 at *4 (B.P.A.I. 2009) (precedential), which ToolGen cites
2 but which does not address standards for a motion to add an application.

3 Regardless, Broad has also offered compelling reasons why both Motion 1 and Motion 2
4 should be granted—to correct the currently unjust structure of this Interference and properly
5 determine priority of the generic eukaryotic invention with claims designated to an appropriate
6 count that unequivocally reflect the scope of what was invented and at stake. As Broad explained
7 at the hearing on the motions: “[Motion 2] is part of moving those [claims] in as part of changing
8 the count to be able to make clear that we have broader claims than the single-guide claims that
9 are out there and that is the appropriate subject matter for the interference.” Paper 19, 10:2-19.

10 At 1:19-2:12, without substantively disputing Broad’s argument that the structure of the
11 Interference is unfair, ToolGen dismisses this argument as “irrelevant.” Opp. 2. Specifically,
12 ToolGen notes that if Broad’s Motion 1 is granted, the unfairness of the current structure of the
13 Interference “would no longer exist for Broad to complain about.” *Id.* at 2:2-3. That does not render
14 Broad’s arguments in Motion 2 “irrelevant,” however—rather, it validates Broad’s point that
15 unless Motions 1 and 2 are granted, the current structure of this Interference is unjust and contrary
16 to the goal of Interference practice to determine priority to the subject matter of what the parties
17 have claimed to invent.

18 This argument is thus not irrelevant to “why the new *claims* (as opposed to the new *count*)
19 are required” as ToolGen contends. The allowance of the claims Broad is seeking to add
20 demonstrates that Broad’s specifications describe and enable CRISPR-Cas9 systems with **both**
21 single- or dual-molecule RNA configurations. If Proposed Count 2 is adopted, then Broad believes
22 claims to this subject matter should be designated as corresponding to Count 2—regardless of the
23 construction of “guide RNA,” as these claims do not raise that issue. Broad’s attempt to address

1 the unfairness of Count 1 and Broad’s attempt to add claims consistent with the scope of what it
2 invented are inextricably intertwined.

3 **B. Broad Addressed the Requirements of SO ¶ 203.2(4)**

4 From 4:4-5:5, ToolGen argues that Broad did not “consider any alternatives to adding the
5 requested claims, or whether such alternatives are inadequate.” Opp. 2. As an initial matter, at
6 3:16-8:21 of its opening motion, Broad addressed why, in accord with the rules for claim
7 correspondence and basic fairness, the requested claims must be designated to Proposed Count 2
8 and no other alternatives would resolve the current issues.

9 ToolGen claims alternative remedies exist that Broad should have addressed, yet only
10 identifies one, claiming “Broad could have requested authorization to add the identical claims to
11 one of its involved pending applications and designate them as corresponding to Count 2.” Opp. 2
12 at 4:9-11. ToolGen cites SO ¶ 208.5.1 as authority for this alleged remedy, but SO ¶ 208.5.1 relates
13 to adding a claim via a responsive motion. SO ¶ 208.5.1 is irrelevant in this situation, which does
14 not involve a responsive motion. Broad is not aware of, and ToolGen does not identify, any
15 alternative remedies it should have addressed with an actual legal basis.

16 Similarly, at 4:19-5-5, ToolGen argues that Broad did not explain any attempts to request
17 the declaration of another interference. Opp. 2. That is because Broad did not make any such
18 attempts, and thus, there is nothing to explain.

19 **C. Broad’s Motion 2 Was Authorized**

20 At 5:21-6:21, ToolGen makes a strained argument that the PTAB should not add Broad’s
21 dual-molecule RNA claims because Broad allegedly mischaracterized the claims it seeks to add as
22 solely generic. ToolGen argues that “the Board’s authorization is also limited to the Broad’s initial
23 characterization of the claims as generic.” Opp. 2. Thus, ToolGen argues that claims 40, 21, 94,
24 and 95 cannot be added.

1 The response is that, first, the subject matter of the claims that Broad sought authorization
2 to add is clear on their face. Two of the claims (the independent claims) are generic as to the RNA,
3 while the other four encompass subject matter wherein the RNA components are either separate
4 molecules (dual-molecule RNA) or part of a single-molecule RNA (“sgRNA”).

5 ToolGen selectively quotes from Broad’s Motion List in a misleading way to claim that
6 Broad made an explicit characterization of all six claims as “generic.” In the Motions List, Broad
7 was relaying the substance of a communication from the Examiner regarding the allowability of
8 certain claims, not making a characterization of each of the six claims at issue—yet ToolGen leaves
9 out this critical context. The full quote on which ToolGen relies begins with “[b]ased upon
10 communications with the Examiner during a January 26, 2021 interview....” But ToolGen does
11 not even include ellipses indicating it has left this portion out of its quote. Put in context, it is clear
12 that Broad was not trying to mislead the PTAB by characterizing each of its claims as generic, but
13 rather conveying that the Examiner had communicated (and Broad understood) that two claim sets
14 with claims broader than single-molecule RNA had been deemed allowable and would soon issue,
15 thus making them available for designation to Proposed Count 2.

16 Moreover, there has been no confusion that Broad is seeking to add claims covering
17 broader, dual-molecule RNA subject matter as part of its position that the broader eukaryotic
18 invention is the proper subject matter of this Interference. At the hearing on motions, Broad
19 explained:

20 ...there are claims that Broad has that do not use the terminology ‘guide RNA,’ and
21 also gets into our second motion, which we have been informed that we have other
22 allowable claims that we—that we could potentially move to be brought in as part
23 of the count being broaden[ed] to encompass those best proofs, because the subject
24 matter on our side includes *both the dual molecule* and the single molecule....

25 Paper 19, 8:24-9:10; MF14. Broad further explained that Motion 2 “is part of moving those in as
26 part of changing the count to be able to make clear that we have broader claims than the single-

1 guide claims that are out there and that is the appropriate subject matter for the interference.” *Id.*
2 at 10:13-19. Broad was not trying to hide that it was adding broader, dual-molecule RNA subject
3 matter via these claims, as ToolGen so implies.

4 And the PTAB’s authorization indicates it understood Broad’s point, stating not just that
5 Broad was seeking to add “generic” claims, but rather that Broad “asserts that these claims
6 encompass both dual and single RNA embodiments of CRISPR-Cas9 systems in eukaryotic cells.”
7 Paper 20, 3:21-22. The PTAB was not confused about the subject matter of the claims or the point
8 of Broad’s motion.

9 Finally, at 5:8-16, ToolGen suggests that Broad requested relief to add claims to Count 1
10 (rather than Proposed Count 2) in observing that claim 41 of the 710 Application and claim 95 of
11 the 260 Application are both limited to sgRNA configurations and thus also correspond to Count
12 1. Opp. 2. Broad did not request this relief, but Broad is unaware of any authority preventing the
13 PTAB at this stage of the Interference from adding allowable claims from applications not
14 currently involved in the Interference if those claims correspond to Count 1; the claims limited to
15 sgRNA configurations can be designated as corresponding to Count 1, if the PTAB believes such
16 a designation is appropriate.

17 **IV. CONCLUSION**

18 For the foregoing reasons, Broad respectfully requests that the PTAB grant the relief
19 requested in Broad Motion 2.

20
21
22
23
24

1 Dated: September 24, 2021

Respectfully submitted,

2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19

/Raymond N. Nimrod/
Raymond N. Nimrod
Reg. No. 31,987
Quinn Emanuel Urquhart & Sullivan, LLP
51 Madison Avenue
New York, NY 10010
Telephone: 212-849-7000
raynimrod@quinnemanuel.com
matthewrobson@quinnemanuel.com

Steven R. Trybus
Reg. No. 32,760
Locke Lord LLP
111 South Wacker Drive
Chicago, IL 60606
Telephone: (312) 443-0699
steven.trybus@lockelord.com
Counsel for Junior Party

1 **APPENDIX A: STATEMENT OF MATERIAL FACTS**

2 **Broad's Material Facts and ToolGen's Responses**

3 **1.** Proposed Count 2 reads as follows:

4 **Proposed Count 2**

5 Broad application 15/160,710, claim 1

6 or

7 ToolGen application 14/685,510, claim 85.

8 Broad Motion 1 at 4.

9 **RESPONSE:** Admitted.

10 **2.** The applications sought to be added are Broad applications 15/160,710 (allowable
11 claims 1, 40, and 41) and 15/430,260 (allowable claims 74, 94, and 95). Exs. 2063 and 2065.

12 **RESPONSE:** Admitted.

13 **3.** The 710 Application has been posted by the Office electronically and is available
14 on Public PAIR. *See* Ex. 2063.

15 **RESPONSE:** Admitted.

16 **4.** The 260 Application has been posted by the Office electronically and is available
17 on Public PAIR. *See* Ex. 2065.

18 **RESPONSE:** Admitted.

19 **5.** Claims 1, 40, and 41 of the 710 Application are in allowable condition as
20 acknowledged in an Office communication dated April 5, 2021. Ex. 2063 at April 5, 2021 Office
21 Communication, page 2. (Part 4 at PDF pp. 230, 253).

22 **RESPONSE:** Admitted that the Examiner has found the claims to be in allowable
23 condition.

24 **6.** Claims 74, 94, and 95 of the 260 Application are in allowable condition as

1 acknowledged in an Office communication dated April 5, 2021. Ex. 2065 at April 5, 2021 Office
2 Communication, page 2. (Part 36 at PDF p. 248).

3 **RESPONSE:** Admitted that the Examiner has found the claims to be in allowable
4 condition.

5 7. Claims 1, 40, and 41 of the 710 Application correspond to Proposed Count 2. Ex.
6 2454, Seeger Decl. ¶¶ 203-06.

7 **RESPONSE:** Denied.

8 8. Claims 74, 94, and 95 of the 260 Application correspond to Proposed Count 2.
9 Ex. 2454, Seeger Decl. ¶¶ 203-06.

10 **RESPONSE:** Denied.

11 **Broad's Responses to ToolGen's Additional Material Facts**

12 9. The Board authorized Broad to file a motion, contingent on the grant of Broad proposed
13 motion to substitute the count, to add claims of Broad applications corresponding to the
14 substituted count—Proposed Count 2. Paper 20, Order – Authorizing Motions and Setting
15 Times, 3:16–4:3.

16 **RESPONSE:** Admitted.

17 10. Broad did not request and the Board did not authorize Broad to file a motion to add
18 claims of Broad applications corresponding to Count 1. See generally Paper 20, Order –
19 Authorizing Motions and Setting Times, 2:17–6:13.

20 **RESPONSE:** Admitted.

21 11. In its Motions List, Broad characterized all six claims—Claims 1, 40, and 41 of the 710
22 Application and Claims 74, 94, and 95 of the 260 Application—as generic, stating: “Broad
23 understands that claims that are generic to encompass both dual RNA and chimeric RNA

1 embodiments . . . are considered ready for allowance These allowable claims therefore are
2 appropriate for addition to this interference” Paper 17, Broad Motions List, 5:21–5:26.

3 **RESPONSE:** Denied.

4 12. In the Order authorizing the motions, the Board accepted and relied on Broad’s
5 representation that all six claims are generic: “Broad asserts that these claims [i.e., all six claims]
6 encompass both dual and single RNA embodiments” Paper 20, Order – Authorizing
7 Motions and Setting Times, 3:16–22.

8 **RESPONSE:** Denied.

9 13. In Motion 2, Broad characterizes claim 1 of the 710 Application and claim 74 of the 260
10 Application as “parallel independent claims” and claims 40 and 41 of the 710 Application and
11 claims 94 and 95 of the 260 Application as “dependent claims,” and for the first time
12 characterizes claims 41 and 95 as limited to single-molecule RNA, and claims 40 and 94 as
13 limited to dual-molecule RNA. Mot. 3:18–4:4.

14 **RESPONSE:** Denied.

15 **Broad’s Additional Material Facts**

16
17 14. At the hearing on motions, Broad explained:

18 . . .there are claims that Broad has that do not use the terminology ‘guide RNA,’ and
19 also gets into our second motion, which we have been informed that we have other
20 allowable claims that we—that we could potentially move to be brought in as part
21 of the count being broaden[ed] to encompass those best proofs, because the subject
22 matter on our side includes *both the dual molecule* and the single molecule. . . .

23 Paper 19, 8:24-9:10.

CERTIFICATE OF FILING AND SERVICE

I hereby certify that on September 24, 2021, a true and complete copy of the foregoing **BROAD REPLY 2** is being filed and served by 5:00 pm PT /8:00 pm ET via the Interference Web Portal and by agreement served by email on the Senior Party by 8:00 pm PT / 11:00 pm ET to:

aminsogna@jonesday.com
tjheverin@jonesday.com
ncgeorge@jonesday.com
rrich@jonesday.com
cplatt@jonesday.com
ToolGenBroad126@jonesday.com

/Raymond N. Nimrod/
Raymond N. Nimrod
Reg. No. 31,987
Quinn Emanuel Urquhart & Sullivan, LLP
51 Madison Avenue
New York, NY 10010
Telephone: 212-849-7000
raynimrod@quinnemanuel.com
matthewrobson@quinnemanuel.com