

Paper No. _____

Filed March 16, 2022

Filed on behalf of Senior Party
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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; Applications 14/704,551; and 15/330,876

Junior Party

v.

SIGMA-ALDRICH CO. LLC

Application 15/456,204

Senior Party

Patent Interference No. 106,133 (DK)
(Technology Center 1600)

**SIGMA OPPOSITION TO BROAD CONTINGENT MOTION 2
(to Add Claims 52-54 of Broad's '403 Application)**

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OPPOSITION TO BROAD CONTINGENT MOTION 2
(to Add Claims 52-54 of Broad’s ’403 Application)

I. INTRODUCTION

Broad Contingent Motion 2 seeks to add Claims 52-54 of Broad’s Application 16/177,403 (“the ’403 application”) to this interference. But Broad fails to carry its burden on this motion for multiple reasons. First, because Broad Motion 1 should be denied, this motion should thereby be rendered entirely moot. *See* Sigma Opp’n 1. Further, contrary to Broad’s assertions, when Broad filed this Contingent Motion 2, *none* of the claims of the ’403 application had been determined to be allowable by the Examiner. In addition, with respect to the two dependent Claims 53-54, Broad fails to recognize or apply the one-way obviousness for evaluating claim correspondence to the count. Finally, Broad fails to address whether Broad P1 provides adequate written description for the full scope of proposed Claims 52-54, whether claims 52-54 are patentable, and the status of proposed Claims 52-54 as claims in an AIA application. Thus, Broad has failed to carry its burden on this motion for multiple reasons, justifying the Board’s exercise of its discretion to deny this motion.

II. PRECISE RELIEF REQUESTED

Sigma respectfully requests that the Board deny Broad Contingent Motion 2 to add Claims 52-54 of Broad’s ’403 application to this interference.

III. LEGAL STANDARDS

“[A] claim corresponds to a count if the subject matter of the count, if treated as prior art, would have anticipated or rendered obvious the subject matter of [each] claim.” SO ¶ 208.3.1; 37 C.F.R. § 41.207(b)(2). As part of this analysis, “additional references and other evidence may be relied upon to establish the obviousness of the differences between the count and the claims.” *Desjardins v Wax*, 2014 Pat. App. LEXIS 214, at *29 n.3 (PTAB Jan. 21, 2014) (granting motion to add claims to the count where the prior art disclosed “the difference between” the count and

1 claims).

2 **IV. DENIAL OF BROAD MOTION 1 WOULD MOOT THIS BROAD CONTINGENT**
3 **MOTION 2**

4 Broad seeks to add Claims 52-54 of the ’403 application to this interference contingent
5 on the grant of Broad Motion 1 to change the Count. Broad Cont. Mot. 2 at 1. Denial of Broad
6 Motion 1 would not satisfy the express contingency for this motion, thereby rendering moot this
7 motion in its entirety.

8 **V. UPON FILING CONTINGENT MOTION 2, BROAD CLAIMS 52-54 HAD *NOT***
9 **BEEN DETERMINED TO BE ALLOWABLE BY THE EXAMINER, AND**
10 **PROSECUTION OF BROAD’S ’403 APPLICATION HAD BEEN (AND**
11 **REMAINS) SUSPENDED**

12 Broad seeks to add Claims 52-54 of the ’403 application to this interference. The Board
13 authorized this Contingent Motion 2 only to the extent that the Broad claims sought to be added
14 had been determined to be allowable by the Examiner:

15 Broad also seeks to add Broad application 16/177,403, claims 52–56, to
16 the interference as corresponding to proposed Count 3. (*See id.* at 7:28–8:27.)
17 Broad notes that the Office has not yet determined these claims are allowable.
18 (*See id.* at 15 8:22–25.)

19
20 Authorization for this motion is GRANTED to the extent the claims
21 argued to be involved in the current interference must have been determined to be
22 allowable by an examiner. The motion shall be entitled “BROAD MOTION 2.”

23 Order Authorizing Motions (Paper 27) at 5 (Sept. 20, 2021) (highlighting added).

24 Contrary to the Board’s express authorization, however, Broad filed this motion while
25 Claims 52-54 remained pending and had *not* been determined to be allowable by the Examiner.
26 Moreover, the ’403 application had been (and remains) suspended in view of this interference.

27 In its Contingent Motion 2, Broad misleadingly contends that Claims 52-54 had been
28 determined by the Examiner to be allowable. Broad Cont. Mot. 2 at 1 (“The claims of the 403
29 application are indicated as *allowable* as of the Office Actions dated October 5 and November
30 15, 2021.”) (emphasis added); *id.* at 3 (“The application to be added is Application No.

1 16/177,403, which contains *allowed* claims 52-54.”) (emphasis added); *id.* at 4 (“The claims of
2 the 403 application are indicated as *allowable* in the Office Actions of October 5, and November
3 15, 2021.”) (emphasis added).¹ In Sigma Opposition 1, however, Sigma explains in detail why
4 that Broad argument is incorrect. Sigma Opp’n 1 at 2-11. When Broad filed this Contingent
5 Motion 2 on December 3, 2021, the Examiner had *not* determined that any of Broad’s claims in
6 the ’403 application were allowable. *Id.* While Sigma Opposition 1 addresses Claim 52 in
7 particular, those issues are the same with respect to all Claims 52-54 of the ’403 application.
8 Accordingly, rather than duplicate those explanations and analyses here, and to avoid
9 unnecessarily consuming the Board’s and Sigma’s resources, Sigma relies here upon its analyses
10 in the context of Broad Motion 1 and Sigma Opposition 1 thereto. *Id.*; see Order Authorizing
11 Motions (Paper 27) at 11 (Sept. 20, 2021) (“The parties are encouraged to find ways to
12 consolidate arguments when briefing the authorized motions.”). Therefore, for this reason alone,
13 the Board should exercise its discretion to deny this motion.

14 **VI. BROAD FAILS TO ADDRESS THE REQUISITE LEGAL ANALYSIS FOR**
15 **DESIGNATING CLAIMS AS CORRESPONDING TO THE COUNT**

16 As set forth above, the Board applies a one-way obviousness test for determining whether
17 a claim corresponds to the count. Here, Broad Claims 53 and 54 are narrower than Proposed
18 Count 3, so conducting the requisite one-way obviousness analyses would be necessary to
19 evaluate claim correspondence. That is, does the broader Proposed Count 3 (Broad Claim 52 or

¹ On December 3, 2021, Broad filed Contingent Motion 2 and served the accompanying exhibits, including Exhibit 2075. At that time, Broad represented that “a complete copy of the 403 application file has been served on Sigma as Exhibit 2075 here.” Broad Cont. Mot. 2 at 4. The latest entry in that ’403 application file is dated October 18, 2021. Ex. 2075 at 1.

1 Sigma Claim 31) render obvious the narrower Claims 53 and 54?

2 In Broad Contingent Motion 2, however, Broad entirely ignores this test for claim
3 correspondence, and thus Broad fails to carry its burden on this Motion. Broad simply argues
4 that “Dependent claims 53 and 54 each separately specify either a dualRNA or sgRNA
5 embodiment of claim 52 respectively.” Broad Cont. Mot. 2 at 1.² But Broad nowhere evaluates
6 or even mentions the required legal inquiry, namely, whether Broad’s Claims 53-54 would have
7 been obvious in view of Proposed Count 3. *See The General Hospital Corp. v. Sienna*
8 *Biopharmaceuticals, Inc.*, 2016 Pat. App. LEXIS 6687, at *31 (PTAB Aug. 9, 2016) (“GHC’s
9 argument that the limitations of proposed claim 74 ‘fall within’ the limitations of Sienna claim 1
10 does not show whether GHC’s narrower limitations would have been obvious over the broader
11 limitations.”). Indeed, the entirety of Broad’s “correspondence” argument is set forth below:

12 Independent claim 52 recites use of a CRISPR-Cas9 system to cleave both strands
13 of DNA in a eukaryotic cell and repair them through integration of a template
14 polynucleotide. It encompasses both dualRNA and sgRNA embodiments.
15 ***Dependent claims 53 and 54 each specify either dualRNA or sgRNA***
16 ***embodiments of independent claim 52 respectively.***
17 * * *

18 Broad has proposed using independent claim 52 of the 403 application as
19 the Broad portion of Proposed Count 3. ***There is thus no question that the***
20 ***claims sought to be added here would correspond to Proposed Count 3 and that***
21 ***adding them to the Interference is proper.***

² Broad also argues, incorrectly, that “Sigma has argued through prosecution of its claims (as well as in related applications), and now in Interference 106,132 (‘132 Interference’), that Donor Template Integration claims are directed to a distinct invention from claims that specify other forms of cleavage and repair.” Broad Cont. Mot. 2 at 3; *see also id.* (“Thus, Proposed Count 3, which is limited to Donor Template Integration subject matter, defines the common subject matter of the parties to the Interference.”). In Sigma Opposition 1, Sigma explains in detail why that Broad-concocted argument is meritless. *See Sigma Opp’n 1* at 15-23.

* * *

Claims 52-54 of the 403 application should be designated as corresponding to Proposed Count 3.

Broad Cont. Mot. 2 at 2-4 (emphases added; citation omitted).

Of course, the question on this motion is not whether Claim 52 encompasses Claims 53-54. Rather, the question is whether Claims 53-54 would have been obvious in view of Proposed Count 3. *See* 37 C.F.R. § 41.207(b)(2); S.O. ¶¶ 208.3.1 & 208.3.2. On this motion, Broad does not even make such a contention, let alone attempt to bear its burden of establishing obviousness. Thus, for this reason alone, the Board may deny this part of Broad Contingent Motion 2.

VII. BROAD FAILS TO ADDRESS THE WRITTEN DESCRIPTION SUPPORT AND PATENTABILITY OF CLAIMS 52-54, AS WELL AS THE AIA STATUS OF THOSE CLAIMS

In its its Contingent Motion 2, Broad nowhere addresses the written description and patentability issues presented by the excessively broad Claims 52-54. *See* Sigma Opp’n 1 at 223-36. Broad bears the burden on those important issues:

A motion to add a claim, including a claim to be added by filing a reissue application, must—

Show the written description for the claim in the disclosure of the involved application or patent to which it would be added.

Certify that the movant is not aware of any reason why the claim is not patentable.

S.O. ¶ 208.5.1.

A. Broad Fails To Address Whether Broad P1 Provides Adequate Written Description For The Full Scope Of Proposed Claims 52-54

On its Contingent Motion 2, Broad nowhere addresses whether Claims 52-54 satisfy the written description requirement of 35 U.S.C. § 112. *See* S.O. ¶ 208.5.1. While Broad Motion 1 endeavors to demonstrate that Broad P1 provides a constructive reduction to practice of Proposed Count 3 (Broad Mot. 1 at 21-22, Appx. C), the limited Section 112 analysis for a

1 constructive reduction practice is not the same as the full Section 112 analysis for compliance
2 with the written description requirement. *See Google LLC v. Parus Holdings, Inc.*, 2021 Pat.
3 App. LEXIS 6203, at *11 (PTAB Oct. 29, 2021) (“Patent Owner relies on a reduction-to-
4 practice theory which, even if true, is not relevant to the issue of whether written
5 description exists in the ’084 patent for limitation 1.i.” (citing *Enzo Biochem, Inc. v. Gen-Probe*
6 *Inc.*, 323 F.3d 956, 969 (Fed. Cir. 2002) (“[P]roof of a reduction to practice, absent an adequate
7 description in the specification of what is reduced to practice, does not serve to describe or
8 identify the invention for purposes of § 112, P 1.”)). In particular, a constructive reduction to
9 practice of a proposed count (here, Broad Claim 52) requires that the specification describe only
10 a **single embodiment** within the scope of the proposed count, where written description of
11 proposed claims to be added to an interference (here, Broad Claims 52-54) requires that the
12 specification adequately supports the **full scope** of the proposed claims. *See id.*; *see also Zynga,*
13 *Inc. v. IGT*, 2014 Pat. App. LEXIS 753, at *24 (PTAB Feb. 14, 2014) (“Zynga’s original
14 specification does not provide written descriptive support for the **full scope** of the subject matter
15 of its involved claims”) (emphasis added); *Kumar v. Sun*, 2019 Pat. App. LEXIS 145, *6
16 (PTAB Jan. 28, 2019) (“To be accorded the benefit of priority of an earlier application, a party
17 must show that the earlier application is a prior constructive reduction to practice by meeting the
18 requirements of 35 U.S.C. § 112, first paragraph, for **at least one embodiment** within a count.”)
19 (emphasis added). Thus, Broad’s arguments related to an alleged constructive reduction to
20 practice in Broad P1 do not satisfy Broad’s burden here of demonstrating that proposed Claims
21 52-54 comply with the requirement that the Broad P1 specification provides support for the full
22 scope of those claims.

23 Sigma Opposition 1 addresses the exceedingly broad Claim 52, and those issues are
24 largely the same with respect to all Claims 52-54 of the ’403 application. *See Sigma Opp’n 1 at*

1 23-36. Accordingly, rather than duplicate those explanations and analyses here, and to avoid
2 unnecessarily consuming the Board’s and Sigma’s resources, Sigma relies here upon its analyses
3 in the context of Broad Motion 1 and Sigma Opposition 1 thereto. *Id.*; *see* Order Authorizing
4 Motions (Paper 27) at 11 (Sept. 20, 2021) (“The parties are encouraged to find ways to
5 consolidate arguments when briefing the authorized motions.”). And on this Contingent Motion
6 2, Broad nowhere addresses how the disclosure of Broad P1 provides adequate support for the
7 full breadth of Claims 52-54 proposed to be added to this interference. Therefore, for this reason
8 alone, the Board should exercise its discretion to deny Broad Contingent Motion 2.

9 **B. Broad Fails To Address Whether Claims 52-54 Are Patentable**

10 On its Contingent Motion 2, Broad nowhere addresses whether proposed Claims 52-54
11 are patentable. *See* S.O. ¶ 208.5.1; *see The General Hospital Corp. v. Sienna*
12 *Biopharmaceuticals, Inc.*, 2016 Pat. App. LEXIS 6687, at *28 (PTAB Aug. 9, 2016) (“When
13 moving to add a claim to an application and the interference, the movant must, among other
14 things, certify that the proposed claim is patentable”) (emphases omitted). Broad Motion 1
15 does contain a perfunctory section arguing that Broad Claim 52 is patentable over the prior art.
16 Broad Mot. 1 at 23-25. However, as Sigma explains in its Opposition 1, in that argument Broad
17 fails to address Sigma P1, which is prior art under 35 U.S.C. § 102(e). *See* Sigma Opp’n 1 at 39-
18 40. With respect to Broad’s dependent Claims 53-54, Sigma P1 discloses that the guiding RNA
19 can be a sgRNA or a dgRNA. *E.g.*, Ex. 1524 ¶¶ [0018] - [0025]. Otherwise, the issues
20 regarding Sigma P1 are the same with respect to all Claims 52-54 of the ’403 application. *See*
21 Sigma Opp’n 1 at 39-40. Accordingly, rather than duplicate those explanations and analyses
22 here, and to avoid unnecessarily consuming the Board’s and Sigma’s resources, Sigma relies
23 here upon its analyses in the context of Broad Motion 1 and Sigma Opposition 1 thereto. *Id.*; *see*
24 Order Authorizing Motions (Paper 27) at 11 (Sept. 20, 2021) (“The parties are encouraged to

1 find ways to consolidate arguments when briefing the authorized motions.”). On this Contingent
2 Motion 2, Broad nowhere addresses the prior art status of Sigma P1. Therefore, for this reason
3 alone, the Board should exercise its discretion to deny this motion.

4 **C. Broad Fails To Address The Status Of Claims 52-54 As Claims In An**
5 **AIA Application**

6 On its Contingent Motion 2, Broad nowhere addresses the AIA status of Broad’s ’403
7 application containing proposed Claims 52-54. Broad Motion 1 does contain a perfunctory
8 section arguing that the priority chain for the ’403 application extends to Broad P1. Broad Mot.
9 1 at 21-22. However, as Sigma explains in its Opposition 1, Broad fails to address the fact that
10 Broad’s intervening AIA Application 61/842,322 disclosed and claimed “wherein the gene
11 product is luciferase,” which limitation was not disclosed or claimed in any of Broad’s pre-AIA
12 applications. *See* Sigma Opp’n 1 at 36-38. With respect to Broad’s dependent Claims 53-54,
13 Sigma P1 discloses that the guiding RNA can be a sgRNA or a dgrRNA. *E.g.*, Ex. 1524
14 ¶¶ [0018] - [0025]. Otherwise, the issues regarding Sigma P1 are the same with respect to all
15 proposed Claims 52-54 of the ’403 application. *See* Sigma Opp’n 1 at 36-38. Accordingly,
16 rather than duplicate those explanations and analyses here, and to avoid unnecessarily consuming
17 the Board’s and Sigma’s resources, Sigma relies here upon its analyses in the context of Broad
18 Motion 1 and Sigma Opposition 1 thereto. *Id.*; *see* Order Authorizing Motions (Paper 27) at 11
19 (Sept. 20, 2021) (“The parties are encouraged to find ways to consolidate arguments when
20 briefing the authorized motions.”). On this Contingent Motion 2, Broad nowhere addresses the
21 AIA status of the ’403 application, and thus the AIA status of proposed claims 52-54. Therefore,
22 for this additional reason, the Board should exercise its discretion to deny this motion.

1 **VIII. CONCLUSION**

2 For the foregoing reasons, Broad has failed to carry its burden on this motion, and
3 accordingly Sigma respectfully requests that the Board deny Broad Contingent Motion 2.

4 Respectfully submitted,

5

6 Dated: March 16, 2022

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APPENDIX 1

LIST OF EXHIBITS CITED

Exhibit No.	Description
1520	16-177,403 (excerpts)
1524	Sigma P1 (Sigma)
2075	A Complete Copy of the 16/177,403 Application File

APPENDIX 2

RESPONSE TO BROAD’S STATEMENT OF MATERIAL FACTS

1. Proposed Count 3 reads as follows:

Proposed Count 3

Broad application 16/177,403, claim 52

or

Sigma Application 15/456,204, claim 31.

Broad Motion 1 at 6-7.

Response: Admitted

2. The application to be added is 16/177,403, allowed claims 52-54. Ex. 2075 (403 prosecution history).

Response: Denied

3. The 403 application has been posted by the Office electronically and is available on Public PAIR. *See id.*

Response: Admitted

4. A complete copy of the application file for Broad’s 403 application has been served on Sigma as Exhibit 2075 here. *Id.*

Response: Admitted

5. The claims of the 403 application were first indicated as allowable on October 5, 2021, pending interference, and prosecution was suspended. *Id.*

Response: Denied

6. Applicants subsequently conducted an interview on October 7, 2021 and discussed potential amendments to the claims, which were subsequently filed on October 15, 2021. *Id.*

Response: Admitted

7. After consideration, the Examiner entered the Amendments on November 15, 2021 and continued suspension of prosecution pending interference. *Id.*

Response: Denied

SIGMA'S STATEMENT OF MATERIAL FACTS

8. The Board's consideration of Broad Contingent Motion 2 is contingent upon the grant of Broad Motion 1 (to change the count). Broad Cont. Mot. 2.

9. The Board authorized the filing of Broad Contingent Motion 2 only to the extent that the Broad claims sought to be added had been determined to be allowable by the Examiner in the prosecution of the '403 application. Order Authorizing Motions (Paper 27) at 5 (Sept. 20, 2021).

10. Upon filing of Broad Contingent Motion 2 on December 3, 2021, the Examiner had not stated that any of Claims 52-54 of the '403 application had been determined to be allowable. Ex. 2075; Ex. 1520.

11. On October 5, 2021, before the filing of Broad Contingent Motion 2 on December 3, 2021, the Examiner suspended prosecution of the '403 application for six months. Ex. 2075; Ex. 1520.

12. The prosecution of the '403 application remains suspended at the time of the filing of this Opposition to Broad Contingent Motion 2 on March 16, 2022.

13. In Broad Contingent Motion 2, Broad does not cite the one-way obviousness analysis for evaluating whether a claim corresponds to the count. Broad Cont. Mot. 2.

14. In Broad Contingent Motion 2, Broad does not apply the one-way obviousness analysis for evaluating whether a claim corresponds to the count. Broad Cont. Mot. 2.

15. In Broad Contingent Motion 2, Broad does not assert that Claim 53 of the '403 application would have been obvious in view of Proposed Count 3. Broad Cont. Mot. 2.

16. In Broad Contingent Motion 2, Broad does not assert that Claim 54 of the '403 application would have been obvious in view of Proposed Count 3. Broad Cont. Mot. 2.

CERTIFICATE OF FILING AND SERVICE

I hereby certify that:

- I. The following paper is being filed March 16, 2022, with the Patent Trial and Appeal Board via:
- ✓ Interference Web Portal at <https://acts.uspto.gov/filing/>. Under SO ¶ 105.3, a paper filed through the Interference Web Portal is considered served. The web portal e-filing system is to send email notification of the filing to counsel for Junior Party THE BROAD INSTITUTE, INC., MASSACHUSETTS INSTITUTE OF TECHNOLOGY, and PRESIDENT AND FELLOWS OF HARVARD COLLEGE.

**SIGMA OPPOSITION TO BROAD CONTINGENT MOTION 2
(to Add Claims 52-54 of Broad's '403 Application)**

- II. A courtesy copy of the above paper is being sent to counsel for Junior Party THE BROAD INSTITUTE, INC., MASSACHUSETTS INSTITUTE OF TECHNOLOGY, and PRESIDENT AND FELLOWS OF HARVARD COLLEGE at the address(es) below on March 16, 2022, via e-mail:

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