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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-ALDRICH NOTICE RE: SIGMA MOTION 2
(to Remove Application 15/330,876 from the Interference)**

1 **NOTICE RE: MOTION 2 (to Remove Application 15/330,876 from the Interference)**

2 On August 10, 2021, Sigma sought authorization to file a motion to remove Broad
3 allowed Application 15/330,876 (“the ’876 application”) from the present interference:

4 None of the claims in the ’876 application recite further¹ that the composition
5 subsequently *integrates a donor DNA sequence into the target DNA molecule,*
6 *nor do they recite further that the composition alters the expression of the gene*
7 *product of the cleaved target DNA molecule.* Thus, none of Broad’s claims in
8 the ’876 application is substantially the same as (*i.e.*, patentably indistinct from)
9 Sigma’s claims in the present interference, and thus none of the claims in the ’876
10 application interferes with any of the claims of Sigma’s involved Application
11 15/456,204. Accordingly, the ’876 application is not properly included in this
12 interference, and therefore Sigma respectfully requests that the ’876 application
13 be removed from this interference.

14
15 Sigma-Aldrich List of Proposed Motions (Paper 22) at 6 (Aug. 10, 2021) (emphasis and footnote
16 added).

17 Simultaneously, and unbeknownst to Sigma, Broad also sought authorization to remove
18 the ’876 application from the present interference:

19 Motion under 37 C.F.R. §§ 41.121(a)(1)(iii) and 41.208(a)(2) to designate
20 as not corresponding to the Count, at least because of the limitation to a selected
21 protein, namely, *Staphylococcus aureus* Cas9, which is patentably distinct from
22 the Count and not disclosed by the Sigma S1 or 204 applications, as follows:

¹ Sigma initially inaccurately stated that “[a]ll of the claims in the ’876 application are directed solely to, *inter alia*, a composition of CRISPR-Cas9 in a eukaryotic cell to simply cleave a target DNA molecule.” Sigma-Aldrich List of Proposed Motions (Paper 22) at 6 (Aug. 10, 2021). More accurately, only dependent Claim 16 of the ’876 application recites “directing cleavage of both strands at the location of the target sequence.” Broad Clean Copy of Claims (Paper 5) at 85. The other composition of matter claims of the ’876 application recite the components of a CRISPR-Cas system, but do not require cleavage of a target DNA molecule. *Id.* at 84-87.

* * *

- 15/330,876 – Claims 1, 16-21, and 30-40 (all involved claims)

Broad List of Proposed Motions (Paper 21) at 9 (Aug. 10, 2021).

Broad further sought authorization to remove certain specific claims of the ’876 application for other reasons. *Id.* at 9-10.

Finally, Broad sought to remove fourteen (14) applications, or certain claims thereof, from the current interference for the following reason:

Motion under 37 C.F.R. §§ 41.121(a)(1)(iii) and 41.208(a)(2), to designate as not corresponding to the Count, Broad’s Involved Claims that are not limited to either (1) use of CRISPR-Cas system in eukaryotic cells with “fused” or “chimeric” RNA or (2) ***requiring a donor polynucleotide and HDR following a DSB.***

Id. at 10-11 (emphases added).

On September 20, 2021, the Board authorized both parties’ motions with regard to, *inter alia*, removal of the ’876 application and requiring a donor polynucleotide and HDR following a DSB. Order Authorizing Motions and Setting Times (Paper 27) at 5-6 (authorizing “Broad Motion 3”) & 9 (authorizing “Sigma Motion 2”) (Sept. 20, 2021). Sigma fully expects that Broad will prepare and file its Motion 3, as Broad has done in previous CRISPR-related interferences. *See CVC v. Broad*, Int’f 106,115, Broad Substantive Motion 3 (Paper 268) (Oct. 14, 2019); *Broad v. ToolGen*, Int’f No. 106,126, Broad Motion 3 (Paper 73) (May 28, 2021).

While certainly not wholly reciprocal, there appears to be significant overlap in the parties’ two proposed motions in this interference with respect to, *inter alia*, the ’876 application and requiring a donor polynucleotide and HDR following a DSB. Addressing those overlapping issues in two parallel motions, rather than sequentially in the context of a single motion, presents the strong likelihood of significant redundancy and inefficiency, which are antithetical to the goals of USPTO interference practice and Sigma’s objectives. Accordingly, Sigma currently

1 intends to address the issues set forth above, if necessary, in Time Period 3 in the context of the
2 authorized and anticipated Broad Motion 3 to, *inter alia*, remove application 15/330,876 from
3 the present interference.

4 Respectfully submitted,

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7 Dated: December 3, 2021

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CERTIFICATE OF FILING AND SERVICE

I hereby certify that:

- I. The following paper is being filed December 3, 2021, 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-ALDRICH NOTICE RE: SIGMA MOTION 2
(to Remove Application 15/330,876 from the Interference)**

- 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 December 3, 2021, via e-mail:

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