THE REGENTS OF THE UNIVERSITY OF CALIFORNIA, UNIVERSITY OF VIENNA, AND EMMANUELLE CHARPENTIER

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

THE REGENTS OF THE UNIVERSITY OF CALIFORNIA, UNIVERSITY OF VIENNA, AND EMMANUELLE CHARPENTIER

Junior Party

(Applications 15/947,680; 15/947,700; 15/947,718; 15/981,807; 15/981,808; 15/981,809; 16/136,159; 16/136,165; 16/136,168; 16/136,175; 16/276,361; 16/276,365; 16/276,368; and 16/276,374),

v.

THE BROAD INSTITUTE, INC., MASSACHUSETTS INSTITUTE OF TECHNOLOGY, and PRESIDENT AND FELLOWS OF HARVARD COLLEGE

Senior Party

(Patents 8,697,359; 8,771,945; 8,795,965; 8,865,406; 8,871,445; 8,889,356; 8,895,308; 8,906,616; 8,932,814; 8,945,839; 8,993,233; 8,999,641; 9,840,713; and Application 14/704,551).

Patent Interference No. 106,115 (DK)
(Technology Center 1600)

OPPOSITION TO BROAD SUBSTANTIVE MOTION 1 (estoppel)
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CVC submits this Opposition pursuant to the Order Authorizing a Response to Broad’s Substantive Motion 1. See Order – Authorization for Opposition to Broad Substantive Motion 1 (Paper 72, dated September 25, 2019) 37 C.F.R. § 41.104(a).

Appendix 1 provides a list of Exhibits cited in this Motion. Appendix 2 is a Statement of Material Facts, cited herein as “Fact x.”

I. Introduction

On page 1, lines 2-7 of the Motion, it is argued that this interference is barred by the PTAB’s final judgment and no-interference-in-fact decision in Interference No. 106,048 (“the ’048 proceeding”), as affirmed by the Federal Circuit. The response is there is no form of “judgment estoppel” that precludes this interference. Contrary to Broad’s pretexts, the Office’s estoppel regulations do not—and cannot—supersede common law estoppel principles, much less the Office’s statutory mandates to issue patents and decide interferences. See, e.g., 35 U.S.C. § 102 (providing that the Office shall issue a patent unless certain conditions are met); 35 U.S.C. § 135 (providing that the PTAB shall determine questions of priority). In an effort to evade a determination of priority of invention for CRISPR technology in eukaryotes, Broad misconstrues the law and mischaracterizes the facts. Having escaped such a priority determination in the ’048 proceeding by urging the PTAB to grant its motion for no interference-in-fact rather than moving to add eukaryotic claims to CVC’s application, Broad now asks the PTAB to expand the scope of estoppel to preclude a priority determination entirely. But Broad fails to cite a single case that applies estoppel principles in the expansive and inequitable manner that Broad proposes here.

Broad’s first estoppel theory is based on the false assumption that this interference concerns the same subject matter as the ’048 proceeding. See Mot. at 15 lines 13-21. It does not.

The ’048 proceeding was directed to Broad’s claims limited to eukaryotes and CVC’s claims that were not so limited. Fact 46; Ex. 3110 (Interference No. 106,048 Decision on Motions). CVC
had suggested an interference directed to the generic use of CRISPR (not limited to use in eukaryotic cells) because CVC viewed the claims of both parties to be directed to the same invention. Despite CVC’s suggestion of a broader count, the PTAB declared the ’048 proceeding with a count limited to the use of CRISPR in eukaryotic cells. CVC filed a motion to change the count (removing the ‘eukaryotic’ limitation), but that motion was never decided—the PTAB terminated the interference because it determined that the claims were directed to different inventions. Thus, no interfering subject matter was ever defined in the ’048 proceeding.

In contrast, the present interference is directed solely to two sets of the parties’ claims that are all limited to eukaryotes. Fact 46; (Paper 23). The present interference therefore does not seek to reopen the PTAB’s final judgment from the ’048 proceeding or re-litigate the no interference-in-fact question that was decided in that proceeding. Rather, the present interference will finally address, for the first time, priority of invention as between two sets of claims that are all limited to CRISPR in eukaryotes. Because the subject matter of this interference is not the same as the subject matter of the ’048 proceeding, Broad’s judgment estoppel theory fails.

Broad’s second estoppel theory is predicated on misreading the first sentence of Rule 127 in isolation from the remainder of the rule and complaining that CVC should be estopped for failure to move in the ’048 proceeding. See Mot. at 19 lines 8-23. But Broad’s interpretation of Rule 127 is untenable, because severing the first sentence from the remainder of the rule improperly renders the remainder of the rule superfluous. Again, Broad fails to cite a single case applying failure-to-move estoppel in the manner Broad urges.

The rule is clear: failure-to-move estoppel is limited to parties that have lost an interference, and the estoppel excludes any contested subject matter for which that party was awarded a favorable judgment. CVC did not lose the ’048 proceeding, because that proceeding
Interference No. 106,115   CVC Opposition to Broad Substantive Motion 1

1 was dissolved upon a finding of no interference-in-fact. See M.P.E.P. § 2308.03(b) (“Neither
2 party has lost the interference for the purpose of estoppel consistent with 37 C.F.R. §
3 41.127(a)(1), even if one of the parties suggested the interference.”). In fact, CVC exited the
4 ’048 proceeding with dominating claims in its involved application that the Office has since
5 issued. Fact 47; USPN 10,266,850. (Ex. 4173). Thus, CVC no more lost the ’048 proceeding
6 than did Broad. No authority supports Broad’s efforts to expand failure-to-move estoppel to
7 parties that did not lose a prior interference.
8
9 Despite Broad’s conjecture regarding CVC’s intentions preceding this interference,
10 CVC’s prosecution history shows that CVC was the first party to file a patent application
11 identifying the necessary and sufficient components of a CRISPR-Cas system that cleaves or
12 edits DNA. Fact 48; Ex. 3002. Beginning with CVC’s first provisional application filed on May
13 25, 2012, CVC’s patent applications have always been directed to the use of CRISPR in a variety
14 of environments, including outside of cells, in prokaryotes, and in eukaryotes. Fact 49; See P1
15 (Ex3002); P2 (Ex3003); P3 (Ex3004); ’859 (Ex4032); ’504 (Ex4033); ’604 (Ex4034); involved
16 applications (Ex 4018-4031). Indeed, CVC’s first provisional application—filed more than six
17 months before Broad’s first patent application—including claims directed to CRISPR in
18 eukaryotes, as well as claims that were not limited to CRISPR in any particular environment.
19 Fact 51; Ex. 3002 (compare, e.g. claim 54 with claims 61-69). CVC’s prosecution of its non-
20 provisional applications first centered on CVC’s claims that were not limited to a particular
21 environment. There was nothing improper or even uncommon in CVC allocating its resources to
22 prosecuting broader claims before prosecuting claims limited to CRISPR in eukaryotes.
23
24 Broad speculates that CVC made a so-called tactical decision to “wage [a] serial
25 interference campaign.” Motion at 1:15-17. Rather, CVC suggested the ’048 proceeding on
belief that its claims that were not limited to eukaryotes interfered-in-fact with Broad’s
eukaryotic claims—a belief the examiner and PTAB also shared. Ex. 4169, Interference Initial
Memoranda; Ex. 3101; Interference No. 106,048, Declaration of Interference issued on January
11, 2016 (Paper 1) and Redeclaration of Interference issued on March 17, 2016 (Paper 32)
(declaring an interference between CVC’s generic-environment claims and Broad’s eukaryotic-
environment claims).

CVC’s subsequent efforts to obtain its own patent claims on CRISPR in eukaryotes
cannot fairly be labeled as a mere attack on Broad’s claims. CVC’s desire to obtain such claims
has always been evident from CVC’s prosecution history, including in claims presented in
CVC’s applications filed before Broad’s first application, as well as in claims presented by
amendment in April 2015, within the statutory time period defined by § 135(b). See 35 U.S.C. §
135(b)(1). Fact 50; Ex. 4172, U.S. Appl. No. 13/842,859, Amendment and Reply and Response
to Restriction Requirement. Having found such eukaryotic claims allowable to CVC but for
resolving priority of invention, the Examiner suggested the present interference, and the PTAB
declared it sua sponte. See “Communication Regarding a Potential Interference.” By alleging
that CVC “provoke[d] a second interference,” Broad distorts the facts. The PTAB properly
declared this interference because the ’048 proceeding resulted in no interference. And Broad has
not established—or even alleged—that any law or regulation precludes the PTAB from sua
sponte declaring an interference and determining priority of invention when it is faced with two
sets of claims directed to the same invention. Rather, §§ 135 and 102(g) require the PTAB to
resolve the priority of invention issue on the merits. 35 U.S.C. §§ 102(g), 135.

Unlike Broad, CVC has never evaded the priority of invention issue. It is not surprising
that Broad again seeks to evade the issue here, because Broad was actually the fourth entity to
file a patent application directed to CRISPR in eukaryotes. See Fact 52; Exs. 4001; 4002; 4008;

Compare Exs. 4010-4012 with Exs4013-4017. Despite being the fourth filer, Broad obtained its
patents without an interference by accelerating examination of its applications, and changing its
applications’ designation from post-AIA to pre-AIA during prosecution so that it could swear
behind CVC’s earlier-filed application.¹ Fact 53 (Compare Application Data Sheets (“ADSs”)
filed in U.S. Application Nos. 14/256,912 (issued as the 8,945,839 patent); 14/105,031 (parent of
U.S. Pat. Nos. 8,889,356 and 8,932,814); 14/258,458 (issued as U.S. Pat. No. 8,932,814);
14/105,035 (parent of U.S. Pat. Nos. 8,795,965 and 8,871,445); 14/104,977 (parent of U.S. Pat.
Nos. 8,865,406 and 8,895,308); 14/222,930 (issued as U.S. Pat. No. 8,865,406 patent);
14/104,990 (parent of the 8,906,616 patent); 14/105,017 (issued as the 8,993,233 patent); and
14/226,274 (issued as the 8,999,641 patent).); with AIA 35 U.S.C. § 102(a); MPEP § 2152.01
(“AIA 35 U.S.C. 102(a)(1) and (a)(2) make no mention of the date of the invention . . . . As a
result, it is no longer possible to antedate or ‘swear behind’ certain prior art disclosures by
making a showing under 37 CFR 1.131 that the applicant invented the claimed subject matter
prior to the effective date of the prior art disclosure.”) and Ex. 4174 (U.S. Pat. No. 8,697,359

In the ’048 proceeding, Broad again evaded a priority determination, by moving for no
interference-in-fact. But if Broad had wanted the ’048 proceeding to finally resolve all issues of
priority of invention as to CRISPR in eukaryotes, it could and should have moved to add a
eukaryotic claim to CVC’s involved application,² rather than avoid the issue by seeking

¹ Nothing in this Opposition should be construed as a concession that Broad’s swear-behind was
proper.

² See Standing Order ¶ 208.5.1.
termination of the proceeding. Broad has enjoyed the benefits of its issued patents for five-and-
a-half years but must now finally face the unresolved question of priority of invention for
CRISPR in eukaryotes; no principles of collateral estoppel or res judicata prohibit the PTAB
from resolving the issue now via this interference. Broad and the public have long been on notice
that this issue remained unresolved as between Broad and CVC. The present interference,
mandated by §§ 102(g) and 135, presents the proper vehicle for finally resolving priority of
invention.

CVC’s involved claims have been found allowable but for resolution of issues under 35
U.S.C. §102(g). Fact 54. The integrity of the patent system and the public interest in ensuring
that patents are granted to the proper entities demands resolution of the outstanding question of
priority of invention for this ground-breaking technology. Broad cannot cite its previous
avoidance of a priority determination to bootstrap an estoppel theory and thereby evade a priority
determination once again.

II. The Motion Should be Denied Because Broad Seeks to Expand the Scope of Estoppel
Beyond that Available Under the Law—Relief the PTAB Does Not Have Authority to
Grant

On page 1, line 21 of the motion, it is argued that “[j]udgment estoppel under Rule
127(a)(1) bars this interference on two grounds.” The response is that neither ground is
supported by fact or law. To the contrary, Broad’s interpretations of the relevant guidance and
regulations would invite the Office to commit legal error by exceeding its authority.

Agencies have the statutory authority to apply general preclusion and res judicata
principles only because “Congress may be presumed, when enacting a statute granting to an
agency adjudicatory authority, to mandate adherence to the doctrine of collateral estoppel.”
Duvall v. Atty. Gen., 436 F.3d 382, 387 (3d Cir. 2006). This is because, as an administrative
agency, the Office’s actions must be authorized by statute. See, e.g., Soriano v. United States,
494 F.2d 681, 683 (9th Cir. 1974) (“an administrative agency is a creature of statute, having only those powers granted to it by Congress or included by necessary implication from the Congressional grant.”). Where, as here, an agency’s authorizing statute does not expressly address the role of estoppel, an agency nonetheless is understood to have authority to apply finality to its own proceedings in accordance with well-established common law estoppel doctrine and because Congress is presumed to legislate against that backdrop. Duvall, 436 F.3d at 387, 390 (“Congress is expected to legislate against the backdrop of well-established common law principles”) (citing analysis in Astoria Fed. Sav. & Loan Ass ’n v. Solimino, 501 U.S. 104, 108 (1991).

Furthermore, when Congress affirmatively confers jurisdiction on an agency, the agency cannot promulgate or apply procedural rules in a manner that unilaterally contracts its jurisdiction to make it more narrow than what Congress has provided. Union Pac. R. Co. v. Bhd. of Locomotive Engineers & Trainmen, 130 S. Ct. 584, 590 (2009) (“[T]here is surely a starting presumption that when jurisdiction is conferred, a court may not decline to exercise it. The general rule applicable to courts also holds for administrative agencies directed by Congress to adjudicate particular controversies.”); Pruidze v. Holder, 632 F.3d 234, 240 (6th Cir. 2011) (“[A]n agency cannot contract its power to hear claims that fall plainly within its statutory jurisdiction.”).

Congress authorized the Office to administer interferences to decide priority of invention. It did not authorize the Office to promulgate estoppel rules beyond common law estoppel doctrine. Broad’s attempt to derive a special, far-reaching application of interference estoppel from the PTAB’s regulations and the MPEP is contrary to both the language of those regulations and the PTAB’s authority.
1. **Broad Misconstrues Rule 127 and the Relevant Facts**

   In an effort to avoid a priority determination on the merits, Broad misconstrues Rule 127 beyond its reasonable or even possible limits. Tellingly, Broad could not cite a single case that applies Rule 127 so expansively as to preclude an interference under the current circumstances.

   Fact 55. Broad argues that the first sentence of Rule 127 “estop[s] a party from provoking an interference with the same opponent for the same subject matter.” But Rule 127’s statement that “[a] judgment disposes of all issues that were, or by motion could have properly been, raised and decided” is nothing more than a recognition of common law principles of finality and res judicata. The present interference does not violate those principles, because it does not disrupt the finality of the ’048 proceeding or re-litigate any issue underlying the judgment. Specifically, the present interference does not reopen the question of whether claims that are limited to eukaryotes interfere with claims that are not so limited.

   At page 2, line 1-2, Broad asserts that this interference is barred because it is for “the same subject matter” as the ’048 proceeding. Broad is wrong to selectively look only at its own claims. The subject matter of an interference is defined by two sets of claims: Broad’s and CVC’s. Here, CVC’s involved claims are patently distinct from the claims involved in the ’048 proceeding, because they contain a eukaryotic limitation that CVC’s previously involved claims did not. The subject matter of the ’048 proceeding therefore related to Broad’s eukaryotic claims and CVC’s claims that were not so limited. As the Federal Circuit stated, that “case [was] about the scope of two sets of applied-for claims, and whether those claims are patently distinct.” *Regents of Univ. of Cal. V. Broad Inst. Inc.*, 903 F.3d 1286, 1296 (Fed. Cir. 2018). (emphasis added) (defining the subject matter of the holding without reference to any count).

   In contrast to the two sets of applied-for claims that were the subject of the ’048 proceeding, the present interference involves two sets of claims that are all limited to eukaryotes.
This interference thus presents a new two-way test under 37 C.F.R. § 1.601(n) and defines different subject matter. No authority supports Broad’s mischaracterization of the subject matter at issue in each proceeding, and no authority supports Broad’s proposed expansion of estoppel principles to prevent the PTAB from adjudicating a fundamentally different dispute—priority of invention as between two sets of eukaryotic claims.

The PTAB is now poised to answer who was first to invent CRISPR in eukaryotes. That question was not (and could not have been) litigated or decided in the previous interference given the no interference-in-fact determination. No principle of collateral estoppel or res judicata prevents deciding an issue that was not previously litigated. *B&B Hardware, Inc. v. Hargis Indus., Inc.*, 135 S. Ct. 1293, 1303 (2015) (noting “[t]he general rule is that ‘[w]hen an issue of fact or law is actually litigated and determined by a valid and final judgment, and the determination is essential to the judgment, the determination is conclusive in a subsequent action between the parties, whether on the same or a different claim.’”) (quoting Restatement (Second) of Judgments § 27, p. 250 (1980)); *Biogen MA, Inc. v. Japanese Found. for Cancer Research*, 785 F.3d 648, 658 (Fed. Cir. 2015) (“Claims that are not patentably distinct from lost counts were already adjudicated in the prior interference and are thus conclusive.”) (emphasis added).

See also *Purdue Pharma L.P., et al. v. Iancu*, 2019 U.S. App. LEXIS 11205 (Fed. Cir. 2019) (confirming that failing to distinguish a prior art reference in a prior proceeding did not estop a party from doing so in a subsequent litigation because silence does not “actually litigate[]” an issue for purposes of collateral estoppel); *Cromwell v. County of Sac*, 94 U.S. 351, 353 (1877) (“the inquiry must always be as to the point or question actually litigated and determined in the original action, not what might have been thus litigated and determined.”)
Termination for no-interference-in-fact is a dismissal for lack of jurisdiction. Cf. Medicem, S.A. v. Rolabo, S.L., 353 F.3d 928, 935-36 (Fed. Cir. 2003) (describing the two-way test for interference-in-fact as a jurisdictional predicate). A dismissal for lack of jurisdiction does not preclude a second action based on the same cause of action that includes claims that overcome the initial defect of jurisdiction. See, e.g., Hughes v. U.S., 71 U.S. 232, 237 (1866) (“[i]n order that a judgment may constitute a bar to another suit, it must be rendered in a proceeding between the same parties or their privies, and the point of controversy must be the same in both cases, and must be determined on its merits. If the first suit . . . was disposed of on any ground which did not go to the merits of the action, the judgment rendered will prove no bar to another suit”); 18A Charles Alan Wright, Arthur R. Miller & Edward H. Cooper, Federal Practice and Procedure: Jurisdiction § 4435 at 139 (2d ed. 2002). Cf. also Rule 41.201 (explaining that a no-interference-in-fact determination deprives all parties of standing to contest priority of invention).

The analogy between termination for no interference-in-fact in the interference context and dismissal for lack of jurisdiction in the district court context is particularly apt when considering that for purposes of Fed. R. of Civ. P. 41(b), courts construe “jurisdiction” very broadly to include any reason for termination that is more of a pre-condition than a consideration of the merits. See Costello v. U.S., 365 U.S. 265, 285-87 (1961); This is true even if the technical basis for dismissal was for failure to state a claim. Id. (holding that FRCP 41 codified the common law rule that a dismissal on any ground not going to the merits was not a bar to a subsequent action on the same claim). A count that fails to define interfering subject matter is similar to a complaint’s failure to state a claim. Under such circumstances, res judicata only bars future complaints that suffer the same flaw as the complaint already dismissed. It does not bar a
second suit that properly states a claim, even where a plaintiff could have sought leave to amend the previous complaint to properly state a claim, and did not. *Id.*

Moreover, under Broad’s own theory, Rule 127 merely “estop[s] a party from provoking an interference;” it does not preclude the Office from declaring an interference. Here, CVC did not provoke this interference. Fact 56; Ex. 4169. The examiner suggested the interference, and the PTAB declared it *sua sponte* consistent with its mandate under 35 U.S.C. §135. *Id.* Nothing in the rules or in the notice of proposed rulemaking suggests that the PTAB is estopped or otherwise precluded from *administering* an interference, or that CVC is estopped from participating in an interference the PTAB declared *sua sponte*.

Broad’s reliance on MPEP § 2308.03(b) is of no avail because it overlooks an important limitation in that provision. Section 2308.03(b) bars “any further interference between the same parties for claims to the same invention as the count of the interference,” not any subsequent interference that presents a new question not previously litigated. *Compare* MPEP § 2308.03(b) (no “further” interference) *with* MPEP § 2308.03(c) (“no “second” interference”). By “further interference,” the provision is referring to the concept further elucidated in § 2308.03(c), which explains that a judgment of no-interference-in-fact has finality, and that “that holding may not be reopened in further examination.” MPEP § 2308.03(c). Nothing is being reopened here. The present interference does not purport to reopen the no-interference-in-fact holding of the '048 proceeding for further litigation.

To the extent that MPEP 2308.03(b) is construed to bar the present interference, the MPEP is contrary to the law and therefore invalid. As the Broad admits, the MPEP does not have the force and effect of law, and it certainly cannot prevent the Office from fulfilling its statutory mandates under 35 U.S.C. §§ 135 and 102 to issue patents after resolving any questions of
priority of invention. Moreover, as the PTAB has frequently noted, it is not bound by the MPEP. This is particularly true here, where MPEP 2308.03(b) is internally illogical by referring to a judgment of no interference-in-fact barring a further interference for claims to the same invention as the count of the interference. Similarly, to the extent the PTAB interprets Rule 127(a) as broadly as Broad advocates, it ought to be waived or suspended under the present circumstances, pursuant to Rule 42.5(b), in the interests of a just resolution of this proceeding and the public interest in awarding patents to the proper entities. 37 C.F.R. §§ 41.1, 42.5(b).

The “count” preceding a judgment of no interference-in-fact does not actually define anything for estoppel purposes. See 37 C.F.R. § 41.201 (“Count means the Board’s description of the interfering subject matter that sets the scope of admissible proofs on priority.”) (emphasis added). Where there is no interfering subject matter, there is no “count” as defined in the regulations. Han v. Lee, Interference No. 104,670, 63 U.S.P.Q.2d 1364 (P.T.O. Mar. 26, 2002) (“To use the words of Wu, there is no ‘subject matter of the interference.’ To use the words of the Notice of Final Rule, there are no ‘controversies as to all interfering subject matter defined by one or more counts’ because there is no interfering subject matter.”).

Broad therefore cannot rely on the scope of the “count” for estoppel purposes, because (a) there was no count, i.e., no interfering subject matter, according to the PTAB and Federal Circuit, and (b) the failed count was not the count CVC proposed, nor was CVC’s motion to change the count ever reached. Again, Broad’s theory that MPEP 2308.03(b) should preclude an interference here is unsupported by case law, as Broad fails to cite a single case applying estoppel in the manner Broad seeks. At bottom, Broad’s strained interpretation of Rule 127 cannot create a new form of estoppel more expansive than that provided for under common law.
2. **Broad’s failure-to-move arguments misread the law and mischaracterize the facts**

On page 19, line 20 through page 20, line 4 of the Motion, it is argued that Rule 127 bars this interference because CVC did not seek authorization to file a contingent, responsive motion seeking to add eukaryotic claims to the ’048 proceeding. The response is Broad improperly seeks to expand the doctrine of failure-to-move estoppel and mischaracterizes the facts in its motion. Again, Broad could not identify a single case applying failure-to-move estoppel following a judgment of no interference-in-fact. It is not surprising that no panel has ever applied estoppel in the distorted and inequitable manner Broad urges here in its efforts to avoid a priority determination on the merits.

Rule 41.127(a)(1) (2004), entitled “Estoppel,” sets forth the effect of a prior judgment in an interference on future proceedings within the Office:

A judgment disposes of all issues that were, or by motion could have properly been, raised and decided. A losing party who could have properly moved for relief on an issue, but did not so move, may not take action in the Office after the judgment that is inconsistent with that party’s failure to move, except that a losing party shall not be estopped with respect to any contested subject matter for which that party was awarded a favorable judgment.

37 C.F.R. § 41.127(a)(1) (emphasis added). The first sentence of Rule 127 sets forth the general principle of finality, whereas the second sentence of Rule 127 clarifies the effect of the first sentence, by specifying that failure-to-move estoppel is confined to the losing party. Broad misconstrues Rule 127 by reading the first sentence of the rule in isolation from the rest of the rule and the larger regulatory framework of 37 C.F.R. §§ 41.100 et seq. and 41.200 et seq.

Broad’s interpretation of the rule is faulty because it renders the second sentence superfluous. Were all parties estopped by virtue of the first sentence from raising any issue that could have by motion been raised and decided in a prior interference, there would be no need to
specify in the second sentence that losing parties are so estopped. The Broad’s overbroad
interpretation of the first sentence therefore violates basic canons of statutory and regulatory
construction. See Young v. UPS, 135 S. Ct. 1338, 1352 (2015) (finding that the second clause of
an act could not be read to provide for a prohibition that was already accomplished by the first
clause because it would therefore render the first clause superfluous); TRW Inc. v. Andrews, 534
U.S. 19, 31 (2001) (finding that statutes should be construed such that no clause is rendered
“superfluous, void, or insignificant.”); Corley v. United States, 556 U.S. 303, 314 (2009)
(rejecting an interpretation of a subsection under which a subsequent subsection would add
which certain language did “all the necessary work” leaving no need for the additional language
that appeared in the clause).

In arguing that CVC is estopped here for failure to move, Broad seeks to expand
interference estoppel principles in new ways that are unsupported by law or precedent. It is
unsurprising that Broad has failed to cite a single case in which the PTAB has applied failure-to-
move estoppel to a party that did not lose a prior interference. Broad suggests runs contrary to Rule 127’s application of failure-to-move estoppel only to a

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3 Broad cites Tseng v. Doroodian for the proposition that a party can seek to file a
responsive motion to add a claim. Motion at 20, n.4. While the PTAB in that case noted that
party Tseng had an opportunity to file a responsive motion to a no-interference-in-fact motion
that added a claim, it also noted that Tseng did not do so, and considered adding claims sua
sponte based on a preliminary motion that was denied. Nothing in the holding of Tseng suggests
that any estoppel should result either way. Indeed, Tseng is silent as to estoppel, and Broad’s
reliance on it is inapposite.
“losing” party and only for issues on which the losing party did not receive favorable judgment. 37 C.F.R. § 41.127(a)(1). Broad’s interpretation therefore extends failure-to-move estoppel to situations that this tribunal has never previously found it to extend. See MPEP § 2308.03(b); In re Risse, 378 F.2d 948 (C.C.P.A. 1967) (explaining the application of failure-to-move estoppel to a losing party); In re Kyrides, 159 F.2d 1019 (C.C.P.A. 1947) (same).

MPEP § 2308.03(b) is consistent with the rule and cases cited above when it explains that where there is a judgment of no-interference-in-fact, “[n]either party has lost the interference for the purpose of estoppel consistent with 37 C.F.R. § 41.127(a)(1), even if one of the parties suggested the interference.” Broad’s efforts to find estoppel by divorcing the first sentence of Rule 127 from the remainder of the rule runs counter to longstanding application of failure-to-move estoppel only against a party that lost an interference.

Having failed to find any basis in the rules or case law for its requested relief, Broad resorts to relying on comments in the regulations’ drafting history. For example, Broad relies on the comment that “the definition of interference estoppel is designed to encourage parties in interference cases to settle as many issues as possible in one proceeding.” Mot. at 15 lines 6-9 (citing Ex. 3301, 49 Fed. Reg. at 48426). But rulemaking commentary about “encouraging” parties to be efficient is not a requirement that parties raise all conceivable issues on pain of preclusion. Indeed, such an onerous requirement would burden interferences with unnecessary motions practice aimed at preserving hypothetical future disputes. And such an interpretation of Rule 127 would hardly be consistent with ensuring that the rule is “construed to secure the just, speedy, and inexpensive resolution of every proceeding before the Board.” 37 C.F.R. § 41.1. The PTAB should not rely on such non-binding comments to countenance Broad’s interpretation of Rule 127.
Broad also references the comment that “a decision of no interference-in-fact could also estop a party from provoking an interference with the same opponent for the same subject matter under the first sentence.” Mot. at 13 lines 16-20 (quoting Ex. 3302, Notice of Proposed Rulemaking, 68 Fed. Reg. 66648, 66661). This sentence does not support the Broad’s overbroad interpretation of the first sentence of Rule 127 either. As noted above, CVC did not provoke the present interference, and nothing in the rule or comment precludes the Office from *sua sponte* declaring and administering an interference to resolve a not-yet-resolved question of priority of invention. Moreover, the non-binding comment merely recognizes that a party cannot re-provoke a substantively identical interference following a judgment of no interference-in-fact. It says nothing about failing to move.

In other words, neither Rule 127’s text nor the rule-making comments state or imply that, following a judgment of no interference-in-fact, a *non-losing* party “who could have properly moved for relief on an issue, but did not so move, may not take action in the Office after the judgment that is inconsistent with the party’s failure to move.” 37 C.F.R. § 41.127(a)(1). That kind of failure-to-move estoppel is expressly reserved for a losing party, and limited to issues for which the losing party was not awarded favorable judgment. *Id*. Applying estoppel any more broadly would impose an inequitable result on a party that had not lost the prior proceeding. Yet, such overly broad failure-to-move estoppel is exactly what Broad advocates in its Motion even though CVC undisputedly *did not lose* the previous interference. Mot. at 19 lines 11-17. The PTAB should not expand the scope of failure-to-move estoppel in the way Broad urges.

In arguing estoppel based on failure to move, Broad—without basis—repeatedly suggests that CVC acted with improper intentions. But Broad mischaracterizes the facts. There is nothing untoward or even uncommon about CVC’s initial pursuit of broad claims that were not limited to
eukaryotes, followed by subsequent pursuit of eukaryote-limited claims. Broad cannot credibly argue that it or the public was somehow surprised or prejudiced by CVC’s ultimate pursuit of claims limited to eukaryotes. Broad and the public were on notice of CVC’s pursuit of eukaryotic claims, because claims directed to CRISPR in eukaryotes were included in CVC’s first published PCT application filed March 15, 2013 (and published on November 28, 2013) before Broad filed its first non-provisional application. Fact 57; Fact 51; Ex. 4188; Ex. 3002; Ex. 4172. Similarly, Broad cannot complain that CVC was somehow dilatory in filing eukaryotic claims in its non-provisional applications. CVC complied with 35 U.S.C. § 135(b), and Broad has not argued otherwise. Fact 50.

Broad’s complaint that CVC did not move to add eukaryotic claims to the ’048 proceeding is undermined by the fact that, at the time of the ’048 proceeding, CVC did not have any claims to CRISPR in eukaryotes in condition for allowance. Permitting ex parte examination of such claims before introducing them into an interference is most consistent with permitting the PTAB proceeding to proceed efficiently under Rule 1. And CVC can hardly be faulted for not moving to add such not-yet-allowed eukaryotic claims to the ’048 proceeding when Rule 127 expressly reserves failure-to-move estoppel for parties that have lost an interference. Moreover, CVC’s belief that there was no need to seek to add a not-yet-allowed eukaryotic claim via a responsive motion was more than reasonable when the PTAB, in reference to not-yet-allowed claims, had just ordered:

Under the facts and circumstances of this interference, where UC [i.e., CVC] believes all of its current claims interfere with all of Broad’s claims, there is no reason why UC should need to add a new claim. If UC’s claims in other applications are ultimately found to be allowable, UC may suggest additional interferences to the examiner. At this point in the proceeding, though, a determination of priority may proceed on the subject matter commonly and
currently claimed by the parties. A priority determination does not require the addition of any other claims.

Furthermore, it is unclear why it would be fair to Broad to allow UC to add a claim. The claim UC seeks to add is currently being examined. Thus, allowing UC to move to add a claim would effectively subject Broad to the burden of completing examination of that claim as well.

Ex. 3107; Interference No. 106,048, Order, pgs. 5-6 (May 11, 2016) (emphasis added). Thus, even the PTAB’s order in the ’048 proceeding recognizes the possibility of additional interferences once CVC’s claims were first found to be allowable in ex parte prosecution, undermining Broad’s assertion here that the ’048 proceeding was required to resolve any conceivable interference between the parties, even as to not-yet-allowed claims.

If Broad’s interpretation of Rule 127 were correct, then there would be no possible set of circumstances under which CVC could suggest additional interferences for claims currently being examined—making the PTAB’s guidance to suggest such future interferences categorically wrong. CVC did not (and does not) believe that the PTAB’s observation that it could suggest additional interferences for claims in other applications was wrong. CVC used that suggestion as guidance in how to proceed in the ’048 proceeding with regard to claims that had not yet been deemed allowable. Because CVC did not have any eukaryotic-limited claims in condition for allowance during the pendency of the ’048 proceeding, it did not attempt to add such claims in a responsive motion. CVC’s actions were consistent with the PTAB’s explanation that “If [CVC]’s claims in other applications are ultimately found to be allowable, [CVC] may suggest additional interferences to the examiner.” Ex. 3107; Interference No. 106,048, Order, p. 5 (May 11, 2016).

While res judicata precludes issues that could have been raised by motion but were not, the precluded issues are limited to those that are properly within the scope of the previous action,
and do not encompass all conceivable disputes that could ever arise. See, e.g., State of Ohio ex rel. Susan Boggs v. City of Cleveland, 655 F.3d 516 (6th Cir. 2011). In Boggs, the plaintiff sued an airport over disputed runway expansion construction. The plaintiff subsequently brought a second complaint against additional runways that were planned, but not yet under construction, during the first suit. The airport argued that the plaintiff could have moved to add claims directed to these runways during the first suit but failed to do so. The Sixth Circuit found that while plaintiff knew about the runway plans, the issue need not have been raised in the earlier suit because the runways were not actually under construction. Id.; see also Rawe v. Liberty Mut. Fire Ins. Co., 462 F.3d 521, 529–30 (6th Cir. 2006) (“unripe claims cannot later serve as a basis for res judicata”). As such, there were any number of reasons the proposed runways might not have required litigation.

Indeed, where, as here, CVC subsequently obtained claims that were deemed allowable but for necessitating a new interference—claims that were not yet deemed allowable at the time of the ’048 proceeding—that change in circumstance gives rise to a new cause of action; a new priority determination. Like the runway plans in Boggs, the question of priority for CVC’s unexamined eukaryotic claims was not yet ripe for adjudication during the pendency of the ’048 proceeding.

A further fallacy of Broad’s estoppel theory is that the very same section of the Standing Order that Broad cites for the proposition that CVC should have added a eukaryotic-limited claim to the ’048 proceeding also provides that Broad could have moved to add such a claim to CVC’s involved application. See Standing Order ¶ 208.5.1 (citing In re Ogiue, 517 F.2d 1382, 1390 (C.C.P.A. 1975) (considering a motion to add a claim to an opponent’s involved application to permit interference). If Broad wanted to insulate its claims against the possibility
of future interferences after CVC’s claims in other applications were found to be allowable,

Broad could have sought to add such claims to the ’048 proceeding. Instead, Broad sought to avoid any priority determinations in the ’048 proceeding, just as Broad again seeks to avoid a priority determination here.

Broad was on notice that the PTAB advised of the possibility of additional interferences with CVC, and its own actions deferred the priority determination to this proceeding. See Ex. 3107, Interference No. 106,048, Order at 3-4. While the no interference-in-fact decision in the ’048 proceeding allowed Broad to avoid a priority determination on its claims for a few more years, Broad did not win the ’048 proceeding. Likewise, CVC did not lose the ’048 proceeding, and CVC is therefore not precluded from litigating issues that were not decided in the ’048 proceeding, such as priority of invention for claims directed to CRISPR in eukaryotes. See M.P.E.P. § 2308.03(b) (“Neither party has lost the interference for the purpose of estoppel consistent with 37 C.F.R. § 41.127(a)(1), even if one of the parties suggested the interference.”).

Broad’s estoppel theory fails under both the law and the facts.

III. The Equitable Doctrine of Estoppel Does Not Supersede the Board’s Statutory Mandates to Resolve Questions of Priority and Issue Patents

Section 135 of the Patent Act gave the Office jurisdiction to decide interferences. 35 U.S.C. § 135. If the subject matter at issue in a later interference is indistinguishable from that in an earlier interference where the PTAB resolved the priority of invention issue, then the PTAB may apply preclusion principles. In that situation, the PTAB has already adjudicated the issue once, and need not do so again. But if the Office applies its preclusion rules to refuse to adjudicate an interference dispute that it has not already adjudicated, it is declining to exercise jurisdiction to decide in the first instance a matter that Congress has clearly instructed it to decide.
Applying Broad’s expansive estoppel theories in this case would thus cause the Office to abrogate its statutory mandates to decide interferences under § 135 and to issue patents to all those entitled to them under § 102. See 35 U.S.C. § 135(a) (“The Board of Patent Appeals and Interferences shall determine questions of priority of the inventions’’); 35 U.S.C. § 102(a) (“a person shall be entitled to a patent unless”). Were the Office to apply its preclusion rules to refuse to adjudicate the present interference—which it has not already adjudicated—it would be declining to exercise jurisdiction to decide a matter that Congress has clearly instructed it to decide. In other words, Broad’s novel, unsupported, and overreaching estoppel theories cannot override the Office’s Congressional mandate to issue patents and decide interferences in accordance with the requirements of Title 35.

IV. Policy Considerations Favor Adjudicating Priority and Awarding Patents to the Rightful First Inventors

For patent applications that are subject to pre-AIA law, it is in the public interest that any patents issuing on such applications be awarded to, or maintained by, the inventors that have established priority of invention. It is not in the public interest to allow a party, such as Broad, to dodge a determination of priority of invention, particularly when Broad filed its first application more than six months after CVC filed its first application. The facts here compel resolution of the priority of invention issue, despite Broad’s efforts to evade it.

As the Federal Circuit has stated, it would “contradict the legislative purpose if the Board were to refrain from deciding priority, when the result of such restraint would be the issuance or preservation of a facially invalid patent.” Perkins v. Kwon, 886 F.2d 325, 328 (Fed. Cir. 1989). Rather, “[t]he public interest in the benefits of a patent system is best met by procedures that resolve administratively questions affecting patent validity that arise before the PTO,” and “[t]o
do otherwise is contrary to the PTO’s mission to grant presumptively valid patents, … and thus
disserves the public interest.” *Id.* at 329. The ’048 proceeding did not resolve questions of
priority or patent validity under § 102(g). On appeal of the ’048 proceeding, the Federal Circuit
noted that the case “is not a ruling on the validity of either set of claims.” *Regents of Univ. of
Cal. v. Broad Inst. Inc.*, 903 F.3d 1286, 1296-1297 (Fed. Cir. 2018). Here, it would contradict
the PTAB’s legislative mandate if it were to refrain from deciding the outstanding priority of
invention issue, particularly where Broad’s patents are facially invalid in view of CVC’s earlier-
filed patent applications disclosing CRISPR in eukaryotes.

**V. The PTAB Can—and Should—Deny this Motion on an Expedited Basis on Purely
Legal Grounds, But Cannot Grant It Without Resolving Factual Issues in Dispute**

The PTAB can—and should—reject Broad’s flawed interpretations of the law and deny
the motion on that basis alone in an expedited fashion. Broad improperly seeks to expand the
scope of estoppel beyond the limits provided for by regulation or under common law. Moreover,
Broad’s misguided interpretations of Rule 127 and reliance on non-codified comments from the
rule-making history or MPEP cannot abrogate the PTAB’s statutory mandate to adjudicate the
unresolved issue of priority of invention that is presented for the first time in this interference.

Were the PTAB somehow nonetheless inclined to grant the motion, it would need to
ascertain the scope of any estoppel, which calls for resolution of disputed factual issues that have
not been fully developed and tested on the present, curtailed record. For example, Broad argues
that the prior no interference-in-fact judgment bars a further interference for “claims to the same
invention as the count of the interference.” But the parties apparently disagree as to whether a
claim reciting a single molecule RNA is patentably distinct from the ’048 proceeding’s count,
although Broad has relied on the idea of its separate patentability in support of its Motion 3. Fact

58. In arguing that it is not, Broad states it “disagrees” with CVC’s characterization of the prior
art, revealing a disputed factual issue that renders granting the motion on an expedited basis improper in the absence of a fulsome evidentiary record. Motion at 17:9-18:3, including n.3.

Without a developed evidentiary record to resolve disputed factual issues, the PTAB cannot properly determine the scope of any estoppel, e.g., whether it should reach single molecule RNA claims or any other potentially patentably distinct claims. However, the PTAB can and should deny the motion on purely legal grounds or on the basis that Broad otherwise failed to meet its burden as the movant, for all the reasons presented herein.

Even if the PTAB were to accept Broad’s judgment estoppel theories—which it should not—such estoppel would only bar an interference for those claims that are to the same invention as the previous count (under Broad’s own interpretation of the regulations). Broad has contended that at least some of its claims are limited to single molecule RNAs (e.g., “fused” or “covalently linked”) whereas other claims are not so limited. Fact 59; Paper 268. Therefore, even under Broad’s interpretation of judgment estoppel law governing interference practice, this interference would only be partially barred, and the PTAB would still need to reach the issue of priority of invention for claims patentably distinct from the prior count. The need to first resolve underlying factual disputes precludes granting this motion before allowing for adequate development of the factual record.

VI. Unless the PTAB Resolves Priority Under 102(g) Against CVC on the Merits, CVC’s Claims Must Issue as Patents

CVC is entitled to a patent unless one of the criteria for patentability is not satisfied. The Office has already determined that CVC’s claims are in condition for allowance subject only to a determination of priority under 102(g). If the PTAB declines to make a determination on the merits under 102(g), then it must issue CVC’s claims. 35 U.S.C. § 102(a) ("a person shall be
entitled to a patent unless….”). 4 Here, where CVC did not lose the ’048 proceeding, there is no
basis for denying a patent to CVC under 102(g). Unless the PTAB makes a priority of invention
determination adverse to CVC under 102(g), the PTAB lacks any basis on which to finally refuse
CVC’s claims. In other words, there is no prior art, subject matter eligibility, or other statutory
impediment to the Office issuing CVC’s claims involved in this interference. In the absence of
such a determination, the Office is statutorily mandated to issue CVC’s patents.

Stretching the law once again, Broad cites 35 U.S.C. § 101 for the proposition that
CVC’s claims should be finally refused, arguing that only one patent may be granted for an
invention. See Mot. p. 27 lines 4-6. But § 101 simply bars issuing two patents to the same
inventive entity; it says nothing about issuing a patent to a different inventive entity. 35 U.S.C. §
101. Once again, Broad did not—and indeed could not—cite a single case applying the law as it
now urges. Fact 60. In any event, the law is clear: the Office’s estoppel provisions cannot be
used to abrogate the Office’s mandate to determine issues of priority and to issue patents subject
to the conditions of 35 U.S.C. §§ 102, 103, and 112. The Office has already found that CVC’s
claims are allowable but for a potential § 102(g) conflict. If the PTAB declines to resolve priority
under § 102(g), then the Office must issue CVC’s patents.

VII. Conclusion

Broad has not met its burden to show that this interference is barred by estoppel. The
PTAB should deny Broad’s Substantive Motion 1 and proceed with the motions phase of this
interference.

4 Any issues that arise as a result of two entities holding patents to the same subject
Respectfully submitted,

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Date: Oct. 18, 2019

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Date: Oct. 18, 2019
### APPENDIX 1

#### List of Exhibits

<table>
<thead>
<tr>
<th>Exhibit No.</th>
<th>Description</th>
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<tbody>
<tr>
<td>Exhibit 4001</td>
<td>Sigma-Aldrich Urgent Petition submitted in App. Nos. 15/188,911; 15/188,924; and 15/456,204, filed July 19, 2019</td>
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<tr>
<td>Exhibit 4008</td>
<td>U.S. Appl. No. 14/685,568</td>
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<td>Exhibit 4010</td>
<td>U.S. Appl. No. 15/188,911</td>
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<td>Exhibit 4011</td>
<td>U.S. Appl. No. 15/188,924</td>
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<td>Exhibit 4012</td>
<td>U.S. Appl. No. 15/456,204</td>
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<tr>
<td>Exhibit 4013</td>
<td>U.S. Patent No. 8,697,359</td>
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<td>Exhibit 4014</td>
<td>U.S. Patent No. 8,771,495</td>
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<tr>
<td>Exhibit 4015</td>
<td>U.S. Patent No. 8,795,965</td>
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<tr>
<td>Exhibit 4016</td>
<td>U.S. Patent No. 8,856,406</td>
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<td>Exhibit 4017</td>
<td>U.S. Patent No. 8,871,455</td>
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<tr>
<td>Exhibit 4018</td>
<td>U.S. Appl. No. 15/947,680</td>
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<td>Exhibit 4019</td>
<td>U.S. Appl. No. 15/981,807</td>
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<td>Exhibit 4020</td>
<td>U.S. Appl. No. 16/136,168</td>
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<td>Exhibit 4021</td>
<td>U.S. Appl. No. 16/136,175</td>
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<td>Exhibit 4023</td>
<td>U.S. Appl. No. 15/947,718</td>
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<td>Exhibit 4024</td>
<td>U.S. Appl. No. 15/981,808</td>
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<td>Exhibit 4025</td>
<td>U.S. Appl. No. 15/981,809</td>
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<td>Exhibit 4026</td>
<td>U.S. Appl. No. 16/136,159</td>
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<td>Exhibit 4027</td>
<td>U.S. Appl. No. 16/276,361</td>
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<td>Exhibit 4028</td>
<td>U.S. Appl. No. 16/276,365</td>
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<td>Exhibit 4029</td>
<td>U.S. Appl. No. 16/276,368</td>
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<td>Exhibit 4030</td>
<td>U.S. Appl. No. 16/276,374</td>
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<td>Exhibit 4031</td>
<td>U.S. Appl. No. 16/136,165</td>
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<td>Exhibit 4169</td>
<td>Interference Initial Memorandum, 58 pages</td>
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<td>Exhibit 4170</td>
<td>U.S. Pat. Appl. No., 15/947,680, Office communication regarding potential interference, filed January 7, 2019, 2 pages</td>
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<td>Exhibit 4172</td>
<td>U.S. Pat. Appl. No. 13/842,859, Amendment and reply and response to restriction requirement, filed April 13, 2015, 21 pages</td>
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<td>Exhibit 4173</td>
<td>U.S. Patent No. 10,266,850</td>
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<td>Exhibit 4175</td>
<td>U.S. Pat. Appl. No. 15/947,700, Office communication regarding potential interference, filed January 7, 2019, 2 pages</td>
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<td>Exhibit 4177</td>
<td>U.S. Pat. Appl. No. 15/981,807, Office communication regarding potential interference, filed January 25, 2019, 2 pages</td>
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<td>Exhibit 4178</td>
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<td>Exhibit 4179</td>
<td>U.S. Pat. Appl. No. 15/981,809, Office communication regarding potential interference, filed January 25, 2019, 2 pages</td>
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<td>Exhibit 4180</td>
<td>U.S. Pat. Appl. No. 16/136,159, Office communication regarding potential interference, filed May 29, 2019, 7 pages</td>
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<tr>
<td>Exhibit 4181</td>
<td>U.S. Pat. Appl. No. 16/136,165, Office communication regarding potential interference, filed May 29, 2019, 7 pages</td>
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<tr>
<td>Exhibit 4182</td>
<td>U.S. Pat. Appl. No. 16/136,168, Office communication regarding potential interference, filed May 29, 2019, 6 pages</td>
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<tr>
<td>Exhibit 4183</td>
<td>U.S. Pat. Appl. No. 16/136,175, Office communication regarding potential interference, filed May 29, 2019, 6 pages</td>
</tr>
<tr>
<td>Exhibit 4184</td>
<td>U.S. Pat. Appl. No. 16/276,365, Office communication regarding potential interference, filed August 21, 2019, 6 pages</td>
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<tr>
<td>Exhibit 4185</td>
<td>U.S. Pat. Appl. No. 16/276,368, Office communication regarding potential interference, filed August 21, 2019, 6 pages</td>
</tr>
<tr>
<td>Exhibit 4186</td>
<td>U.S. Pat. Appl. No. 16/276,374, Office communication regarding potential interference, filed August 21, 2019, 6 pages</td>
</tr>
<tr>
<td>Exhibit 4187</td>
<td>Paper 39, Senior Party Miscellaneous Motion 2 (Request for Reconsideration of Order Authorizing Motions/Setting Times), <em>The Broad Institute, Inc. v. The Regents of the University of California</em>, Interference No. 106,048, March 31, 2016, 18 pages</td>
</tr>
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APPENDIX 2

Senior Party Alleged Facts 1-45

1. A CRISPR-Cas9 system is a combination of protein (Cas9) and ribonucleic acid ("RNA") that can alter the genetic sequence of an organism. In their natural environment, CRISPR-Cas systems protect bacteria against infection by viruses. Ex. 3109, 048 Int., Decision on Motions 37 C.F.R §41.125 (a) at 2.

Response: Admitted, to the extent that Fact 1 intended to cite Ex. 3110 instead of Ex. 3109.

2. On October 5, 2012, Dr. Zhang submitted a manuscript to the journal Science reporting his successful implementation of CRISPR-Cas9 systems in eukaryotic cells. Ex. 3201 at 823.

Response: Admitted only that the Science article provided as Ex. 3201 names Dr. Zhang as one of the authors, notes an October 5, 2012 date without stating that it is a submission date, and states that “Cas9 nucleases can be directed by short RNAs to induce precise cleavage at endogenous genomic loci in human and mouse cells”; otherwise denied.


Response: Admitted only that Cong 2013 provided as Ex. 3201 states that the article “published online January 3, 2013”; otherwise denied.

Response: Admitted.

5. The 527 application disclosed successful engineering of CRISPR in eukaryotic cells.

Response: Denied.


Response: Admitted.


Response: Admitted.

9. The 086 application did not include any eukaryotic cell experiments. Id.

Response: Admitted only to the extent that the 61/652,086 provisional did not report a working example using the CRISPR-Cas9 system in a eukaryotic cell.

10. In June 2012, the CVC inventors published a paper, Jinek et al., A Programmable Dual-RNA-Guided DNA Endonuclease in Adaptive Bacterial Immunity, 337(6096) SCIENCE 816-21 (“Jinek 2012”), reporting the results of their cell-free experiments and disclosing a system with a covalently-linked, single molecule RNA. Ex. 3202.

Response: Admitted.

Response: Admitted.

12. The 256 provisional did not include any experiments in eukaryotic cells. Id.

Response: Admitted only to the extent that the 61/716,256 provisional did not report a working example using the CRISPR-Cas9 system in a eukaryotic cell.

13. In the 5 months since the filing of the 086 provisional, the CVC team experienced “many frustrations” trying to make CRISPR work in eukaryotes, as lead inventor Dr. Doudna later reported. Regents of Univ. of Cal. v. Broad, 903 F.3d at 1293 (“[Doudna] explained that she had ‘many frustrations’ in getting CRISPR-Cas9 to work in human cells, and that she thought success in doing so would be ‘a profound discovery.’” Ex. 3203, Pandika at 3; Ex. 3110, Dec. on Mot. at 15.

Response: Denied.


Response: Admitted.

15. The 640 provisional did contain examples indicated as being CRISPR experiments in eukaryotic cells. Id.

Response: Admitted that the 61/757,640 provisional reported a working example using the CRISPR-Cas9 system in a eukaryotic cell.

Response: Admitted that CVC filed the 13/842,859 application on March 15, 2013; denied that Ex. 4103 is CVC’s 13/842,859 application.

17. The 859 Application originally included claims reciting a eukaryotic cell limitation; for example, dependent claim 130 recited “wherein the host cell is a eukaryotic cell.” Ex. 3005, 859 Application, Original Claims at 215.

Response: Admitted.

18. In January 2015, CVC deleted all pending claims, including those reciting a eukaryotic environment. Ex. 3006, 859 App. Prelim. Amendment. CVC submitted a new set of claims that were all environment-free, with no claims reciting a eukaryotic limitation. Id.

Response: Admitted that CVC deleted pending claims reciting a eukaryotic-environment limitation, and submitted a new set of claims that did not recite a eukaryotic-environment limitation in the Preliminary Amendment filed on January 8, 2015 in the 13/842,859 application (Ex. 3006).

19. In April 2015, CVC filed a Suggestion for Interference seeking an interference between the 859 application and all of the claims in Broad’s eukaryotic CRISPR-Cas9 patents. See Ex. 3007, 859 Application, Suggestion for Interference Pursuant to 37 C.F.R. § 41.202 at 2.

Response: Admitted only that CVC filed a Suggestion for Interference in April 2015 seeking an interference between its 13/842,859 application and all claims of the following Broad patents: 8,697,359; 8,771,945; 8,795,965; 8,865,406; 8,871,445; 8,889,356; 8,895,308; 8,906,616; 8,932,814; and 8,945,839.

20. CVC proposed provoking the interference with its claims to environment-free, single-molecule RNA systems. Id at 2-3.
Response: Admitted that CVC filed a Suggestion for Interference in April 2015 seeking an interference involving its 13/842,859 application, which included claims limited to single-molecule systems and did not include claims limited to use in eukaryotic environments.

21. CVC suggested a count with alternative claims—the first half directed to a CRISPR-Cas9 system with a single RNA molecule as in its claims and the second half directed to a CRISPR-Cas9 system functioning in a eukaryotic cell as in Broad’s claims. Id. at 22, 50.

Response: Admitted.

22. In its Suggestion for Interference, CVC asserted that “there is an interference-in-fact between Claim 203 of the ’859 Application and Claim 18 of [Broad’s] ’359 Patent.” Id. at 55.

Response: Admitted.

23. CVC noted that claim 18 of Broad’s patent recites “the guide RNAs [sic] comprise a guide sequence fused to a tracr sequence” and asserted that “the guide RNA of Claim 18 of the ’359 Patent has essentially the same structure as the single molecule DNA-targeting RNA of the ’859 Application.” Id. at 54.

Response: Admitted.

24. According to CVC, the only distinction between the claims was Claim 18’s recitation of functionality in a eukaryotic cell. Id. at 54-55.

Response: Denied.

25. CVC asserted that it “would have been obvious for one of ordinary skill in the art to apply the Type-II CRISPR Cas system to eukaryotic cells once the system was demonstrated to function in vitro.” Ex. 3008, 859 Application, Suggestion for Interference Pursuant to 37 C.F.R. § 41.202, Appendix E at E-6, E-15.
Response: Admitted.

26. On January 11, 2016, the PTAB declared the 048 interference. Ex. 3101, 048 Int., Declaration of Interference.

Response: Admitted.

27. The PTAB designated all claims of Broad’s twelve issued patents and one allowed application as corresponding to Count 1 in the 048 Interference. Id at 12-13.

Response: Admitted to the extent that in the ’048 proceeding, the PTAB designated all claims of Broad’s twelve issued patents in the January 11, 2016 Declaration and all claims of Broad’s one allowed application in the March 17, 2016 Redeclaration as corresponding to Count 1.

28. CVC sought and obtained authorization to file a motion to substitute a count (UC Motion 3). Ex. 3104, 048 Int. Order at 10; Ex. 3108.

Response: Admitted.

29. CVC’s proposed count was directed to a CRISPR-Cas9 system with a single molecule RNA ("covalently linked"), but did not recite eukaryotic functionality. Ex. 3108 at 4.

Response: Admitted that CVC’s proposed count was directed to a CRISPR-Cas9 system with a single molecule RNA ("covalently linked"), and did not recite a eukaryotic-environment limitation.

30. Broad sought and obtained authorization to file a motion for no interference-in-fact based solely on the eukaryotic cell limitation recited in the 048 count and all of Broad’s claims, but not recited in any of CVC’s claims. Ex. 3109, 048 Int., Broad Substantive Motion 2 at 1-3.

Response: Admitted.
31. On a teleconference with the PTAB in March 2016, CVC specifically represented that it wanted to reserve the ability to address a responsive motion to add a claim. Ex. 3103, 048 Int., Int. Tel. Call Tr., March 10, 2016 Tr. at 24:3-22.

Response: Admitted only that CVC’s counsel stated: “I want to make sure that we reserve at least some point in time for us to address responsive motions because [CVC] certainly would want an opportunity to address a no interference in fact motion, any unpatentability attack, or any assertion that claims should be undesignated because any of the categories of undesignation we certainly have support for interfering claims, should [Broad] convince you that any of that subject matter is separately patentable. We just want to make sure we can address all of the issues with the parties.”

32. During the Initial Teleconference in the 048 Interference, CVC’s counsel acknowledged the ability to seek authorization to file a responsive motion to add a claim in response to a motion for no interference-in-fact. Id.

Response: Admitted only that CVC’s counsel stated: “I want to make sure that we reserve at least some point in time for us to address responsive motions because [CVC] certainly would want an opportunity to address a no interference in fact motion, any unpatentability attack, or any assertion that claims should be undesignated because any of the categories of undesignation we certainly have support for interfering claims, should [Broad] convince you that any of that subject matter is separately patentable. We just want to make sure we can address all of the issues with the parties.”

33. The discussion during the May 6, 2016 Conference Call regarding whether CVC should be permitted to “add a claim” was in the context of CVC’s proposed motion to substitute the Count. Id. at 23:20-24:22.
Response: Denied as incomplete. During the Conference Call, there was a discussion of CVC’s proposed motion to substitute the count. But the Board understood that CVC’s motion to add a claim was its Proposed Motion 5, “which would argue that each of UC’s involved claims should be designated as not corresponding to Count 1 and that a new claim, which does correspond to Count 1, should be added. Ex. 4187 (Request, Paper 39, at 13:1-14:7.)” Additionally, it appears that Fact 33 should cite Ex. 3106 instead of Ex. 3103.

34. In its May 11, 2016 Order, the PTAB reiterated its prior ruling that CVC was not authorized to add such a claim “because UC suggested this proceeding based on its assertion that its current claims interfere with all of the claims of Broad’s involved patents.” Ex. 3107 at 4.

Response: Denied as incomplete. The quoted language was one of multiple explanations in the PTAB’s decision. Other explanations include that the claim CVC sought to add was still in examination and that CVC could suggest additional interferences in the event that the claim was allowed. Id.

35. In the 048 Interference, the PTAB determined that there was no interference-in-fact between the claims of the parties. See Ex. 3110, Dec. on Mot. at 49.

Response: Admitted.

36. The PTAB found CVC’s environment-free claims did not render Broad’s claims obvious: “[T]he evidence shows that the invention of such systems in eukaryotic cells would not have been obvious over the invention of CRISPR-Cas9 systems in any environment, including in prokaryotic cells or in vitro, because one of ordinary skill in the art would not have reasonably expected a CRISPR-Cas9 system to be successful in a eukaryotic environment.” Id. at 2.
Response: Admitted that the PTAB found: “[T]he evidence shows that the invention of such systems in eukaryotic cells would not have been obvious over the invention of CRISPR-Cas9 systems in any environment, including in prokaryotic cells or *in vitro*, because one of ordinary skill in the art would not have reasonably expected a CRISPR-Cas9 system to be successful in a eukaryotic environment.” *Id.* at 2.

37. The PTAB further found that the evidence showed that a POSA in 2012 would not have expected success absent experiments in eukaryotic cells: “The contemporaneous statements cited by both parties persuade us that one of ordinary skill in the art would not have reasonably expected success before experiments in eukaryotic cells were done.” *Id.* at 23.

Response: Admitted only that the quoted language appears in Ex. 3110, Dec. on Mot. at 23.


Response: Admitted.


Response: Admitted.

40. On September 10, 2018, the Federal Circuit issued its decision affirming the PTAB’s Final Judgment. *Id.* at 1296.

Response: Admitted.

41. CVC’s claim 203 involved in the 048 Interference recited every element of its current claim 155, except the “eukaryotic cell” limitation. *Compare* Ex. 3008 at E-4-7; Paper 7, at 22.
Response: Admitted, to the extent that Fact 41 intended to refer to claim 156 of CVC’s 15/981,807 application instead of “current claim 155.”

42. On January 24, 2019, CVC submitted “Remarks” attempting to provoke a second interference against each of the Broad’s eukaryotic CRISPR claims at issue in the 048 Interference. Ex. 3009, U.S. Application 15/947,680, Remarks.

Response: Denied.

43. CVC proposed an interference count “limited to a single-guide RNA and a eukaryotic environment.” Id. at 1.

Response: Admitted only that CVC submitted Remarks in response to an examiner’s communication regarding a potential interference in the 15/947,680 application on January 24, 2019, and the Remarks proposed that the Office should consider “an interference count specifying that the Type-II CRISPR-Cas system is limited to a single-guide RNA and a eukaryotic environment.”

44. CVC’s Remarks identified all claims of the twelve Broad patents and one Broad application at issue in the 048 interference. Id. at 8.

Response: Admitted only to the extent that the Remarks submitted in the 15/947,680 application on January 24, 2019, identified 13 Broad patents and one Broad application, which include the 12 Broad patents and one Broad application at issue in the ’048 proceeding.

45. In a press release dated September 17, 2019, CVC stated that “PTAB’s recently declared interference” between fourteen CVC patent applications and Broad’s patents and one application “jeopardizes essentially all of the Broad's CRISPR patents involving eukaryotic cells.” Ex. 3204, Press Release, Univ. of Cal. Off. of the Pres. at 2.
Response: Admitted only to the extent that this press release was issued by the University of California, not CVC.
Junior Party Facts in Support of Opposition 1

46. The ’048 proceeding was directed to Broad’s claims limited to eukaryotes and CVC’s claims that were not so limited. Ex. 3110 (048 Decision on Motions). The present interference is directed to two sets of the parties’ claims that are all limited to eukaryotes. (Paper 23).

47. CVC exited the 048 proceeding with claims in its involved application dominating Broad’s claims involved in that proceeding, which the Office has since issued as U.S. Pat. No. 10,266,850. (Ex. 4173).

48. CVC was the first party to file a patent application identifying the necessary and sufficient components of a CRISPR-Cas system that cleaves or edits DNA. Ex. 3002 (CVC’s first provisional application.)

49. CVC’s patent applications have published with claims directed to the use of CRISPR in a variety of environments, including outside of cells, in prokaryotes, and in eukaryotes. See Ex3002; Ex3003; Ex3004; Ex4032; Ex4033; Ex4034; Ex 4018-4031.


51. CVC’s first provisional application—filed more than six months before Broad’s first patent application—included claims directed to CRISPR in eukaryotes, as well as claims that were not limited to CRISPR in any particular environment. (Ex. 3002) (compare, e.g. claim 54 with claims 61-69).

52. Broad was the fourth entity to file a patent application directed to CRISPR in eukaryotes. See Exs. 4001; 4002; 4008; Compare Exs. 4010-4012 with Exs4013-4017.
53. Broad accelerated examination of its applications, and changed its applications’ designation from post-AIA to pre-AIA during prosecution so that it could swear behind CVC’s earlier-filed application. (Compare Application Data Sheets (“ADSs”) filed in U.S. Application Nos. 14/256,912 (issued as the 8,945,839 patent); 14/105,031 (parent of the ’8,889,356 and 8,932,814 patents); 14/258,458 (issued as the 8,932,814 patent); 14/105,035 (parent of the 8,795,965 and 8,871,445 patents); 14/104,977 (parent of the 8,865,406 and 8,895,308 patents); 14/222,930 (issued as the 8,865,406 patent); 14/104,990 (parent of the 8,906,616 patent); 14/105,017 (issued as the 8,993,233 patent); and 14/226,274 (issued as the 8,999,641 patent)); the 8,697,359 patent Prosecution History, Declaration Under 37 C.F.R. §§ 1.132 and 1.131, filed January 30, 2014 (“Zhang Declaration”). Broad then obtained its involved patents without interference.

54. CVC’s involved claims have been found allowable but for resolution of issues under 35 U.S.C. §102(g). See Ex. 4187; Ex. 4188; Ex. 4189; Ex. 4190; Ex. 4191; Ex. 4192; Ex. 4193; Ex. 4194; Ex. 4195; Ex. 4196; Ex. 4197; Ex. 4198; Ex. 4199; Ex. 4200.

55. Broad has not cited a single case that applies Rule 127 to preclude an interference following a judgment of no-interference-in-fact or that applies any principle of estoppel based on a non-losing party’s failure to move to add claims.

56. CVC did not file a suggestion of interference here; the examiner suggested the interference before CVC filed any remarks related to a proposed interference count, and the PTAB declared it *sua sponte*. (Ex. 4169, Interference Initial Memoranda; Communication Regarding a Potential Interference); Ex. 4170, the 15/947,680 application, Notice issued on January 7, 2019; Ex. 4175, the 15/947,700 application, Notice issued on January 7, 2019; Ex. 4176, the 15/947,718 application, Notice issued on January 7, 2019; Ex. 4177, the 15/981,807
application, Notice issued on January 25, 2019; Ex. 4178, the 15/981,808 application, Notice
issued on January 25, 2019; Ex. 4179, the 15/981,809 application, Notice issued on January 25,
2019; Ex. 4180, the 16/136,159 application, Notice issued on May 29, 2019; Ex. 4181, the
16/136,165 application, Notice issued on May 29, 2019; Ex. 4182, the 16/136,168 application,
Notice issued on May 29, 2019; Ex. 4183, the 16/136,175 application, Notice issued on May 29,
2019; the 16/276,361 application, Notice issued on August 14, 2019 (not available on PAIR); Ex.
4084, the 16/276,365 application, Notice issued on August 21, 2019; Ex. 4185, the 16/276,368
application, Notice issued on August 21, 2019; Ex. 4186, the 16/276,374 application, Notice
issued on August 21, 2019; Interference No. 106,115, Declaration issued on June 24, 2019
(Paper 1) and Redeclaration issued on August 26, 2019 (Paper 23).

57. Broad and the public were on notice of CVC’s pursuit of eukaryotic claims,
because claims directed to CRISPR in eukaryotes were included in CVC’s first published
application filed March 15, 2013 (and published on November 28, 2013) before Broad filed its
first non-provisional application. Ex. 4188; Ex. 3002; Ex. 4172.

58. According to Broad, “CVC argued that the use of single-molecule RNA presents
a patentable distinction from the invention involved in the ’048 proceeding, while “Broad
disagrees” and argues that “CVC’s single-molecule RNA limitation does not provide a
patentable distinction over the count of the ’048 proceeding.” Motion at 17:9-18:3, including n.3.

59. Broad has contended that at least some of its claims are limited to single molecule
RNAs (e.g., “fused” or “covalently linked”) whereas other claims are not so limited. (See
generally Broad Substantive Motion 3 (Paper 268).)

60. Broad does not cite any case applying 35 U.S.C. § 101 as a basis to reject claims
directed to subject matter claimed in an issued patent.
CERTIFICATE OF SERVICE

I hereby certify that the foregoing OPPOSITION TO BROAD’S SUBSTANTIVE
MOTION 1 was filed via the Interference Web Portal by 5:00 PM Eastern Time on October 18,
2019, and thereby served on the attorney of record for the Senior Party pursuant to ¶ 105.3 of the
Standing Order. The foregoing was also served via email by 8:00 pm ET on counsel for the
Senior Party at:

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