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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

ASTERIAS BIOTHERAPEUTICS, INC,
Plaintiff,
v.
VIACYTE, INC.,
Defendant.

Case No. [12-cv-04813-WHO](#)

**ORDER DEFINING SCOPE OF CASE
AND DISCOVERY**

Re: Dkt. No. 48

INTRODUCTION

The present action is an appeal of an interference proceeding held before the Patent and Trademark Office (“PTO”). Defendant ViaCyte Inc. has moved to define the scope of the case and discovery in the appeal. After consideration of the memoranda and argument of counsel, the Court defines the scope of the case and discovery as set forth below.

BACKGROUND

Plaintiff Asterias Biotherapeutics, Inc. is the assignee of two patent applications filed by Gregory Fisk, the ‘447 application and the ‘875 application (collectively, the “Fisk Applications”). The Fisk Applications relate to a method for turning human stem cells into populations of cells capable of differentiating into insulin-producing cells normally found in the pancreas. The inventions disclosed in the then-pending Fisk Applications were published to the public on June 19, 2003.

Several months later, a patent application relating to the same invention was filed by an inventor named D’Amour. That application issued in 2009 as U.S. Patent No. 7,510,876 (the “D’Amour Patent”), while the Fisk Applications were still pending. The D’Amour Patent was subsequently assigned to defendant ViaCyte.

1 After seeing that the D’Amour Patent had been issued and covered the same invention
2 disclosed in his pending applications, Fisk instituted an interference proceeding with the Board of
3 Patent Appeals and Interferences of the PTO (the “Board”), seeking to demonstrate that he
4 invented the common subject matter of the Fisk Applications and the D’Amour Patent first. An
5 interference proceeding determines which invention has priority. Before reaching the priority
6 phase, the Board may address preliminary motions raising issues of patentability of the
7 applications and patents involved in the interference, such as lack of enablement, insufficient
8 written description, and inequitable conduct. If a decision on a preliminary motion determines that
9 one of the applications or patents is not patentable, the priority phase will not be reached.

10 Two separate interference proceedings were instituted by the Board: one between the ‘447
11 Application and the D’Amour Patent, in December 2009 (the “‘734 interference”), and one
12 between the ‘875 Application and the D’Amour Patent, in October 2011 (the “‘827 interference”).
13 Because the Fisk Applications were filed earlier than the application for the D’Amour Patent, Fisk
14 was declared the senior party in the interference proceeding and accorded a presumption of
15 priority (first inventor of the common subject matter).

16 Asterias asserts that the following motions filed by the parties were fully briefed and
17 addressed by the Board in the interference between the ‘477 application and the D’Amour Patent.

18 **1. Enablement**

19 D’Amour filed a motion arguing that the claims of Fisk’s ‘477 application were not
20 enabled, meaning that the application did not teach or “enable” a person of skill in the
21 art how to make and use the invention. On July 16, 2012, the Board granted
22 D’Amour’s motion, finding that the claims of the ‘477 application were not enabled.
23 Dkt. No. 48-3.

24 **2. Inequitable conduct**

25 Fisk filed a motion a seeking to take discovery regarding D’Amour’s alleged
26 inequitable conduct, beyond the limited discovery permitted in interference
27 proceedings. Dkt. No. 48-4. Fisk sought production of documents and to depose five
28 individuals: two of the inventors of the D’Amour patent, a ViaCyte employee who,

1 Fisk alleges, submitted a misleading declaration to the PTO during the prosecution of
2 the D'Amour patent, a ViaCyte employee who consulted regarding the declaration, and
3 the patent prosecutor that represented D'Amour during the prosecution. *Id.* at 9-10.

4
5 The Board denied Fisk's motion for additional discovery. Dkt. No. 48-5. The Board
6 surmised that Fisk did not have a *prima facie* case of inequitable conduct (if he had, he
7 would not be seeking deposition testimony of D'Amour witnesses). Consequently,
8 "[g]iven the Board's current backlog, it would not be the most efficient use of Board
9 resources from an overall docket management point of view to spend those resources
10 conducting trials to take live cross-examination testimony." *Id.* at 4. The Board noted
11 that its "decision declining to get into inequitable conduct in this interference does not
12 foreclose consideration of the issue in the event D'Amour ultimately prevails in the
13 interference and thereafter files an infringement action against Fisk. Inequitable
14 conduct can be raised in the infringement action, where Fed. R Civ. P. discovery is
15 available and the same clear and convincing standard of proof would be applicable."
16 *Id.* at 6.

17 **3. Anticipation**

18 Fisk filed a motion arguing that his '477 application anticipated¹ the claims of the
19 D'Amour patent, rendering the D'Amour patent invalid. The Board denied Fisk's
20 motion.

21 **4. Obviousness**

22 Fisk filed a motion asserting that the claims of the D'Amour patent are obvious
23 combinations of the '477 Application and other prior art references. The Board denied
24 Fisk's motion.

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26 _____
27 ¹ If a single item of prior art describes a claim, that item of prior art "anticipates" the claim and the
28 claim must be rejected under 35 U.S.C. Section 102. Sometimes, however, a claim is not
described in a single item of prior art, but instead is an obvious combination of two or more items
of prior art. In that case, the claim must be rejected under 35 U.S.C. Section 103 on
"obviousness" grounds.

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5. Definiteness

Fisk filed a motion asserting that the D’Amour patent fails to particularly point out and describe the bounds of the subject matter of the invention, as required under 35 U.S.C. Section 112, paragraph 2 (often called the definiteness requirement). The Board denied Fisk’s motion.

6. Exclusion of D’Amour’s expert witness

Fisk filed a motion to exclude the testimony of D’Amour’s expert witness, Dr. Wells. The Board denied Fisk’s motion.

Two additional motions fully briefed by the parties but not addressed by the Board are at issue:

7. Earlier priority dates

The parties filed various motions arguing that they were entitled to earlier priority dates. Asterias asserts that these motions were mooted when ViaCyte conceded priority. Dkt. No. 49 at 9. Asterias notes that “ViaCyte appears to continue to concede priority in this Section 146 action as well.” *Id.*

8. Amendment of claims of the Fisk applications

Fisk filed a motion to amend the claims of his ‘875 application. The Board did not address this motion.

In January 2012, ViaCyte withdrew its challenge to the Fisk Applications’ priority, but it continued to argue that the applications were not enabled. On July 16, 2012, the Board granted ViaCyte’s motion for judgment on the grounds that the Fisk Applications do not provide an enabling disclosure so that a person of skill in the art would be able to make and use the subject matter of the Fisk claims (Motion No. 1 listed above). The Board determined that the Fisk application does not enable the creation of the type of cells (definitive endoderm cells, or DE cells) required by the invention. Dkt. No. 48-3 at 13 (“D’Amour has demonstrated by a preponderance that HNF4 α is not a marker for DE cells, thus demonstrating that the cells

1 produced in Example 4 of the Fisk ‘477 Application are not the cells required by claim 15.’”).

2 The Board also found that Fisk’s ‘477 application and his ‘875 application were not
3 patentably distinct and granted a motion filed by D’Amour to bind the parties in the ‘827
4 interference—between the ‘875 application and the D’Amour Patent—to the Board’s enablement
5 decision in the ‘734 interference—between the ‘477 application and the D’Amour Patent. Dkt.
6 No. 48-6. The Board found that since the claims of the ‘477 application were not enabled, neither
7 were the claims of the ‘875 application. The Board granted judgment for ViaCyte, after which
8 Asterias filed the present action before this Court.

9 **LEGAL STANDARD**

10 A party dissatisfied with an adverse decision in an interference proceeding before the
11 Board may file a complaint in a district court. 35 U.S.C. § 146. Unlike a direct appeal to the
12 Federal Circuit under 35 U.S.C. Section 141, the parties in a Section 146 action before a district
13 court are not limited to the evidentiary record before the Board. “Because the record before the
14 district court may include the evidence before the Board as well as evidence that was not before
15 the Board,” the Federal Circuit has described a Section 146 action as “a hybrid of an appeal and a
16 trial *de novo*.” *Winner Int’l Royalty Corp. v. Wang*, 202 F.3d 1340, 1345 (Fed. Cir. 2000) (citation
17 omitted).

18 A district court in a Section 146 action may only consider issues which were adequately
19 raised in the interference proceeding. “In order for an issue to have been raised adequately so that
20 it qualifies for consideration in a § 146 proceeding, the issue should have been raised as specified
21 in the PTO’s interference rules, for example, through preliminary motions, motions to correct
22 inventorship, miscellaneous motions, belated motions delayed for good cause, or opposition to
23 these motions.” *Conservolite, Inc. v. Widmayer*, 21 F.3d 1098, 1102 (Fed. Cir. 1994).

24 **DISCUSSION**

25 Asterias’s Complaint requests that the Court overturn the Board’s decisions or find for
26 Asterias on each of the eight motions listed above. *See* Dkt. No. 49 at 11 (citing Compl. at 6:15-
27 21). Asterias also seeks to take discovery concerning the issues raised in each of those motions.
28 In contrast, ViaCyte argues that the Court’s review should be limited to four issues decided by the

1 Board: the enablement motion filed by ViaCyte and granted by the Board, and the anticipation,
2 obviousness, and indefiniteness motions filed by Fisk (Asterias), which the Board denied.

3 ViaCyte argues that the Court should not review the issue of inequitable conduct because
4 that issue was not addressed by the Board, Asterias’s assertion notwithstanding, and because it is
5 irrelevant to enablement, which will control the outcome of this matter. ViaCyte likewise argues
6 that the motions regarding earlier priority dates and amendment of the Fisk claims should not be
7 considered by the Court because they were not addressed by the Board and are irrelevant.

8 ViaCyte concedes that Fisk’s motion to exclude ViaCyte’s expert, Dr. Wells, was addressed by the
9 Board. But ViaCyte argues that the motion is moot because “just like Asterias, ViaCyte is entitled
10 to present live testimony to supplement the record. If Dr. Wells testifies on ViaCyte’s behalf, then
11 this Court will be able to judge for itself what weight to give Dr. Wells’ testimony. If a different
12 expert testifies on ViaCyte’s behalf, then the weight the Board gave to Dr. Wells’ testimony is
13 irrelevant.” Dkt. No. 50 at 7 n.3.

14 In sum, the parties dispute whether this action should include the issues of inequitable
15 conduct, exclusion of ViaCyte’s expert witness, amendment of the Fisk pleadings, priority of
16 invention, and the appropriate scope of discovery.

17 The Court finds that the public interest and judicial economy are best served if the Court
18 limits its review to the Board’s decisions on enablement, anticipation, obviousness, and
19 indefiniteness. If the issues not reached by the Board remain relevant after the Court’s review, the
20 Court will remand them to the Board for initial determination of the complex factual and legal
21 questions involved. It is central to the Court’s analysis that if the Court agrees with the Board that
22 the Fisk applications are not enabled, then the central dispute between the parties—which party
23 may claim the common subject matter of the D’Amour Patent and the Fisk Applications—is
24 resolved.

25 **A. Scope of district courts’ review in Section 146 Cases**

26 The Federal Circuit has explained that the “public interest in ensuring that only those
27 patents that claim patentable subject matter are issued and maintained is best served when a
28 district court considering review of a decision of the Board resolves all issues of priority and

1 patentability that have been raised *and fully developed*.” *Rexam*, 182 F.3d at 1370 (emphasis
 2 added). District courts may limit their review on Section 146 actions to those matters actually
 3 decided by the Board and refrain from addressing matters not decided by the Board. To the extent
 4 the unaddressed matters remain relevant after the district court’s review of the Board’s decision,
 5 those matter may be remanded to the Board. *See, e.g., Plumley v. Mockett*, No. 98-cv-6117, slip
 6 op. at 9 (C.D. Cal. June 4, 1999); *Enzo Therapeutics, Inc. v. Yeda Research & Dev. Co. of*
 7 *Weizmann Inst. of Sci.*, 477 F. Supp. 2d 699, 711 (E.D. Va. 2007); *Bio-Tech. Gen. Corp. v. Novo*
 8 *Nordisk Pharm., Inc.*, 2004 WL 1739722, *37-38 (D. Del. Aug. 3, 2004), *Goliath Hundertzehnte*
 9 *Vermögensverwaltungsgesellschaft mbH v. Yeda Research & Dev. Co., Ltd.*, 2003 WL
 10 22830014, *1 (D.D.C. Oct. 6, 2003).

11 Remanding issues not addressed by the Board is “consistent with the modern scheme of
 12 administrative law in which specialized agencies are responsible for initial decisions on complex
 13 factual and legal matters but are accountable on review to Article III judges.” *Plumley*, No. 98-cv-
 14 6117, slip op. at 9. Any party can then appeal the Board’s decision in a further Section 146 action.

15 **B. Inequitable conduct**

16 Asterias moved the Board for permission to take discovery to establish that D’Amour
 17 committed inequitable conduct by withholding material information and misleading the PTO
 18 during the prosecution of the D’Amour Patent. The motion did not seek to invalidate the
 19 D’Amour patent based on inequitable conduct; presumably that would have been the next step if
 20 Asterias obtained the discovery it hoped for. Recognizing as much, the Board noted that Asterias
 21 sought discovery because it lacked a *prima facie* case. The Board concluded that it did “not
 22 believe it is the interest of judgment to prolong this interference with yet *another motion*—a
 23 motion for “judgment” based on alleged in equitable conduct.” Dkt. No. 48-5 at 6 (emphasis in
 24 original). Nonetheless, it appears that Asterias asks the Court not only to overturn the denial of its
 25 motion to take discovery regarding inequitable conduct, but also to include the presumably
 26 subsequent allegations of inequitable conduct within the boundaries of this Section 146 action.

27 This the Court declines to do. If the Court affirms the Board’s finding of lack of
 28 enablement, the dispute between the parties will be resolved because Asterias will no longer have

1 a valid pending patent application. On the other hand, as ViaCyte notes, “[i]f this Court reverses
2 the Board’s decision, then the proceeding before this Court is over because ViaCyte does not
3 contest priority of invention.” Dkt. No. 50 at 6. As the Board noted, Asterias can still raise the
4 inequitable conduct issue if ViaCyte ultimately prevails in the interference and files an
5 infringement action against Asterias.

6 At oral argument, counsel for Asterias argued that in *Rexam*, the Federal Circuit instructed
7 that public interest is served by district courts addressing all issues of priority and patentability
8 raised in the interference proceeding, even where one issue resolves the dispute between the
9 parties. The Court does not agree that *Rexam* compels the Court to reach the issue of inequitable
10 conduct.

11 In *Rexam*, the Board declared an interference between Kodak and Rexam. The Board
12 entered judgment deciding the priority issue in favor of Kodak. *Rexam*, 182 F.3d at 1368. Rexam
13 then challenged the Board’s decision in a Section 146 action in district court. While the Section
14 146 action was pending, the Board declared an interference between Kodak and Avery, involving
15 the same Kodak claims at issue in the interference with Rexam. Kodak and Avery executed an
16 agreement that neither party would challenge the Board’s priority decision in the interference.
17 The Board entered judgment deciding priority in favor of Avery. Pursuant to its agreement with
18 Avery, Kodak allowed the Board’s decision to become final. As a result, Kodak’s claims—the
19 same claims which had been awarded priority in Kodak’s interference with Rexam—became
20 unpatentable to Kodak.

21 Even though Kodak’s claims had become unpatentable through the interference with
22 Avery, the Federal Circuit allowed Kodak to defend its award of priority against Rexam in the
23 Section 146 action. As the Federal Circuit explained, “[t]he reasoning is that, if Kodak has been
24 determined by the Board to have priority over Rexam, then Avery, which has similarly been
25 determined to have priority over Kodak, must have priority over Rexam, and Rexam should not
26 retain its patent.” *Rexam*, 182 F.3d at 1370. In other words, the Board had already determined
27 that Avery’s application invalidated Kodak’s application, and Kodak’s application invalidated
28 Rexam’s application, rendering Rexam’s application antedated (and invalidated) by both Avery’s

1 application (which was still patentable) and Kodak’s application. Accordingly, allowing Kodak to
2 defend its award of priority against Rexam in the Section 146 action was in the public interest as it
3 prevented Rexam from “retaining an invalid patent.” *Rexam*, 182 F.3d at 1371 (“Inasmuch as
4 Kodak’s award of judgment of priority by the Board prevents Rexam from retaining an invalid
5 patent, Kodak’s ability to defend its judgment reflects public policy.”).

6 *Rexam* is fundamentally different than this case and has no bearing on it. Unlike *Rexam*, in
7 this case there has been no determination by the Board that ViaCyte “should not retain its patent,”
8 because of inequitable conduct or otherwise. *Id.* at 1370. Unlike *Rexam*, limiting the scope of this
9 matter does not allow ViaCyte to “retain[] an invalid patent.” *Id.* at 1371. On the other hand, as
10 noted above, remanding the inequitable conduct issue to the Board if that issue becomes relevant
11 is “consistent with the modern scheme of administrative law in which specialized agencies are
12 responsible for initial decisions on complex factual and legal matters but are accountable on
13 review to Article III judges.” *Plumley*, No. 98-cv-6117, slip op. at 9; *see also Enzo*, 477 F. Supp.
14 2d at 711 (“To the extent that any of the parties’ claims relating to issues not yet resolved by the
15 Board remain after this proceeding, they will be remanded for further review by the Board.”); *Bio-*
16 *Tech.*, 2004 WL 1739722, *37-38; *Goliath*, 2003 WL 22830014, *1.

17 For the reasons stated, this action shall not encompass allegations of inequitable conduct
18 and Asterias shall not be permitted to take discovery regarding ViaCyte’s alleged inequitable
19 conduct.

20 **C. Exclusion of Dr. Wells’ testimony**

21 A ruling on the admissibility of Dr. Wells’ testimony is premature, as Asterias conceded at
22 oral argument. To the extent that ViaCyte intends to rely on Dr. Wells in the course of this action,
23 Asterias can raise objections to that testimony at that time. ViaCyte may also elect not to use Dr.
24 Wells. The Court presumes that both parties will seek to supplement the record, as they are
25 entitled to do. The Court will rule on evidentiary objections at the time that evidence is presented.

26 **D. Priority of invention**

27 ViaCyte has conceded priority. Accordingly, priority shall not be raised in this action and
28 discovery relating to priority of invention is precluded as it is irrelevant to this matter.

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E. Amendment of claims

Asterias concedes that “the Board never reached this issue of amendment of the Fisk claims.” Dkt. No. 49 at 17. The Court declines to reach it here. Rather, if necessary, the Court will remand the issue to the Board to allow the Court to benefit from the PTO’s specialized knowledge of the complex factual and legal matters at issue.

F. Scope of discovery

The question of the appropriate scope of discovery remains. ViaCyte argues that discovery regarding prosecution of the D’Amour Patent and enablement, conception and reduction to practice of the invention described in the D’Amour Patent is irrelevant to determining whether the Fisk applications are enabled. Dkt. No. 48 at 14 (“Because it is the specification of Plaintiff’s patent applications that is relevant to the question of enablement in this case, discovery related to the invention, or prosecution, of the D’Amour ‘876 patent serves no purpose.”). ViaCyte argues that discovery regarding the D’Amour patent is also irrelevant to the obviousness, anticipation and indefiniteness questions because “relevant evidence is limited to the prior art and the four corners of the D’Amour ‘876 patent.” *Id.* at 15. According to ViaCyte, “any information possessed by ViaCyte, or its employees, is completely irrelevant to the questions of both enablement and invalidity that have been decided by the Board.”

Asterias counters that discovery from ViaCyte is relevant because “it is probative of the knowledge and activities of skilled artisans in the field at the time of the Fisk invention, and whether undue experimentation is required to practice the Fisk invention.” Dkt. No. 49 at 23.

In its Reply, ViaCyte responds that its internal development documents and other confidential material are irrelevant to the issues of enablement, indefiniteness, obviousness and anticipation, because those issues are measured against the knowledge of a person of ordinary skill in the art at the time, and its confidential materials “do not constitute part of the knowledge of a person of ordinary skill in the art.” Dkt. No. 50 at 16. ViaCyte also notes that it invented its claimed subject matter after the Fisk application was filed and, consequently, its knowledge is not knowledge at the time of the Fisk application.

At oral argument, Asterias’s counsel urged that if ViaCyte was practicing the invention as

1 disclosed in the Fisk Applications, that would suggest that the Fisk Applications were enabled,
2 contrary to the Board’s finding of lack of enablement.

3 Both parties raise legitimate points. ViaCyte is correct that its confidential information is
4 not relevant to the knowledge of a person of ordinary skill in the art. *See, e.g., Custom*
5 *Accessories, Inc. v. Jeffrey-Allan Indus., Inc.*, 807 F.2d 955, 962 (Fed. Cir. 1986) (“The person of
6 ordinary skill is a hypothetical person who is presumed to be aware of all the pertinent prior art.”);
7 *Kimberly-Clark Corp. v. Johnson & Johnson*, 745 F.2d 1437, 1453 (Fed. Cir. 1984) (prior art is
8 “knowledge that is available, including what would be obvious from it, at a given time, to a person
9 of ordinary skill in an art”). But Asterias is correct that if ViaCyte employees successfully
10 practiced the Fisk Applications, that would be probative of the Fisk Applications’ enablement.

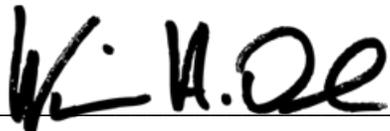
11 Accordingly, Asterias may seek discovery directly from ViaCyte relating to ViaCyte’s
12 practice or use of the Fisk Applications, but not with respect to the broader category of
13 confidential material it sought. There are other sources for evidence demonstrating what a person
14 of ordinary skill in the art would have known besides a competitor’s employees who were working
15 with proprietary information on a different patent.

16 **CONCLUSION**

17 The scope of this case shall be limited to whether the Fisk applications have sufficient
18 enabling support for the subject matter claimed, whether the claims of the D’Amour Patent are
19 invalid as anticipated or obvious, and whether the claims of the D’Amour Patent are indefinite.
20 The scope of discovery in this case from ViaCyte shall be limited to enablement, specifically
21 ViaCyte’s practice or use of the Fisk Applications.

22 **IT IS SO ORDERED.**

23 Dated: January 9, 2014

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25 _____
26 WILLIAM H. ORRICK
27 United States District Judge
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