In the United States Court of Federal Claims

No. 15-1549C
(E-Filed: December 20, 2019)

UNIVERSITY OF SOUTH FLORIDA, BOARD OF TRUSTEES, Plaintiff, v. THE UNITED STATES, Defendant.	Patent; Invalidity and Government License Defenses Challenged by Plaintiff's Motions for Partial Summary Judgment; RCFC 56; Genuine Disputes of Material Fact.

Steven B. Kelber, Washington, DC, for plaintiff. Jerry Stouck, Washington, DC, of counsel.

Walter W. Brown, Senior Litigation Counsel, with whom were Joseph H. Hunt, Assistant Attorney General, and Gary L. Hausken, Director, Commercial Litigation Branch, Civil Division, United States Department of Justice, Washington, DC, for defendant.

OPINION

CAMPBELL-SMITH, Judge.

In this patent infringement suit, the court has before it the parties' briefing of four motions for partial summary judgment filed by plaintiff, which address various defenses raised by defendant against plaintiff's infringement contentions based on United States Patent No. 5,898,094, hereinafter the '094 patent. The court has considered the following filings: (1) plaintiff's final infringement contentions, ECF No. 105; (2) defendant's final invalidity contentions, ECF No. 106; (3) plaintiff's motion for partial summary judgment asserting that "Claims 7, 8, 10 and 11 Are Not Invalid under 35 U.S.C. § 112" (Section 112 Motion), ECF No. 116; (4) plaintiff's motion for partial summary judgment asserting that the "Patent . . . Is Not Invalid by Reason of Prior Inventorship [under] 35 U.S.C. § 102(g)" (Section 102(g) Motion), ECF No. 117; (5) plaintiff's motion for partial summary judgment asserting that the "United States Does Not Enjoy a License under 35 U.S.C. § 202" (Section 202 Motion), ECF No. 118; (6) plaintiff's motion for partial summary judgment asserting that the "Patent . . . is Entitled to an Effective Filing Date of

October 21, 1996" (Effective Date Motion), ECF No. 119; (7) plaintiff's exhibits, ECF No. 121; (8) defendant's response to Section 112 Motion, ECF No. 129; (9) defendant's opposition to Section 102(g) Motion, ECF No. 130; (10) defendant's opposition to Section 202 Motion, ECF No. 131; (11) defendant's opposition to Effective Date Motion, ECF No. 132; (12) defendant's exhibits, ECF No. 134; (13) plaintiff's reply in support of Effective Date Motion, ECF No. 135; (14) plaintiff's reply in support of Section 202 Motion, ECF No. 136; (15) plaintiff's reply in support of Section 102(g) Motion, ECF No. 137; (16) plaintiff's submission of recent authority, ECF No. 138; (17) defendant's supplemental response to plaintiff's submission of recent authority, ECF No. 140; and (18) plaintiff's supplemental reply brief, ECF No. 141. Oral argument was deemed unnecessary. Plaintiff's four motions for partial summary judgment are ripe for decision. For the reasons set forth below, all of plaintiff's motions for partial summary judgment are **DENIED**.

I. Background

Plaintiff University of South Florida, Board of Trustees (USF) holds the rights to the '094 patent, which is titled "Transgenic Mice Expressing APPK670N,M671L and a Mutant Presenilin Transgenes." ECF No. 121-10 at 2-12. The '094 patent issued on April 27, 1999. Id. at 2. The invention in the '094 patent is presented in fourteen claims. Id. at 11-12. The claims all discuss a "transgenic mouse" or the methods for screening transgenes and/or for preparing the transgenic mice, id., which are also sometimes described as "doubly transgenic" mice, id. at 8. Such mice are of utility in the research of Alzheimer's Disease (AD) and other neurodegenerative disorders. Id. at 5.

On December 28, 2015, plaintiff filed suit under 28 U.S.C. § 1498(a) (2012), seeking "recovery of monetary compensation for the unlicensed use, manufacture and infringement by or on behalf of the United States of" the '094 patent. ECF No. 1 at 1 (complaint). Plaintiff asserts that all fourteen of the claims in the '094 patent have been infringed by the United States, although plaintiff will only rely on claims 1, 3, 5, and 7-13 as it attempts to prove in this suit that these particular claims have been infringed. ECF No. 105 at 1.

The court will not discuss, in detail, the science underlying the invention in the '094 patent, because each of plaintiff's motions has a narrow focus on a legal question. The court also finds it unnecessary to relate the lengthy procedural history of this matter. The disputes now before the court are premised on plaintiff's final infringement contentions, ECF No. 105, and defendant's final invalidity contentions, ECF No. 106.

According to defendant, the '094 patent describes a transgenic mouse with two useful mutations: a mutation involving the Amyloid Precursor Protein (APP) gene and another mutation involving the presenilin-1 (PS-1) gene, located on chromosomes 21 and 14, respectively. ECF No. 106 at 7 & n.8. In defendant's view, the "resulting '094 Patent discloses a single transgenic mouse strain that produces ('expresses') one

particular APP mutation (APPswe) and one particular PS-1 mutation (M146L) such that the mouse has accelerated brain deposition of Aβ protein." Id. at 12; see also id. at 8 (explaining that the APPswe mutation references a mutation that was "isolated in two Swedish families"). The accumulation of brain deposits of Aβ protein, hereinafter Aβ, Aβ-42, or amyloid deposits/plaques, is linked to Alzheimer's Disease. Id. at 6.

Plaintiff does not concur with defendant's interpretation of the '094 patent. The invention has been infringed, in plaintiff's view, because "each of the accused [transgenic] mice comprises a transgene encoding the APP gene with site mutations K670N and M671L (together often referred to as the APPswe or Swedish mutation) and a mutant presenilin transgene, both transgenes operatively linked to promoters so that the accused [transgenic] mice express both transgenes." ECF No. 105 at 1-2. It is not important, for the purposes of this opinion, to address the parties' dispute as to the scope of the invention in the '094 patent.

Plaintiff's four motions for partial summary judgment are focused on eliminating four challenges to either the validity of the '094 patent or plaintiff's infringement contentions. These challenges, and others, were raised, or at least mentioned, in the government's final invalidity contentions filing, ECF No. 106. Once the court has resolved plaintiff's four motions for partial summary judgment, the parties will undertake expert discovery and trial preparation. See ECF No. 127 (scheduling order).

For their arguments regarding three of defendant's four challenges to the '094 patent and plaintiff's infringement contentions, the parties agree that this case is governed by statutes that were in place in 1999, because the '094 patent issued on April 27, 1999, not by various revisions to those statutes instituted by the Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) (AIA). ECF No. 106 at 15 n.22; ECF No. 116 at 1 n.1; ECF No. 117 at 6 n.2; ECF No. 119 at 1 n.2. For plaintiff's Section 202 Motion, ECF No. 118, the parties have not specified what version of the United States Code applies. For the court's discussion of plaintiff's Section 202 Motion, the court relies on 35 U.S.C. §§ 201-202 (1994). The court turns, first, to the standard of review for summary judgment motions. The court will then consider each of plaintiff's motions for partial summary judgment, in turn.

II. Legal Standard

According to the Rules of the United States Court of Federal Claims (RCFC), summary judgment is appropriate "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." RCFC 56(a). "[A]ll evidence must be viewed in the light most favorable to the nonmoving party, and all reasonable factual inferences should be drawn in favor of the nonmoving party." Dairyland Power Coop. v. United States, 16 F.3d 1197, 1202 (Fed. Cir. 1994) (citations omitted).

The Supreme Court of the United States has instructed that "the mere existence of some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no genuine issue of material fact." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 247-48 (1986). A genuine dispute of material fact is one that could "affect the outcome" of the litigation. Id. at 248.

A summary judgment motion is properly granted against a party who fails to make a showing sufficient to establish the existence of an essential element to that party's case and for which that party bears the burden of proof at trial. Celotex Corp. v. Catrett, 477 U.S. 317, 324 (1986). A nonmovant will not defeat a motion for summary judgment "unless there is sufficient evidence favoring the nonmoving party for [the fact-finder] to return a verdict for that party." Anderson, 477 U.S. at 249 (citation omitted). "A nonmoving party's failure of proof concerning the existence of an element essential to its case on which the nonmoving party will bear the burden of proof at trial necessarily renders all other facts immaterial and entitles the moving party to summary judgment as a matter of law." Dairyland Power, 16 F.3d at 1202 (citing Celotex, 477 U.S. at 323).

III. Analysis

A. Section 112 Motion (asserting that claims 7, 8, 10, and 11 are not invalid under 35 U.S.C. § 112 (1994))

Plaintiff asserts that "Claims 7, 8, 10 and 11 of the patent-in-suit . . . are not invalid by reason of failure to satisfy the written description and enabling disclosure requirement of 35 U.S.C. §112, first paragraph." ECF No. 116 at 1 (citing 35 U.S.C. § 112, ¶ 1 (1994)) (footnote omitted). Plaintiff references in its motion defendant's final invalidity contentions, ECF No. 106. Defendant has withdrawn this particular invalidity challenge to the '094 patent. See ECF No. 129 at 1. Because defendant has withdrawn its challenge to "claims 7, 8, 10 and 11 of the '094 patent . . . for failure to satisfy the written description and enabling disclosure requirement of 35 U.S.C. §112, first paragraph," ECF No. 129 at 1, the court denies plaintiff's Section 112 Motion, ECF No. 116, as moot.[1]

B. Section 102(g) Motion (asserting that the '094 patent is not invalid by reason of prior inventorship under 35 U.S.C. § 102(g) (1994))

[1] Although plaintiff sees the withdrawal of this infringement defense as the government's concession that the'094 patent meets all requirements of section 112, ¶ 1, ECF No. 135 at 1, defendant avers that the government has made no such concession, ECF No. 129 at 1. The court does not reach the topic of the government's alleged concession regarding section 112 in this opinion.

Plaintiff's Section 102(g) Motion focuses on the efforts of two teams of scientists to produce doubly transgenic mice that would be useful in AD research. The inventors who filed the '094 patent, Dr. John Hardy and Dr. Karen Duff, led the Hardy/Duff team at the University of South Florida. ECF No. 117 at 5, 8-9. Dr. David Borchelt and Dr. Sangram Sisodia at Johns Hopkins University, along with other colleagues, were the Borchelt team, who were also breeding and studying transgenic mice. Id. at 5, 10-12. One of defendant's invalidity challenges to the '094 patent, under 35 U.S.C. § 102(g) (1994), relies on the allegation that the Borchelt team was the prior inventor of the invention described in Claims 7, 8, 10, and 11 of the '094 patent. ECF No. 106 at 14-17.

Plaintiff's Section 102(g) Motion argues that Dr. Borchelt did not have a conception of the invention in the '094 patent before April 25, 1997, when, at the latest, the Hardy/Duff team achieved reduction to practice of the invention. ECF No. 117 at 15-16. This factual assertion is the basis for plaintiff's conclusion that no prior inventorship, under section 102(g) and Hitzeman v. Rutter, 243 F.3d 1345 (Fed. Cir. 2001), invalidates the '094 patent. ECF No. 117 at 15-18. The dominant theme in plaintiff's motion is that Dr. Borchelt did not conceive of the invention within a time-frame that could possibly invalidate the '094 patent. Id. at 5, 10-12, 15-20.

Plaintiff asserts only one argument that would permit the entry of partial summary judgment on this invalidity defense brought by defendant.[2] Plaintiff contends that because there are no genuine disputes of material fact as to the timing of Dr. Borchelt's conception of the invention in the Claims 7, 8, 10, and 11 of the '094 patent, plaintiff is entitled to summary judgment as a matter of law on defendant's section 102(g) challenge to the '094 patent. See id. at 15 ("The undisputed facts show this is not something the United States can prove."). Plaintiff's Section 102(g) Motion cannot be granted, however, because there are genuine disputes of material fact regarding the timing of Dr. Borchelt's conception of the invention in the '094 patent.

1. Prior Inventorship Invalidity, Based on Conception Prior to a Competitor's Reduction to Practice

The narrow question here is whether the Borchelt team conceived of the invention described in Claims 7, 8, 10, and 11 of the '094 patent before April 25, 1997. As alleged by defendant, prior inventorship is demonstrated by the Borchelt team having been "'the first party to conceive of the invention and then [having] exercised reasonable diligence in reducing that invention to practice.'" ECF No. 130 at 26 (quoting Mycogen Plant Sci., Inc. v. Monsanto Co., 243 F.3d 1316, 1332 (Fed. Cir. 2001)). When attempting to overcome this type of prior inventorship invalidity defense, a patentee, such as USF, could challenge its competitor's date of conception, as well as the competitor's

[2] Plaintiff also raises a new argument in its reply brief which, as discussed infra, is waived as untimely.

"reasonable diligence" and "reduction to practice" of the invention. See 35 U.S.C. § 102(g) (1994) (noting that for prior inventorship questions, "there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other"); see also ECF No. 130 at 38 (citing Monsanto Co. v. Mycogen Plant Sci., Inc., 261 F.3d 1356, 1369 (Fed. Cir. 2001), for the "reasonable diligence" requirement for prior inventorship invalidity); id. (citing Teva Pharm. Indus. Ltd. v. AstraZeneca Pharm. LP, 661 F.3d 1378, 1383 (Fed. Cir. 2011), for the "reduction to practice" requirement for prior inventorship invalidity). Because plaintiff's Section 102(g) Motion focuses solely on the conception issue, the facts relevant to the timing of the Borchelt team's conception of the invention inform the resolution of plaintiff's motion.

2. Conception Caselaw

The parties cite to a number of cases which discuss the aspects of conception that are relevant to defendant's prior inventorship challenge to the '094 patent. Among these cases are Hitzeman, cited by plaintiff, ECF No. 117 at 15-16, 18; ECF No. 137 at 4-5, and Burroughs Wellcome Co. v. Barr Labs., Inc., 40 F.3d 1223 (Fed. Cir. 1994), cited by defendant, ECF No. 130 at 31, 35. Although Hitzeman and Burroughs Wellcome are not in conflict, the court finds that Burroughs Wellcome presents the articulation of the law that is most instructive here.

The court notes that in Hitzeman, the Federal Circuit itself describes Burroughs Wellcome as providing the articulation of the "legal standard for conception." Hitzeman, 243 F.3d at 1356. Thus, although Hitzeman is relevant precedent for this case, it is not essential to apply Hitzeman when addressing the elements of conception in the context of plaintiff's Section 102(g) Motion.

The Federal Circuit's definition of "conception" includes this statement:

> It is the formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice. Conception is complete only when the idea is so clearly defined in the inventor's mind that only ordinary skill would be necessary to reduce the invention to practice, without extensive research or experimentation.

Burroughs Wellcome, 40 F.3d at 1228 (internal quotations and citations omitted). The Federal Circuit offered additional commentary:

> An idea is definite and permanent when the inventor has a specific, settled idea, a particular solution to the problem at hand, not just a general goal or research plan he hopes to pursue. The conception analysis necessarily turns on the inventor's ability to describe his invention with particularity. Until he

> can do so, he cannot prove possession of the complete mental picture of the invention. These rules ensure that patent rights attach only when an idea is so far developed that the inventor can point to a definite, particular invention.

Id. (citations omitted). Further, the Federal Circuit noted that "an inventor need not know that his invention will work for conception to be complete. He need only show that he had the idea; the discovery that an invention actually works is part of its reduction to practice." Id. (citations omitted).

Two other aspects of conception, as used in a prior inventorship invalidity defense, are made clear by the parties' citation to precedent. First, the evidence of conception must show that the putative prior inventor's "completed thought [was] expressed in such clear terms as to enable those skilled in the art to make the invention." Coleman v. Dines, 754 F.2d 353, 359 (Fed. Cir. 1985) (internal quotations and citation omitted); see ECF No. 130 at 29 (citing Coleman); ECF No. 137 at 4 (citing Coleman). Second, the prior inventor must be shown to have possessed a contemporaneous "recognition or appreciation of the existence of the [invention]." Silvestri v. Grant, 496 F.2d 593, 597 (C.C.P.A. 1974) (citations omitted); see ECF No. 130 at 31 (citing Silvestri).

3. Conception Not Always Susceptible to Resolution on Summary Judgment

Plaintiff acknowledges that conception "may be difficult to resolve in the absence of testimony." ECF No. 137 at 1 (citing generally to Fox Grp., Inc. v. Cree, Inc., 700 F.3d 1300 (Fed. Cir. 2012)). In this case, the conception issue which is relevant to Claims 7, 8, 10, and 11 of the '094 patent requires a close examination of the evidence proffered by the parties regarding the research activities and communications of Dr. Borchelt and the Borchelt team. In analogous cases, the Federal Circuit has held that conflicting evidence would require further factual development before conception could be proved or disproved. For example, in Burroughs Wellcome, the invention of a drug that would boost T-cells in HIV-positive patients could not be clearly proved to have been "conceived" of by certain researchers until further factual development had occurred at the trial court level. 40 F.3d at 1232. Judgment entered by the district court for the moving party on the issue of conception in that case, for that particular patent, was inappropriate because the evidence was mixed and favorable inferences were to be accorded to the nonmoving party. Id.

In an analogous decision, the Federal Circuit again held that summary judgment should not have been entered on the conception issue. Invitrogen Corp. v. Clontech Labs., Inc., 429 F.3d 1052 (Fed. Cir. 2005). In Invitrogen, the patentee was "not . . . the first to explore the" science of its invention. Id. at 1058. An alleged infringer convinced the district court that a team of researchers at Columbia University had conceived of the invention so as to invalidate Invitrogen's patent pursuant to the prior inventorship provision of section 102(g). Id. at 1058-60. The Federal Circuit disagreed, because, in

part, the district court ignored genuine issues of material fact as to the conception of the invention by the Columbia researchers. Id. at 1057, 1063-69. Indeed, neither party could prevail on the conception issue at the summary judgment phase of that litigation. Id. at 1069.

Simply put, a summary judgment motion, from either party, which attempts to establish or disprove conception by a team of researchers may be defeated if there are genuine disputes of material fact. The court notes, too, that as regards plaintiff's Section 102(g) Motion in this case, all favorable factual inferences must be accorded defendant, the nonmovant. See id. (noting in the Invitrogen case that "the factual inferences must be drawn adverse to" the party moving for summary judgment on the conception issue). Defendant's evidence regarding conception by the Borchelt team, however, must itself be adequate to support an inference of conception in order to create a genuine dispute of material fact. See Creative Compounds, LLC v. Starmark Labs., 651 F.3d 1303, 1312-13 (Fed. Cir. 2011) (finding that a speculative email as to the potential viability of a method for producing a certain dietary supplement was not sufficient to create a genuine issue of material fact regarding conception for the purpose of a section 102(g) invalidity challenge). In other words, failure to adduce sufficient evidence in support of prior inventorship can justify summary judgment in favor of the patentee, because the challenger of the patent bears the burden of proof on its invalidity defense. See, e.g., Apotex USA, Inc. v. Merck & Co., 254 F.3d 1031, 1036 (Fed. Cir. 2001) (stating that "the party challenging a patent must prove facts supporting a determination of invalidity by clear and convincing evidence" (citing Am. Hoist & Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350, 1360 (Fed. Cir. 1984))).

4. Genuine Disputes of Material Fact in the Evidence of Conception by the Borchelt Team

The court reviews here the parties' principal sources of evidence addressing the question of whether the Borchelt team possessed conception of the invention in Claims 7, 8, 10, and 11 of the '094 patent before April 25, 1997. The parties rely extensively on statements made by Dr. Borchelt in his deposition, ECF No. 121-2, and in a declaration submitted in support of defendant's opposition to plaintiff's Section 102(g) Motion, ECF No. 134-14. Defendant also relies extensively on Dr. Borchelt's laboratory notebooks to establish the dates of certain research activities. ECF No. 134-3; ECF No. 134-5; ECF No. 134-6. Finally, defendant relies on contemporaneous documentation of Dr. Borchelt's research activities, such as documents related to his National Institutes of Health (NIH) grants, to indicate the objectives and timing of some of Dr. Borchelt's research. ECF No. 134-12. As the court explains infra, when defendant is accorded all reasonable favorable inferences as to the meaning of this evidence, genuine disputes of material fact prevent the entry of summary judgment in favor of plaintiff on its Section 102(g) Motion.

The court has compared the text of Dr. Borchelt's deposition with the conclusions drawn by the parties based on excerpts from his deposition. In the court's view, Dr. Borchelt's deposition testimony is not conclusive as to the conception issue. Indeed, the parties' own briefs show that Dr. Borchelt's deposition testimony can be read in a number of ways.

Plaintiff contends that Dr. "Borchelt testified he made the conscious decision NOT to pursue research into th[e] subject matter [of the '094 patent] for a very clear and understandable reason." ECF No. 117 at 5. According to plaintiff, Dr. "Borchelt's group made a decision in 1996 not to wait to conduct experiments on doubly transgenic mice to see if they would form amyloid plaques or deposits earlier than the parental lines because it would take too much time to age the mice, and Borchelt wanted to publish something new before then." Id. at 10-11 (citing ECF No. 121-2 at 11) (deposition transcript of Dr. David Borchelt). Plaintiff concludes that Dr. "Borchelt himself testified that he did not make or have that conception [of doubly transgenic mice showing accelerated AD pathology] in 1996." Id. at 16.

Defendant characterizes plaintiff's argument as a distortion and misrepresentation of Dr. Borchelt's statements. ECF No. 130 at 8, 12. According to defendant, Dr. Borchelt's deposition testimony shows that he bred mice for the study of amyloid deposits at an early stage of his research. Id. at 19 (citing ECF No. 121-2 at 18, 38). Thus, defendant concludes that "Dr. Borchelt made clear that his group was seeking to make models that exhibited aspects of the pathology for Alzheimer's disease, particularly accelerated Aβ deposition (or plaques), so as to better understand the mechanisms of the disease." Id. at 32 (citing ECF No. 121-2 at 8-9, 23).

It would not be appropriate for the court to weigh the evidence in Dr. Borchelt's deposition testimony during the summary judgment phase of this litigation. Anderson, 477 U.S. at 255. The Borchelt team's possession, or lack of possession, of the conception of the invention before April 25, 1997, is the subject of a genuine dispute of material fact when Dr. Borchelt's deposition testimony relevant to this topic is considered. Further, the other types of evidence relied upon by the parties also give rise to genuine disputes of material fact.

Plaintiff seeks to discount Dr. Borchelt's declaration: "The Government's efforts to pursue further testimony from Dr. Borchelt after his deposition was concluded offers no suggestion, much less evidence, that Dr. Borchelt and his co-workers understood or appreciated the doubly transgenic mice they were breeding would exhibit accelerated Alzheimer's Disease related pathology." ECF No. 137 at 6. Indeed, plaintiff characterizes Dr. Borchelt's declaration as "ex parte inadmissible hearsay." Id. at 8. Defendant, on the other hand, points to Dr. Borchelt's declaration as evidence that helps to establish the timing and nature of Dr. Borchelt's research activities. ECF No. 130 at 35-36 (citing ECF No. 134-14 at 3-4) (Declaration of Dr. David Borchelt). In the court's

view, the statements in Dr. Borchelt's declaration, coupled with his deposition testimony, create genuine disputes of material facts on the conception issue.

Lastly, the court considers the contemporaneous documentation relied upon by defendant, which includes Dr. Borchelt's laboratory notebooks and grant materials. "Documentary or physical evidence that is made contemporaneously with the inventive process provides the most reliable proof that the inventor's testimony has been corroborated." Sandt Tech., Ltd. v. Resco Metal & Plastics Corp., 264 F.3d 1344, 1350-51 (Fed. Cir. 2001) (citing Woodland Trust v. Flowertree Nursery, Inc., 148 F.3d 1368, 1373 (Fed. Cir. 1998)). Defendant's version of events is buttressed by numerous citations to Dr. Borchelt's laboratory notebooks and grant materials. ECF No. 130 at 18-21, 32-33, 35-36. Defendant has shown that there is relevant documentary evidence regarding the research activities of the Borchelt team that, coupled with Dr. Borchelt's statements, might be sufficient to establish conception before April 25, 1997.

But the evidence in the record regarding conception by the Borchelt team is mixed, with genuine disputes of material fact preventing the entry of summary judgment for plaintiff. When such disputes exist, the "record will benefit from further factual development." Oney v. Ratliff, 182 F.3d 893, 897 (Fed. Cir. 1999). As informed by the relevant law, the court must deny plaintiff's Section 102(g) Motion.

5. Lack of Corroborating Evidence Challenge Waived

Plaintiff raises a new argument in its reply brief, contending that the evidence of Dr. Borchelt's conception of the invention in Claims 7, 8, 10, and 11 of the '094 patent before April 25, 1997, fails as a matter of law because of a lack of corroborating evidence. ECF No. 137 at 7-9, 11. According to plaintiff's reply brief, "[p]rior conception presents the special requirement of corroboration of any evidence provided by an alleged inventor." Id. at 6 (citing Price v. Symsek, 988 F.2d 1187, 1195 (Fed. Cir. 1993)). In this case, plaintiff states that "[n]o one, at all, corroborates such an invention made by Borchelt et al" within the appropriate time-frame. Id. at 11. Plaintiff concludes that "the absence of such corroboration is . . . fatal to the Government's defense of prior inventorship." Id.

Because this argument was not made until plaintiff filed its reply brief, it is waived. See, e.g., Arakaki v. United States, 62 Fed. Cl. 244, 246 n.9 (2004) ("The court will not consider arguments that were presented for the first time in a reply brief or after briefing was complete." (citing Novosteel SA v. United States, 284 F.3d 1261, 1274 (Fed. Cir. 2002); Cubic Def. Sys., Inc. v. United States, 45 Fed. Cl. 450, 467 (1999))).[3]

[3] Even if this argument were not waived, the factual basis for plaintiff's corroboration argument is insufficiently developed, preventing the court from concluding that there are no genuine disputes of material fact regarding the adequacy of the corroboration of the Borchelt

C. Section 202 Motion (asserting that the United States does not enjoy a license to the invention under 35 U.S.C. § 202 (1994))

Plaintiff's Section 202 Motion addresses the issue of whether the United States can defeat plaintiff's infringement contentions by asserting a "government license" to the invention. See ECF No. 118. When the government asserted various invalidity defenses against the '094 patent, defendant noted that its government license defense was not specifically addressed in its brief. ECF No. 106 at 3 n.1. Plaintiff challenges defendant's government license defense, which is founded on the provisions codified at 35 U.S.C. § 202 (1994).

Defendant's citation to the legislation giving rise to section 202 is to the Bayh-Dole Act, also known, more formally, as An Act to Amend the Patent and Trademark Laws, Pub. L. No. 96-517, 94 Stat. 3015 (1980). ECF No. 131 at 22 & n.5. In essence, the parties' dispute focuses on whether there was a funding agreement supplying federal funds from NIH to the Hardy/Duff team's research activities before April 25, 1997, so as to support, under section 202, a government license to the invention in the '094 patent.

Defendant acknowledges that it bears the burden of proof on its affirmative defense of a government license to the invention. Id. at 25. Defendant argues, however, that summary judgment for plaintiff is not appropriate, here, "based on the numerous issues of material fact, as the weight of the evidence strongly supports the government's position that National Institutes of Health (NIH) grant funds were used to develop the claimed inventions of U.S. Patent No. 5,898,094 (the '094 patent)." Id. at 6. Essential to the government's position is NIH Grant No. 1P01AG014633 (AG14633 grant), awarded to the Mayo Clinic (Mayo), and an alleged subgrant, or subcontract, between Mayo and USF. Id.

In its motion, plaintiff asserts that the United States is not entitled to a license under section 202, because there was no subcontract between Mayo and USF at the relevant time. ECF No. 118 at 1-2, 17. Plaintiff argues that Dr. "Duff testified no such subcontract, implied or otherwise, existed as of the first actual reduction to practice" of the invention in April 1997. ECF No. 141 at 3. Plaintiff contends that the first subcontract between Mayo and USF was dated November 8, 1997, too late to create the government license alleged by defendant. ECF No. 136 at 5-11. Plaintiff concludes that "[t]here are no material facts in dispute, the government bears the burden of this

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team's alleged conception of the invention before April 27, 1997. See, e.g., Berges v. Gottstein, 618 F.2d 771, 776 (C.C.P.A. 1980) ("[E]ach corroboration case must be decided on its own facts with a view to deciding whether the evidence as a whole is persuasive.").

affirmative defense and speculation is insufficient to meet that burden and preclude summary judgment." ECF No. 141 at 3.

The court agrees with defendant that genuine disputes of material fact preclude the entry of summary judgment for plaintiff on its Section 202 Motion. The court begins with the contract formation theories upon which the parties rely. The court then turns to the disputed facts that are most relevant here.[4] The court observes, at the outset, that the resolution of a summary judgment motion does not provide the court with an opportunity to weigh evidence. See, e.g., Anderson, 477 U.S. at 255 (stating that "the weighing of the evidence[] and the drawing of legitimate inferences from the facts are jury functions, not those of a judge, whe[n] he is ruling on a motion for summary judgment"); Engage Learning, Inc. v. Salazar, 660 F.3d 1346, 1355 (Fed. Cir. 2011) (noting that at the summary judgment stage of proceedings, "the court's function is not to make credibility determinations and weigh the evidence so as to determine the truth, but rather to determine whether a genuine factual dispute exists for trial") (citing Anderson, 477 U.S. at 249, 255); Ford Motor Co. v. United States, 157 F.3d 849, 854 (Fed. Cir. 1998) ("'[A]t the summary judgment stage the judge's function is not himself to weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial.'") (quoting Anderson, 477 U.S. at 249) (alteration in original); Jay v. Sec'y of Dep't of Health & Human Servs., 998 F.2d 979, 983 (Fed. Cir. 1993) (noting that a judicial officer may not "weigh conflicting evidence" to resolve a motion for summary judgment).

1. Implied Contract Theories and the Alleged Mayo/USF Subcontract

The government argues, and plaintiff does not dispute, that subcontracts may give rise to government licenses in inventions, as may the award of federal grants, because subcontracts are included in the definition of "funding agreements" to which the provisions of section 202 apply. ECF No. 131 at 23 (citing 35 U.S.C. § 201(b) (1994)); see also ECF No. 118 at 12 (acknowledging that a subcontract between a federally "funded party" and USF might give rise to a government license to an invention). Indeed, the statutory definition of "funding agreement" refers to a "subcontract of any type." 35 U.S.C. § 201(b). Here, the parties dispute whether a subcontract existed between Mayo, the grantee of the AG14633 grant, and USF before April 25, 1997. Because there is no express contract in the record established by the parties, defendant relies largely on the theories of implied in fact contracts and implied in law contracts to

[4] At this point in the proceedings, it is not necessary to explore each provision of section 202 that may be relevant to government licenses which arise when government funds have supported research underlying the invention disclosed in a patent.

support its contention that a subcontract existed between Mayo and USF in the relevant time-frame.[5] ECF No. 131 at 26-27.

Plaintiff argued, in its submission of recent authority (filed as a notice), that the government is required to meet the contract formation test set forth in American Bankers Association v. United States, 932 F.3d 1375 (Fed. Cir. 2019), "to demonstrate that such a contract exists between the United States and a private party like USF." ECF No. 138 at 1. This argument appears to have been abandoned by plaintiff because it is not mentioned in plaintiff's supplemental reply brief. See ECF No. 141. In any case, American Bankers is not applicable to plaintiff's Section 202 Motion because here the government is alleging that a contract of some kind was formed between Mayo and USF, not between the NIH and USF. See ECF No. 140 at 4 (stating that "there is no dispute between the parties regarding any alleged government contract or license with a private party").

In plaintiff's supplemental reply brief, USF argues that any implied contract formation between Mayo and USF would be governed by Estate of Winton v. Amos, 51 Ct. Cl. 284 (1916), aff'd in part, rev'd in part sub nom. Winton v. Amos, 255 U.S. 373 (1921). ECF No. 141 at 3. Indeed, according to plaintiff, the "essential requirements for an implied contract remain unchanged from that date [1916] to this." Id. The court does not find Winton to be helpful here.

The characteristics of implied in fact contracts and implied in law contracts are firmly established in more recent binding precedent. An implied in fact contract "is one 'founded upon a meeting of minds, which, although not embodied in an express contract, is inferred, as a fact, from conduct of the parties showing, in the light of the surrounding circumstances, their tacit understanding.'" Atlas Corp. v. United States, 895 F.2d 745, 754 (Fed. Cir. 1990) (quoting Porter v. United States, 496 F.2d 583, 590 (Ct. Cl. 1974)). In another expression of the rule, "[b]efore a contract may be implied in fact, there must be a meeting of the minds which is inferred from the conduct of the parties, and in the light of the surrounding circumstances, shows their tacit understanding." Somali Dev. Bank v. United States, 508 F.2d 817, 822 (Ct. Cl. 1974) (citing Baltimore & Ohio R.R. Co. v. United States, 261 U.S. 592 (1923)).

Implied in law contracts, in contrast, typically sound in equitable principles, provide "a recovery in the nature of quantum meruit or quantum valebant," and rely on the theories of "quasi-contract or unjust enrichment." Lumbermens Mut. Cas. Co. v. United States, 654 F.3d 1305, 1315-16 (Fed. Cir. 2011) (citations omitted). "The theory

[5] Defendant lists other potential theories which might establish a subcontract between Mayo and USF, such as an express oral contract, or a satisfactorily proved "lost or missing contract[]." ECF No. 131 at 26-27. Such theories, while potentially relevant, are not critical for the resolution of plaintiff's Section 202 Motion.

[underlying a contract implied in law] is that if one party to a transaction provides goods or services to the other party that the parties intended would be paid for, but the recipient refuses to pay for them, the law will imply a contract for the recipient to pay the fair value of what it has received." Perri v. United States, 340 F.3d 1337, 1343 (Fed. Cir. 2003) (citing United States v. Amdahl Corp., 786 F.2d 387, 393 (Fed. Cir. 1986)). Defendant contends that either a subcontract implied in fact, or a subcontract implied in law, was formed between Mayo and USF. ECF No. 131 at 26-27, 34-35; ECF No. 140 at 4. The court now turns to the parties' dispute regarding the evidence that might support such theories.

2. Genuine Disputes of Material Fact

Plaintiff argues that the absence of a written subcontract in the record, coupled with evidence supporting plaintiff's contention that no subcontract should be implied absent a paper trail, show that there was no possibility that a subcontract between Mayo and USF existed before April 25, 1997, as is required of funding agreements under section 202. ECF No. 118 at 5-6, 13-17; ECF No. 136 at 3-12; ECF No. 141 at 1-5. Further, plaintiff contends that the consortium agreement dated November 8, 1997, shows that there was no earlier subcontract between Mayo and USF that disbursed funds from the AG14633 grant to USF. See ECF No. 136 at 11 ("Since the funding for USF under AG14633 could not have been received until the Funding Agreement [between Mayo and USF] was adopted in November of 1997, the invention of the '094 Patent, actually reduced to practice no later than April 25, 1997 cannot give rise to a license to the government under that patent pursuant to 35 U.S.C. § [2]02.") (citing ECF No. 134-9 (Consortium Agreement between Mayo Foundation and University of South Florida)). Finally, in a variety of ways, plaintiff attacks the evidence on which defendant relies for its position. In analyzing plaintiff's arguments, which are summarized here, the court addresses the arguments in reverse order.

First, the court is not persuaded that plaintiff has successfully challenged defendant's citations to evidence in the record. For example, plaintiff attempts to discredit some of the testimony relied upon by defendant because it is recollection proffered during deposition testimony, not documentation. See id. at 3 (describing the testimony of Dr. David Morgan as "only a 20-year old recollection"). Yet plaintiff, too, relies extensively on deposition testimony for its thesis that no implied contract existed between Mayo and USF, through plaintiff's citations to deposition transcripts in its briefs. See id. at 7 & n.3, 8-10; see also ECF No. 118 at 8-11, 14; ECF No. 141 at 2, 4-5. Each party relies on isolated statements in these depositions, and it is not appropriate, on summary judgment, for the court to attempt to weigh the evidence the parties have presented.

Plaintiff also proffers its own interpretations of the evidence on which defendant relies to support the government's assertion that an implied contract existed between Mayo and USF before April 25, 1997. Plaintiff, in effect, reinterprets that evidence in an

effort to contradict the conclusions drawn by defendant. In one instance, plaintiff avers that "[t]here is a simple, straightforward explanation that comports with the facts" related to the funding of Dr. Marcia Gordon's research on transgenic mice at USF. ECF No. 136 at 9. Yet, defendant presents its own reasonable explanation of the facts relevant to Dr. Gordon's funding that is supportive of defendant's implied contract thesis. ECF No. 131 at 7 & n.2, 9-10, 14-20, 27-34. The court is not convinced that plaintiff's interpretation of the evidence is the only reasonable one. And, the court must accord all favorable factual inferences to the government as it resists summary judgment. E.g., Dairyland Power, 16 F.3d at 1202 (citations omitted). In sum, the evidence defendant has presented in support of its implied contract theories is substantial and survives plaintiff's attempts to establish otherwise.

Turning now to the consortium agreement signed on November 8, 1997, the court cannot agree with plaintiff that this particular agreement is proof that no prior subcontract between Mayo and USF existed. As defendant notes, "the existence of an agreement for that [later] time period does not foreclose another agreement between Mayo and USF for the use of AG14633 Grant funding for the period including April 1997." ECF No. 140 at 5. Plaintiff urges the court to see the logic in the conclusions it draws from Dr. Morgan's deposition testimony discussing a USF accounting document, dated Auguspt 29, 1997, as well as the consortium agreement between Mayo and USF, dated November 8, 1997. ECF No. 136 at 10 ("The only explanation that is consistent with the facts both parties recognize is that AG14633 was awarded to the Mayo Clinic in late 1996, but no subcontract thereunder with USF, the ONLY source of Government/Mayo Clinic funding for USF for that project, existed until November 8, 1997."); see also id. at 7 n.4 (asserting that plaintiff's interpretation of the subcontracting activity between Mayo and USF is "logical and consistent"). But even if plaintiff successfully proves its version of events at trial, the court cannot ignore the hotly disputed issues concerning the record on summary judgment.

Plaintiff relies extensively on Dr. Morgan's testimony regarding an accounting document that preceded the November 8, 1997 consortium agreement between Mayo and USF, but plaintiff has failed to provide a record citation for the court's consideration. ECF No. 118 at 10-11, 14; ECF No. 136 at 7 & n.4, 8-12. Defendant relies on a combination of deposition testimony and documentary evidence related to USF accounting records and the November 8, 1997 consortium agreement which tends to support the existence of a subcontract between Mayo and USF before that date. See ECF No. 131 at 14, 18-19; ECF No. 140 at 5-6. The evidentiary record relevant to the November 8, 1997 consortium agreement between Mayo and USF is not free of conflict. Nor does it foreclose the possibility that an earlier subcontract, implied or otherwise, provided funding to USF from the AG14633 grant before April 25, 1997.

Finally, the court addresses plaintiff's overarching argument that the record before the court, devoid of any written, express subcontract entered into by Mayo and USF

before April 25, 1997, fails to fulfill the funding agreement requirements of section 202 and entitles plaintiff to summary judgment on defendant's government license defense. There does not appear to be much, if any, caselaw that directly addresses implied contract theories as they might apply to funding agreements between a grantee and a subgrantee that would satisfy section 202. And the Bayh-Dole Act does not appear to address the issue directly. Cf. Bd. of Trustees of Leland Stanford Junior Univ. v. Roche Molecular Sys., Inc., 583 F.3d 832, 845 (Fed. Cir. 2009) ("'[T]he primary purpose of the Bayh-Dole Act is to regulate relationships of small business and nonprofit grantees with the Government, not between grantees and the inventors who work for them.'" (quoting Fenn v. Yale Univ., 393 F. Supp. 2d 133, 141-42 (D. Conn. 2004))), aff'd, 563 U.S. 776 (2011).

Plaintiff cites Madey v. Duke University, 413 F. Supp. 2d 601, 611-12 (M.D.N.C. 2006), for the proposition that the government must point to a funding agreement to establish a government license defense under section 202, but the Madey decision contains no further guidance that might be dispositive in this case. ECF No. 118 at 12. Almost all of the other court decisions cited by plaintiff also fail to address the issue before the court here. Id. at 16; ECF No. 136 at 2-3. The case most on point cited by plaintiff is Ciba-Geigy Corp. v. Alza Corp., 804 F. Supp. 614 (D.N.J. 1992). ECF No. 136 at 5.

According to the district court in Ciba-Geigy,

> Under 35 U.S.C. § 202(c), . . . a funding agreement must contain certain provisions. For example, a funding agreement must state that the contractor can elect to retain rights to the patent. Although, defendants have produced documents that show the inventors received money from federal agencies, no party has produced any documents that contain the provisions required by § 202(c).

804 F. Supp. at 628. Plaintiff interprets this construction of section 202 by the Ciba-Geigy court to require a level of detail in the subcontract between Mayo and USF that is incompatible with defendant's implied contract theories. See ECF No. 136 at 5 ("The idea that somehow Mayo and USF reached an oral agreement of this complexity and requiring a written response even though the contract itself is not in writing is a non-starter."). Defendant had no opportunity to respond to this argument because it was raised in a reply brief.

As defendant notes, however, there is an established protocol for the "Disposition of rights," 35 U.S.C. § 202, in federally-funded research and the patents arising from that research. ECF No. 131 at 22-24. The protocol depends on regulations, standard contract clauses, and agency policies to ensure compliance with the provisions of section 202. Id. Moreover, as defendant points out, the evidence provided by the consortium agreement between Mayo and USF dated November 8, 1997, which gives effect to the required

provisions of section 202, shows that any subcontract between Mayo and USF for the previous year would likely have included the same provisions required by section 202. See id. at 23-24 & nn.6-8 (citing ECF No. 134-9 at 5; ECF No. 134-10 at 11; ECF No. 134-13 at 8, 12). In the federally-funded research context of 1996-97, the court sees no categorical impediment to the formation of a subcontract between Mayo and USF before April 25, 1997, that would satisfy section 202, perhaps through an implied contract, because the terms essential to such subcontracts appear to the court to have been well-established in the research university setting at that time.

Aside from the documentary evidence relied upon by plaintiff and defendant, the court notes that the parties rely on testimony from the same deponents to support their arguments regarding the government license defense. Both parties rely on Dr. Morgan's deposition testimony. E.g., ECF No. 118 at 4; ECF No. 131 at 16. Both parties rely on Dr. Gordon's deposition testimony. E.g., ECF No. 131 at 19; ECF No. 136 at 7 n.3. In addition, both parties rely on Dr. Stephen Snyder's deposition testimony. E.g., ECF No. 118 at 14; ECF No. 131 at 13. Moreover, these excerpts of deposition testimony are susceptible to different readings.

The court has considered the conflicting evidence in the documents cited by the parties and in the deposition testimony relied upon by the parties. This conflicting evidence appears to be relevant to proving, or disproving, the existence of a funding agreement between Mayo and USF before April 24, 1997. Because there are genuine issues of material fact that prevent the entry of summary judgment, the court denies plaintiff's Section 202 Motion, ECF No. 118.

D. Effective Date Motion (asserting that the '094 patent is entitled to an effective filing date of October 21, 1996)

Plaintiff asserts that the '094 patent, which was not filed until July 30, 1997, should nonetheless benefit from an effective date, or priority date, of October 21, 1996. See ECF No. 119 at 1-2. Plaintiff relies on the fact that the Hardy/Duff team filed U.S. Provisional Patent Application No. 60/028,937 (the '937 application) on October 21, 1996, and asserts that the '937 application satisfies all of the criteria established by 35 U.S.C. § 119(e) (1994) and 35 U.S.C. § 112, ¶ 1 (1994). ECF No. 119 at 1-2, 17-18. According to plaintiff, no material fact is in dispute and summary judgment should be entered for plaintiff holding that the '094 patent benefits from an effective date of October 21, 1996. Id. at 2.

Defendant disagrees. According to defendant, every claim in the '094 patent relies on a particular mutation, the APPswe transgene (sometimes known as the Swedish mutation), but the APPswe transgenic mouse is not disclosed in the '937 application. ECF No. 106 at 13. Defendant also argues that as of October 21, 1996, any claims in the '937 application were merely prophetic and were couched in conditional terms. Id.

The parties focus on two separate requirements of section 112, ¶ 1, the "written description" requirement and the "enablement" requirement. See Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1354 (Fed. Cir. 2010) (en banc) (reaffirming the Federal Circuit's "written description doctrine"); Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956, 963 (Fed. Cir. 2002) (holding that section 112 requires that a patent supply both a written description of the invention and enablement so that others may practice the invention (citing Vas Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563 (Fed. Cir. 1991))). Pursuant to this precedent, a patent must provide a "written description of the invention," and also must "enable one of skill in the art to make and use it." Ariad, 596 F.3d at 1344.

Here, in plaintiff's terms, the only question is whether the '937 application "contains a written description of an enabling disclosure" of the invention described in the claims of the '094 patent. ECF No. 119 at 2. Both the written description and enablement requirements must be met for plaintiff to benefit from the October 21, 1996 effective date. As explained infra, disputes of material fact foreclose the entry of summary judgment for plaintiff on the effective date issue.

1. Written Description

a. Relevant Case Law

The written description requirement, in order for the patentee to obtain an earlier effective date based on a provisional patent application, is perhaps most succinctly summarized in this statement of the law by the Federal Circuit:

> [F]or the non-provisional utility [patent] application to be afforded the priority date of the provisional application, . . . the written description of the provisional must adequately support the claims of the non-provisional application.

New Railhead Mfg., L.L.C. v. Vermeer Mfg. Co., 298 F.3d 1290, 1294 (Fed. Cir. 2002) (citing 35 U.S.C. § 119(e)(1)). For an explanation of the written description requirement in section 112, ¶ 1, the following passage from another Federal Circuit decision is informative:

> We have held that the written description requirement with respect to particularly claimed subject matter is met if the specification shows that the stated inventor has in fact invented what is claimed, that he had possession of it. Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991). We have stated that possession is shown by disclosure in the patent. Ariad, 598 F.3d at 1351 ("[T]he hallmark of written description is disclosure . . . the test requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art.").

AbbVie Deutschland GmbH & Co., KG v. Janssen Biotech, Inc., 759 F.3d 1285, 1299 (Fed. Cir. 2014) (alteration in original). The court observes that much of the controversy here is focused on the evidence, or lack of evidence, that is in the record before the court regarding the knowledge and understanding of a person of ordinary skill in the art of AD research at the time the '937 application was filed.

In the context of a dispute over a priority date that might be established by a provisional patent application, "[t]he written description requirement of 35 U.S.C. § 112 ¶ 1 is a question of fact." Cordis Corp. v. Bos. Sci. Corp., 561 F.3d 1319, 1331-32 (Fed. Cir. 2009) (citation omitted). This court must deny a summary judgment motion claiming the earlier effective date if there is "a triable issue as to whether the provisional application's disclosure was adequate." Trading Techs. Int'l, Inc. v. eSpeed, Inc., 595 F.3d 1340, 1359 (Fed. Cir. 2010). The state of the scientific art, at the time the provisional application was filed, is a key inquiry. See, e.g., Capon v. Eshhar, 418 F.3d 1349, 1358 (Fed. Cir. 2005) ("The 'written description' requirement must be applied in the context of the particular invention and the state of the knowledge.").

On summary judgment, all factual inferences are seen in the light most favorable to the non-moving party—here, the government. Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587-88 (1986) (citation omitted). Plaintiff also bears the burden of coming forward with evidence supporting its proposed priority date. See Tech. Licensing Corp. v. Videotek, Inc., 545 F.3d 1316, 1327 (Fed. Cir. 2008) (describing the patentee's burden as "to show not only the existence of the earlier application, but why the written description in the earlier application supports the [patent's] claim"). The government, however, bears the ultimate burden of persuasion on its invalidity defenses, some of which depend on the priority date of the '094 patent. Id. at 1327-28. Thus, the ultimate burden of persuasion for the government's challenge to the written description of the '937 application remains with the government. Id.

b. Genuine Disputes of Material Fact

There are a great number of disputed facts and numerous contested legal conclusions in the parties' briefing of plaintiff's Effective Date Motion. The court will briefly note here some of the parties' areas of disagreement that focus on the question of whether the '937 application meets the written description requirement.[6] For the court,

[6] The court will not address—beyond this mention—a cursory comment in plaintiff's reply brief. In the conclusion section of that brief, plaintiff asserts that "[t]he Government concedes that the '937 Application otherwise meets the test for a constructive reduction to practice." ECF No. 135 at 13. There is no page citation indicating where this alleged concession occurred in defendant's brief, there is no explanation of the term "constructive reduction to practice," and there is no citation to precedent as to the significance of a "constructive reduction to practice." This comment on the final page of plaintiff's reply brief, to the extent that it contains a legal argument, is inadequately developed and thus, unpersuasive. Moreover, any argument contained

however, the primary concern is the paucity of relevant evidence going to the state of knowledge in AD research in October 21, 1996, and, more specifically, the lack of evidence that would establish a person of ordinary skill in the art's understanding of the '937 application at that moment in time.

One of the areas of dispute between the parties is whether the '937 application demonstrates that the Hardy/Duff team already possessed the invention that is disclosed in the '094 patent. Defendant relies on the New Railhead and Ariad opinions, as well as on Lockwood v. American Airlines, 107 F.3d 1565, 1572 (Fed. Cir. 1997), to emphasize the importance of the "possession of the invention" aspect of the written description requirement. ECF No. 132 at 19-20. Based on the record evidence of the Hardy/Duff team's research efforts in 1996-97, and the purported "equivocation" in the '937 application regarding the type of APP transgene that would be useful in doubly transgenic mice, defendant concludes that the '937 application does not show that the Hardy/Duff team possessed the invention of the '094 patent on October 21, 1996. Id. at 22, 24-25.

In its reply brief, plaintiff acknowledges that Ariad is a "landmark decision on written description." ECF No. 135 at 5. Plaintiff also asserts that "[i]n October of 1996, no one had yet prepared and measured such mice" as are claimed in the '937 application and the '094 patent. Id. at 12. The court does not find in plaintiff's reply brief, however, any direct rebuttal of defendant's "possession of the invention" argument.

Plaintiff in its reply brief makes passing, and sometimes cryptic, references to various holdings of the Federal Circuit. The referenced holdings might have some relevance to the "possession of the invention" inquiry, but plaintiff has failed to explain the relevance of its citations to caselaw. For example, plaintiff's analysis of the written description requirement, in the context of the '937 application, contains these statements of the law:

> "[T]here is no requirement that the disclosure contain[] ['']either examples or an actual reduction to practice.['']" Alcon Research Ltd.[] v. Barr Labs[.], Inc.[,] 745 F.3d 1180, 11[90-]91 (Fed. Cir. 2014) [(citations omitted)].
>
> The specific name APPswe is not required. Nor was an actual example required—Falko[-]Gunter [Falkner] v. Inglis, 448 F.3d 1357, 1366 (Fed. Cir. 2006).

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therein is also deemed waived because it was not raised before plaintiff filed its reply brief. Arakaki, 62 Fed. Cl. at 246 n.9 (citations omitted).

> Importantly, there is no need to explain in detail that which is known in the prior art. Spectra-Physics, Inc. v. Coherent, Inc., 827 F.2d 1524, 1534 (Fed. Cir. 1987).

ECF No. 135 at 2, 6. To these statements could be added a statement of the law cited in plaintiff's opening brief, ECF No. 119 at 11, although the court quotes the original source material here on the topic of the "written description" test:

> This test requires an "objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art." Given this perspective, in some instances, a patentee can rely on information that is "well-known in the art" to satisfy written description.

Streck, Inc. v. Research & Diagnostic Sys., Inc., 665 F.3d 1269, 1285 (Fed. Cir. 2012) (quoting Boston Sci. Corp. v. Johnson & Johnson, 647 F.3d 1353, 1366 (Fed. Cir. 2011) and Ariad, 598 F.3d at 1351).

Although plaintiff's position on the "possession of the invention" inquiry is less than transparent, the court assumes that defendant and plaintiff are not perfectly in agreement as to this aspect of the written description requirement, insofar as when the requirement is applied to the '937 application. The parties do appear to agree with the court, however, that the perspective of the person of ordinary skill in the art is a key component of this inquiry. Here, as discussed infra, that perspective remains largely unexplored in the record currently before the court. Defendant correctly states, therefore, that there is a genuine dispute of material fact, because it is not certain that the '937 application demonstrates possession of the invention ultimately claimed in the '094 patent. ECF No. 132 at 25.

The other principal dispute between the parties, a dispute that sounds in both fact and law, is whether the doubly transgenic mouse in the '937 application is adequately described so as to meet the written description requirement. In this regard, both parties reference caselaw that addresses the "genus vs. species" issue.

In the words of the Federal Circuit, a genus/species problem may invalidate patent claims that are challenged in litigation: "We have . . . h[e]ld claims invalid in cases where a patent's written description disclosed certain subject matter in terms of a broad genus but its claims specified a particular subgenus or species contained therein." Novozymes A/S v. DuPont Nutrition Biosciences APS, 723 F.3d 1336, 1346 (Fed. Cir. 2013). "On the other hand, in some cases, broad or generic disclosures can adequately describe particular constituent species." Id. at 1347. The parties dispute whether the '937 application avoids the genus/species problem and contains an adequate written description.

Plaintiff's initial argument in this regard is found in its opening brief:

> [I]t was not necessary for Karen Duff, who wrote the provisional application, to specifically write into the provisional patent application instructions to the reader to employ the APPswe expressing mouse of Hsiao et al, (Ex. 13), it was sufficient to note that the reference, familiar to those of skill in the art, described a suitable APP mutation for the invention. Any APP mutation would work, the Swedish mutation was the one available at the time, so Duff referenced the prior art disclosure of that particular mouse.

ECF No. 119 at 11 (citing ECF No. 121-13) (Hsiao article). Defendant responded that "USF's argument rests on the false premise that disclosure of a genus necessarily satisfies the written description requirement of a claimed species." ECF No. 132 at 23.

Plaintiff's rebuttal argument in this regard is presented in its reply brief. The relevant excerpts of that argument are as follows:

> The '937 Application identifies three APP transgenes as suitable for use, and the '094 Patent confines its claims to one of those three transgenes. It is not a violation of the written description requirement to describe multiple inventions in a patent specification if you claim only one of those described.
>
> . . . .
>
> Here—the '937 Application identifies the one and only species at issue by name and provides full disclosure of the mice and mutation in question. The Hsiao article in question is Ex. 13. It identifies the precise mutation in question, how it was introduced into the mice, and the characteristics of the resulting singly transgenic mice. The claims of the '094 Patent, with respect to the APP transgene—have no generic scope—they recite, in each and every claim, the species of APP transgene required—the APPswe transgene. That same transgene is identified in the '937 Application. It is fully described.

ECF No. 135 at 5-6. The logical thread of plaintiff's argument regarding the genus/species problem is not easy to discern.

Even if the court were certain that it has correctly interpreted plaintiff's reply brief, plaintiff's position is not, in the court's view, sufficiently grounded in the perspective of a person of ordinary skill in the art. See Ariad, 598 F.3d at 1351 (requiring that the written description in a patent be measured by what would have been recognized therein by persons of ordinary skill in the art; see also Novozymes, 723 F.3d at 1346 (applying this principle in Ariad to the genus/species issue).

What is lacking in the record before the court is testimony that parses the language of the '937 application from the perspective of the person of ordinary skill in the art. Without this perspective, the court cannot determine whether the genus/species problem

has been avoided by the '937 application and the claims in the '094 patent, in light of the specific references to APP mice therein. Defendant argues, generally, that the language of the '937 application is somewhat ambiguous and equivocal, ECF No. 132 at 22, but what the person of ordinary skill in the art might have discerned in the '937 application cannot be determined on the record currently before the court. In other words, genuine disputes of material fact prevent the court from finding that the written description requirement of 35 U.S.C. § 112, ¶ 1 has been met, or not met, by the '937 application.

Finally, the court must disagree with plaintiff that the deposition testimony of Dr. Borchelt, as cited in plaintiff's Effective Date Motion briefing, resolves any of the genuine disputes of material fact regarding the '937 application's written description. Plaintiff relies, almost exclusively, on three short colloquys between plaintiff's counsel and Dr. Borchelt during his deposition. See ECF No. 119 at 5 (citing ECF No. 121-2 at 21-22, 25); ECF No. 135 at 3 (citing ECF No. 121-2 at 21), 9 (citing ECF No. 121-2 at 25), 10 (citing ECF No. 121-2 at 22). Defendant argues that plaintiff "improperly relies on the out-of-context testimony of Dr. David Borchelt to establish and provide the perspective of the hypothetical person of ordinary skill in the art." ECF No. 132 at 6. Even though Dr. Borchelt might be able to provide important testimony on the topic of the perspective of a person of ordinary skill in the art reading the '937 application, the excerpts of his testimony cited by plaintiff do not provide a clear picture of that perspective on either the "possession of the invention" issue or the genus/species issue.

As defendant notes, Dr. Borchelt's comments during his deposition have been distorted by plaintiff. His testimony as to the credentials of an AD researcher working with transgenic mice is simply that, not an analysis of the '937 application from the perspective of a person of ordinary skill in the art. See ECF No. 132 at 8 (stating that Dr. Borchelt "was never asked about the level of 'ordinary' skill in the art, nor indicated that he was addressing that topic in any way"), 27 (stating that "it is wholly inappropriate to rely on Dr. Borchelt's deposition response as a crude substitute for a factual finding on the level of ordinary skill in the art"). Similarly, when asked about the procedure that could be discerned in the '937 application, he did not provide testimony as to what the specification in that document would have meant at that time from the perspective of a person of ordinary skill in the art. See id. at 9 ("Dr. Borchelt's personal testimony . . . fails to establish how the general disclosure of the provisional application would be understood by one of ordinary skill in the art."). Moreover, other statements in Dr. Borchelt's testimony, that were not quoted by plaintiff, appear to contradict the inferences that plaintiff draws from its cited excerpts of Dr. Borchelt's deposition. Id. at 16 (citing ECF No. 121-2 at 84).

In sum, the court must agree with defendant that Dr. Borchelt's excerpted testimony, and the other evidence relied upon by plaintiff, does not permit the entry of summary judgment as to the sufficiency of the written description in the '937 application. See id. at 27 ("Rather than proffer independent expert testimony specifically addressing

the ordinary skill level, USF relies on personal and out-of-context deposition testimony of Dr. Borchelt to supply this" factual evidence going to the "sufficiency of the ['937] Application's disclosure"). Although plaintiff relies on various statements in Dr. Borchelt's deposition, pieced together, as a substitute for the perspective of a person of ordinary skill in the art on the '937 application, ECF No. 135 at 9-12, the court agrees with defendant that the factual record before the court contains, at a minimum, genuine disputes of material fact regarding the written description requirement.

Plaintiff has attempted to construct the perspective of a person of ordinary skill in the art out of various statements in Dr. Borchelt's deposition testimony, held together by attorney argument. That attorney argument, however, is not moored in expert testimony that clearly addresses the crux of the written description dispute. "Unsubstantiated attorney argument regarding the meaning of technical evidence is no substitute for competent, substantiated expert testimony. It does not, and cannot, support [the movant's] burden on summary judgment." Invitrogen, 429 F.3d at 1068.

Absent the perspective of a person of ordinary skill in the art on the '937 application, the sufficiency of the written description of the invention in the '937 application, as measured by the standard set forth in section 112, ¶ 1 and relevant binding precedent, is a triable issue that cannot be resolved on summary judgment.

2. Discussion of Enablement Dispute Not Required

Plaintiff notes that the en banc Ariad opinion is a "landmark decision." ECF No. 135 at 5. The Ariad decision makes clear that both an adequate written description and enablement are required by section 112, ¶ 1. See Ariad, 598 F.3d at 1348 (agreeing with the parties in that appeal that if the written description requirement is not met, the claim "fails regardless [of] whether one of skill in the art could make or use the claimed invention") (citations omitted). In other words, without an adequate written description, a patent will not survive a challenge based on section 112, ¶ 1, whether or not the enablement criteria is satisfied. Cf. Enzo Biochem, 323 F.3d at 963 (holding that section 112, ¶ 1 requires that a patent satisfy both the written description and enablement requirements) (citing Vas-Cath, 935 F.2d at 1563); see also Ariad, 598 F.3d at 1340, 1358 (finding a patent to be invalid based solely on the written description requirement of section 112, ¶ 1).

Thus, there is no need to determine whether the '937 application meets the enablement requirement of section 112, ¶ 1 as a matter of law, because genuine disputes of material fact as to the written description requirement, alone, prevent the entry of summary judgment in favor of plaintiff on its Effective Date Motion. See, e.g., McDavid, Inc. v. Nike USA, Inc., 892 F. Supp. 2d 970, 986 (N.D. Ill. 2012) (finding a patent invalid due to the written description requirement in 35 U.S.C. § 112, ¶ 1, even though the patent met the enablement requirement) (footnotes omitted); Lift-U v. Ricon Corp., No. 10-CV-01850-LHK, 2011 WL 5118634, at *4 (N.D. Cal. Oct. 28, 2011)

("Because . . . the Court finds these claims invalid for lack of sufficient written description, it need not reach Defendants' arguments that the '433 Patent is invalid for lack of enablement." (citing Ariad, 598 F.3d at 1351)).

As defendant persuasively argues, plaintiff's Effective Date Motion must be denied because,

> [a]t a minimum, there are significant issues of fact as to: 1) how the '937 Application's disclosure would be understood by one of ordinary skill at the time; and 2) whether its disclosure satisfies the written description requirement for the inventions later claimed in the '094 patent.

ECF No. 132 at 22-23. The court finds that genuine disputes of material fact prevent a ruling, on summary judgment, that the '094 patent benefits from an effective date of October 21, 1996. Therefore, plaintiff's Effective Date Motion, ECF No. 119, is denied.

IV. Conclusion

Accordingly, for the foregoing reasons,

(1) Plaintiff's motion for partial summary judgment, ECF No. 116, is **DENIED** as moot;

(2) Plaintiff's motion for partial summary judgment, ECF No. 117, is **DENIED**;

(3) Plaintiff's motion for partial summary judgment, ECF No. 118, is **DENIED**;

(4) Plaintiff's motion for partial summary judgment, ECF No. 119, is **DENIED**; and

(5) On or before **January 10, 2020**, the parties shall **CONFER** and **FILE** a **joint status report** which proposes a detailed revision to the litigation schedule set forth in the court's order of January 31, 2019, ECF No. 127. The proposed litigation schedule shall propose **specific calendar deadlines** for the expert discovery contemplated by the parties.

IT IS SO ORDERED.

s/Patricia E. Campbell-Smith
PATRICIA E. CAMPBELL-SMITH
Judge