

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

_____)	
DR. PHILIPPE BOIS,)	
)	
Plaintiff,)	
)	
v.)	Civil Action No. 11-1563 (ABJ)
)	
U.S. DEPARTMENT OF HEALTH AND)	
HUMAN SERVICES, <i>et al.</i> ,)	
)	
Defendants.)	
_____)	

MEMORANDUM OPINION

Plaintiff Philippe Bois, Ph.D. (“Dr. Bois”) brought this action against the United States Department of Health and Human Services (“HHS”) and a number of HHS officials in their official capacities. Dr. Bois was debarred for three years from contracting, subcontracting, and conducting non-procurement transactions with the federal government after HHS found that he had committed scientific misconduct, and an administrative law judge (“ALJ”) denied his request for a hearing on the findings. He now alleges that the ALJ’s decision violated the Administrative Procedure Act (“APA”) and the Fifth Amendment to the Constitution of the United States.

Plaintiff moved for a preliminary injunction, which the Court consolidated with the merits under Fed. R. Civ. P. 65 on September 2, 2012. [Dkt. # 3]. Defendant was directed to file a combined motion for summary judgment and opposition to the preliminary injunction, which it did. [Dkt. # 11]. Plaintiff filed a memorandum in opposition to the motion for summary judgment and in further support of his motion for preliminary injunction, which requested that the Court grant preliminary injunctive relief and deny defendants’ motion for summary

judgment. [Dkt. # 15]. In the opposition, plaintiff also noted that the Court could grant judgment in favor of the plaintiff *sua sponte*. Pl.'s Mem. in Opp. to Def.s' Mot. for Summ. J. and in Supp. of Pl.'s Mot. for P.I. ("Pl.'s Opp.") at 1 n.1. The Court finds that the ALJ's dismissal of Dr. Bois's hearing request was arbitrary and capricious under the APA because the request raised affirmative defenses that turned upon the resolution of genuine disputes of fact material to the finding of misconduct. Therefore, the Court will deny defendants' motion for summary judgment, reverse the hearing officer's dismissal of Dr. Bois's hearing request, vacate the HHS debarment of Dr. Bois, and remand the matter to HHS for further proceedings.

BACKGROUND

Dr. Bois was a postdoctoral fellow in the laboratory of Dr. Gerard Grosveld, Ph.D. in the Department of Genetics and Tumor Biology at St. Jude Children's Research Center from 1999 to 2004, when he transferred to the laboratory of John Cleveland, Ph.D. in the Department of Biochemistry at St. Jude. Def.'s Opp. to Pl.'s Mot. for P.I. and Mem. in Supp. of Def.'s Mot. for Summ. J. ("Def.'s MSJ") at 3. He later became an Assistant Professor in the Department of Cancer Biology at Scripps Florida, employed under Dr. Cleveland. AR 733, Mem. of Law in Supp. of Pl.'s Mot. for Hr'g Req. ("Pl.'s Hr'g Req.") at 10; AR 820 (Office of Research Integrity Report ("ORI Report") at 3). After Dr. Bois transferred to Dr. Cleveland's laboratory, St. Jude began investigating allegations that Dr. Bois had engaged in research misconduct and gratuitous authorship. *Id.* at 839–40. In its final report, the St. Jude Investigation Committee found that Dr. Bois had intentionally engaged in research misconduct by falsifying or fabricating figures in two separate published articles, and found that the evidence was insufficient or did not support findings of research misconduct as to four other allegations. *Id.* at 837–52.

The findings of that investigation were transmitted to the HHS Office of Research Integrity (“ORI”) on March 16, 2007. *Id.* at 813. ORI reviewed St. Jude’s findings and conducted additional analysis. *Id.* at 818 (ORI Report at 1). On January 8, 2010, ORI notified Dr. Bois by letter (“charge letter”) that it had made two findings of research misconduct based on evidence that he knowingly, intentionally or recklessly fabricated and falsified two figures reported in two separate articles: (1) The FOXO1a Immunoblot in Figure IA of P.R. Bois, K. Izeradjene, P.J. Houghton, J.L. Cleveland, J.A. Houghton, G.C. Grosveld, *FOXO1a Acts as a Selective Tumor Suppressor in Alveolar Rhabdomyosarcoma*, 170 *J. Cell Biol.* 903–12 (Sept. 2005) (Corrected August 2007) (“JCB Article”); and (2) Figure 4(b) of P.R. Bois, R.A. Borgon, C. Vornhein, and T. Izard, *Structural Dynamics of α -Actinin-Vinculin Interactions*, 25 *Mol. Cell Biol.* 6122 (July 2005) (Retracted May 5, 2007) (“MCB Article”). *Id.* at 813–15.

In the same letter, ORI notified Dr. Bois that the Debarring Official proposed debarring him for a period of three years “from eligibility for any contracting or subcontracting with any agency of the United States Government and from eligibility for, or involvement in, nonprocurement programs of the United States Government.” *Id.* at 814–15. The letter also informed him that he could contest the findings and debarment proposal by requesting an administrative hearing before an ALJ with the HHS Departmental Appeals Board. *Id.* at 815.

Dr. Bois filed a request for hearing the next month. *Id.* at 724–76 (Pl.’s Hr’g Req. at 1–53). While he did not dispute many of the specific factual allegations in the charge letter, he took issue with ORI’s overall findings and conclusions, he denied that his actions were motivated by any dishonest intent, and in some instances, he advanced an alternative version of

what had taken place.¹ *Id.* Dr. Bois then filed a motion to supplement his request for hearing, which sought additional time to obtain and review documents which he thought “were critical to his defense,” but to which he had not obtained access: his laboratory files and other records at St. Jude, ORI’s oversight review, and the St. Jude investigation files. *Id.* at 691–98. ORI opposed the motion to supplement, arguing that Dr. Bois failed to meet the standard for supplementation, that Dr. Bois had access to his laboratory files and records at St. Jude throughout the St. Jude investigation, including more than fifty notebooks and six loose-leaf folders, copies of hundreds of pages of reports, laboratory notebooks, electronic records, and interview transcripts, and that Dr. Bois was not entitled to the ORI oversight review or the St. Jude investigation files. *Id.* at 593–602. On April 29, 2010 the ALJ denied Plaintiff’s motion to supplement. The ALJ’s denial of the motion to supplement is not challenged in this case, though Dr. Bois does point to his lack of access to his laboratory notebooks and records in support of his request for a hearing. *See id.* at 37, 42–43.

ORI then filed a motion to dismiss Dr. Bois’s request for hearing. *Id.* at 337–90. On May 3, 2011, the ALJ issued a “Recommended Decision Dismissing Hearing Request” recommending that Plaintiff’s hearing request be dismissed and that Plaintiff be debarred for three years. *Id.* at 35–48. On May 16, 2011, the ALJ *sua sponte* issued an “Amended Decision Dismissing Hearing Request” which was identical to the recommended decision except that it included an additional footnote indicating that the ALJ’s decision was not a “ruling on the merits” of the ORI research misconduct, and therefore was not subject to review by the Assistant

1 The request for hearing also challenged HHS’s jurisdiction to impose administrative sanctions on Dr. Bois, which the ALJ rejected. *See* AR 724–25, 730–31, 35–48 (Pl.’s Hr’g Req. at 1–2, 7–8, 12–25). Dr. Bois does not challenge the jurisdiction determination in the instant case.

Secretary for Health of the HHS under 42 C.F.R. §93.500(c). *Id.* at 33 (ALJ Am. Decision to Dismiss Hr’g Req. (“ALJ Am. Decision”) at 14 n.7).

Dr. Bois filed suit in this Court challenging the ALJ’s dismissal of his hearing request. [Dkt. # 1]. Count I alleges that the ALJ’s decision was arbitrary, capricious, an abuse of discretion, not in accordance with the law, and contrary to Dr. Bois’s constitutional rights, and that the ALJ failed to observe proper procedures, in violation of the APA, 5 U.S.C. § 704, because the ALJ failed to consider material facts raised by Dr. Bois in his hearing request. Compl. ¶¶ 123–28. Count II alleges that the ALJ’s decision violated Dr. Bois’s Fifth Amendment right to due process because it denied him a hearing to resolve issues of material fact.² *Id.* ¶¶ 129–40.

STANDARD OF REVIEW

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.” Fed. R. Civ. P. 56(a). The party seeking summary judgment bears the “initial responsibility of informing the district court of the basis for its motion, and identifying those portions of the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if

² Since the Court’s ruling on Count I will result in a remand of the matter for a hearing, it need not reach Count II.

Dr. Bois also challenges the ALJ’s statement in the Amended Decision that a dismissal of a hearing request is not a ruling on the merits that, under 42 C.F.R. §93.500 (c), would be subject to review by the Assistant Secretary for Health in accordance with §93.523. The Court has difficulty accepting the defendants’ contention that a summary disposition that results in the adoption of findings of research misconduct and that forms the predicate for the imposition of significant sanctions is somehow *not* a “ruling on the merits” for purposes of these regulations. But since the matter is being remanded to the ALJ, it need not reach that question either.

Finally, Dr. Bois alleges that the ALJ engaged in inappropriate *ex parte* communications with ORI, which led the ALJ to amend her opinion *sua sponte*, adding a footnote which indicated that the decision was not subject to the extra level of review. *See* Pl.’s Opp. at 13–15. Again, since the matter will be remanded for a hearing on the merits, the Court need not address this argument.

any, which it believes demonstrate the absence of a genuine issue of material fact.” *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986) (internal quotation marks omitted). To defeat summary judgment, the non-moving party must “designate specific facts showing that there is a genuine issue for trial.” *Id.* at 324 (internal quotation marks omitted). The existence of a factual dispute is insufficient to preclude summary judgment. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247–48 (1986). A dispute is “genuine” only if a reasonable fact-finder could find for the nonmoving party; a fact is only “material” if it is capable of affecting the outcome of the litigation. *Id.* at 248. *See also Laningham v. U.S. Navy*, 813 F.2d 1236, 1241 (D.C. Cir. 1987).

ANALYSIS

A. The Arbitrary and Capricious Standard

“A reviewing court shall set aside agency action, findings, and conclusions found to be ‘arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.’” *United States v. Mead Corp.*, 533 U.S. 218, 229 (2001), quoting *Chevron v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 842–45 (1984). The Court’s review of the ALJ’s decision is “highly deferential.” *Bloch v. Powell*, 348 F.3d 1060, 1070 (D.C. Cir. 2003). Deference is particularly appropriate in cases where the agency’s decision is “based on the evaluation of complex scientific information within the agency’s technical expertise.” *Sanofi-Aventis U.S. LLC v. FDA*, 733 F. Supp. 2d 162, 171 (D.D.C. 2010), quoting and citing *Troy Corp. v. Browner*, 120 F.3d 277, 283 (D.C. Cir. 1997) (emphasizing that “considerable deference” must be shown because courts “review scientific judgments of the agency not as the chemist, biologist, or statistician that we are qualified neither by training or experience to be, but as a reviewing court exercising our narrowly defined duty of holding agencies to certain minimal standards of rationality”).

That being said, agency action may be set aside if the agency “entirely failed to consider an important aspect of the problem.” *Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 43 (1983). Indeed, the Supreme Court “insist[s] that an agency ‘examine the relevant data and articulate a satisfactory explanation for its action.’” *F.C.C. v. Fox Television Stations, Inc.*, -- U.S. --, 129 S.Ct. 1800, 1810 (2009), quoting *Motor Vehicle Mfrs. Assn.*, 463 U.S. at 42. Such a review “is not merely perfunctory. We are to engage in a searching and careful inquiry, the keystone of which is to ensure that the [agency] engaged in reasoned decisionmaking.” *Int’l Ladies’ Garment Workers’ Union v. Donovan*, 722 F.2d 795, 815 (D.C. Cir. 1983) (internal quotation marks omitted).

For the most part, the Amended Decision at issue in this case was a reasoned, supportable determination. But ultimately, the Court concludes that the ALJ’s decision was arbitrary, capricious, and an abuse of discretion because it did not directly address, and it failed to specify the reasons why it rejected, factual claims advanced by Dr. Bois in support of his affirmative defense of honest error. This ruling should not be read as any sort of exoneration, and it does not purport to address the merits of Dr. Bois’s case; rather, it is simply a determination that Dr. Bois must have the opportunity to present his highly factual defense, which may or may not withstand cross-examination and any rebuttal evidence ORI elects to present. The matter will be remanded so that Dr. Bois can have the opportunity to present his case at a hearing, and the ALJ can make any credibility determinations and findings of fact necessary to support her ultimate findings, which will be subject to review in accordance with agency regulations.

B. The HHS Regulatory Framework

Research misconduct is defined as: “fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.” 42 C.F.R. § 93.103.

“Fabrication” involves “making up data or results and recording them,” while “falsification” is “manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.” *Id.* Notably, “research misconduct does not include honest error.” *Id.* § 93.103(d). A finding of research misconduct requires that:

- [1] There be a significant departure from accepted practices of the relevant research community; and
- [2] The misconduct be committed intentionally, knowingly, or recklessly; and
- [3] The allegation be proven by a preponderance of the evidence.

Id. § 93.104.

An individual wishing to contest an ORI finding of research misconduct may request a hearing before an ALJ affiliated with HHS. *See id.* § 93.501(b). The request must:

- (1) Admit or deny each finding of research misconduct and each factual assertion made in support of the finding;
- (2) Accept or challenge each proposed HHS administrative action;
- (3) Provide detailed, substantive reasons for each denial or challenge;
- (4) Identify any legal issues or defenses that the respondent intends to raise during the proceeding; and
- (5) Identify any mitigating factors that the respondent intends to prove.

Id. § 93.501(c). In addition, the hearing request must “specifically deny each finding of research misconduct in the [ORI] charge letter, each basis for the finding and each HHS administrative action in the charge letter, or it is considered an admission by the respondent.” *Id.* § 93.503(b).

The ALJ must grant the hearing request if he or she determines that “there is a genuine dispute over facts material to the findings of research misconduct or proposed administrative actions.” *Id.* § 93.503(a). But a “general denial or assertion of error” is not sufficient to establish a genuine dispute. *Id.* Conversely, if the ALJ determines that the request “[d]oes not raise a genuine dispute over facts or law material to the findings,” or does not “raise any issue

which may properly be addressed in a hearing,” HHS regulations require that the request be dismissed. *Id.* §§ 93.503(b), 93.504(a)(2),(3).

ORI bears the burden of proving the findings of research misconduct by a preponderance of the evidence. *Id.* §93.516(a) and (b). The respondent has the burden of going forward with and the burden of proving any affirmative defenses, also by a preponderance. *Id.* § 93.516(b). The regulation continues: “In determining whether ORI has carried the burden of proof imposed by this part, the ALJ shall give due consideration to admissible, credible evidence of honest error or difference of opinion presented by the respondent.” *Id.*³

Putting all of the applicable regulations together, in reviewing this APA challenge to the ALJ’s decision, the Court must determine:

- whether it was arbitrary and capricious
- for the ALJ to find on this record on this record --
- giving due consideration to any admissible credible evidence of honest error --
- that ORI met its burden to prove,
- by a preponderance of the evidence,
- that Dr. Bois committed research misconduct
- that was intentional, knowing, or reckless
- and not an honest mistake.

Further, the Court must determine whether it was arbitrary and capricious for the ALJ to find that in his request for a hearing, Dr. Bois did not raise a genuine dispute of facts or law material to this finding.

The Court finds that it was certainly reasonable for the ALJ to conclude, based on the undisputed facts, that ORI met its burden to establish – at the very least – reckless research

³ This is an awkwardly crafted regulation that, on the one hand, expressly places the burden on the respondent to establish an affirmative defense by a preponderance of the evidence, but at the same time, seems to shift the burden back to ORI to disprove the defense after the respondent has come forward with “admissible, credible evidence.” Since the Court’s ruling that a hearing is necessary does not rest on a finding that either party met or failed to meet the burdens assigned to them by this provision, the Court will not undertake to interpret the regulation further.

misconduct, by a preponderance of the evidence. The more difficult question is whether it was reasonable for the ALJ to summarily conclude that Dr. Bois could not carry his burden to go forward with and prove his affirmative defenses, and to enter judgment against him notwithstanding his assertion of those defenses. Under section 93.516(b), this determination necessarily involves consideration of a subsidiary question: did the ALJ give “due consideration” to all admissible, credible evidence of honest error or difference of opinion? And to decide that, the Court first must answer: Was there any admissible, credible evidence of honest error proffered in the first place? In other words, did Dr. Bois proffer any *facts* that gave rise to a material factual dispute? Or is he simply quibbling over the conclusion that the ALJ drew from the undisputed facts?

C. The Applicable Legal Precedent

Dr. Bois takes issue with what he asserts were findings made by the ALJ that his explanations are not credible, and he suggests that the ALJ cannot reject his version of events without a hearing. *See* Mem. of Law in Supp. of Pl.’s Mot. for P.I. (“Pl.’s P.I. Mot.”) at 13; Pl.’s Opp. at 4–13. He places heavy reliance on *Singleton v. Babbitt*, 588 F.3d 1078 (D.C. Cir. 2009), and cites it for the proposition that summary treatment is improper when the respondent raises issues related to knowledge or intent. Pl.’s Opp. at 8–11. But the D.C. Circuit has not imposed a *per se* rule against resolving such issues on a cold record.

Singleton involved a false statement made in an application to the National Transportation Safety Board (“NTSB”), and that agency also had a regulation permitting summary judgment in the absence of a material factual dispute. The Court noted:

In the past, the FAA and NTSB have suggested that credibility hearings are the norm in intentional falsification cases because factual determinations about knowledge do not readily lend themselves to adjudication on paper Nonetheless, where a question is sufficiently clear and the proffered explanation

of misunderstanding sufficiently implausible, it may be true that no reasonable factfinder could credit the explanation. In such a case, no hearing would be required.

Id. at 1083.

So *Singleton* brings the Court back to the same question that arises out of reading the regulation: was there “admissible credible evidence of honest error”? If not, the Court does not need to get to the question of whether – according to the ALJ the appropriate level of deference – the consideration accorded the evidence by the ALJ was “due.” *See also Uzelmeier v. U.S. Dept. of Health and Human Services*, 541 F. Supp. 2d 241, 246, 249 (D.D.C. 2008), quoting 42 C.F.R. § 93.503 (“a respondent’s general denial or assertion of error . . . is not sufficient to establish a genuine dispute.”)

Moreover, while ultimately the Court found that Singleton’s claim that he did not understand a question on the pilot’s application was “not inherently implausible,” and it remanded the case for a hearing on whether his answer to the question was intentionally false, that case is distinguishable from the instant case. The NTSB regulation in question prohibited the making of a material, false representation “with knowledge of its falsity.” But research misconduct requires either knowing falsehood or mere recklessness, which is easier to determine on a paper record, and which was the basis for the ALJ’s decision here. *See* AR 20–33 (ALJ Am. Decision at 1–14).

With that legal framework as a backdrop, the Court turns to the consideration of whether Dr. Bois simply offered up general denials or whether he offered evidence that created a genuine factual dispute such that it was unreasonable for the ALJ to dismiss the hearing request and find reckless misconduct by a preponderance of the evidence. The Court will take each finding of misconduct in turn.

D. The ALJ's finding of misconduct as to Figure 1A in the JCB Article was reasonable

Dr. Bois's name appeared first on the list of authors in the JCB article. *See* AR 724–76 (Pl.'s Hr'g Req. at 1–53); AR 820 (ORI Report at 3). The primary conclusion of the JCB article was that a protein called FOXO1a acts as a tumor suppressor in an aggressive tumor usually found in children (“ARMS tumor”), and therefore, agents that restore or increase FOXO1a activity may be effective in ARMS therapy. *See* AR 734 (Pl.'s Hr'g Req. at 11); AR 821 (ORI Report at 4). The research relied on studies using cell lines derived from ARMS tumors rather than studies using the primary ARMS tumor itself, because cell lines were easier to work with in the laboratory than the primary tumors. *Id.* To show that conclusions about the primary ARMS tumors could be extrapolated from the results of studies using ARMS cell lines, the article pointed to an experiment conducted in December 2003 that purportedly demonstrated that ARMS cell lines, like the primary ARMS tumors, did not express FOXO1a. *Id.* Figure 1A was a representation of the “immunoblot film” that showed that result. *Id.*

ORI's charge letter asserted that Dr. Bois actually conducted an immunoblot test much earlier, in February 2003, and that the February results did not support the conclusion in the JCB article. AR 734 (Pl.'s Hr'g Req. at 11); AR 822 (ORI Report at 5). Dr. Bois's records revealed that the February test showed expression of FOXO1a in three of five samples of the cell lines and expression of certain protein controls, and ORI determined that Dr. Bois's handwritten notes labeling the February film demonstrated that he understood both the experiment and the disappointing results. *Id.*

The charge letter also found that the December film, located in Dr. Bois's records and labeled as “ α FOXO1” was completely blank and did not show any results for FOXO1a

expression or for the control proteins. *Id.* There was no written documentation for the December 2003 experiment in Dr. Bois's notebook. *Id.*

Yet, Figure 1A in the JCB article reported only the results supposedly obtained from the December test, and it did not reflect the results of the February test. *Id.* And it reported the December test as affirmatively supporting the researchers' hypothesis, rather than as a null result. *Id.* The ORI charge letter thus concluded that Dr. Bois "intentionally falsified the results presented in the JCB article by suppressing the data from the 2/9/03 experiment, which contradicted the hypothesis of the paper, and selecting data from a blank film from 12/29/03, in which both the experiment and the positive controls also failed."⁴ *Id.*

Dr. Bois submitted a written response to the St. Jude Inquiry Report, in which he claimed that he accidentally used the wrong immunoblot film when he was creating Figure 1A. AR 424–25 (Bois Resp. to Inquiry Report ("Bois IR Resp.") at 2–3). He blamed the erroneous selection on his lack of access to data from his laboratory notebooks or electronic files, which were maintained in Dr. Grosveld's laboratory. *Id.* The manuscript for the article, he alleged, was written after he had already left Dr. Grosveld's laboratory. *Id.* ORI rejected these defenses, citing evidence that he had created the figure before he left Dr. Grosveld's laboratory, including: a file on his computer last modified before he left Dr. Grosveld's laboratory which showed the final version of Figure 1A, and a manuscript of the article that was initially submitted to *Cancer Cell* and *Nature Medicine* before he left Dr. Grosveld's laboratory and which contained the blank FOXO1a ARMS result. AR 822–23 (ORI Report at 5–6).

Dr. Bois also claimed that he repeated the December experiment and actually obtained the favorable results some time in December 2003 or January 2004, even though those were not

⁴ *The Journal of Cellular Biology* retracted the article on May 7, 2007. AR 733 (Pl.'s Hr'g Req. at 10); AR 822 (ORI Report at 5).

the results reported in the JCB article. AR 426 (Bois IR Resp. at 4). ORI rejected this defense as well, explaining that his argument was “not credible because the markings and other identifying characteristics on the undated blank ARMS film he provided were identical to the December 2003 blank film found in [Dr. Bois’s] records, and thus, the experiment could not have been performed in January 2004” AR 823 (ORI Report at 6).

Finally, Dr. Bois claimed that he “forgot” about the February 2003 experiment. AR 424–25 (Bois IR Resp. at 2–3). ORI, however, found that it was “unlikely and improbable” that he would have forgotten key findings from one of only two experiments found in his records that directly contradicted the hypothesis of the entire project and showed results inconsistent with the ones he reported. AR 823 (ORI Report at 6). And, even if he did forget about the results, his conduct publishing the results of the December experiment, which lacked a control that would have indicated the test was erroneous on its face, was sufficient to show misconduct. *Id.* at 823–24 (ORI Report at 6–7).

In his hearing request, Dr. Bois did not dispute that:

- He conducted the FOXO1a experiments on Feb. 2003 and Dec. 2003. AR 735 (Pl.’s Hr’g Req. at 12); AR 824 (ORI Report at 4).
- The Feb. 2003 experiment had a positive control and indicated that FOXO1a was not a tumor suppressor. AR 734 (Pl.’s Hr’g Req. at 11); AR 822 (ORI Report at 5).
- The data from Feb. 2003 was in his laboratory records. AR 735 (Pl.’s Hr’g Req. at 12); AR 822 (ORI Report at 5).
- The data from the Feb. 2003 experiment was inconsistent with his research hypothesis. AR 738 (Pl.’s Hr’g Req. at 15); AR 822 (ORI Report at 5).
- The data from the Dec. 2003 experiment has been proven wrong. AR 738 (Pl.’s Hr’g req. at 15); AR 822 (ORI Report at 5).
- The data from the Dec. 2003 experiment was consistent with his research hypothesis. AR 737 (Pl.’s Hr’g Req. at 14); AR 822 (ORI Report at 5).
- The data presented in Figure 1A of the JCB article was wrong. AR 743 (Pl.’s Hr’g Req. at 20); AR 822 (ORI Report at 5).
- The data presented in Figure 1A was from the Dec. 2003 experiment. AR 739 (Pl.’s Hr’g Req. at 16); AR 822 (ORI Report at 5).

- The Dec. 2003 experiment had no positive control. AR 79 (Pl.'s Hr'g Req. at 16); AR 822 (ORI Report at 5).
- An image file including the false results was last modified on his computer on Jan. 29, 2004. AR 740 (Pl.'s Hr'g Req. at 17); AR 822-23 (ORI Report at 5–6).

Dr. Bois did, however, present a defense that this was a case of honest error. AR 769–70 (Pl.'s Hr'g Req. at 46–47). He again claimed that he did not remember the February experiment and that he actually conducted an experiment that generated the favorable result at some unspecified time in December or January 2003. *Id.*

Dr. Bois's claim not to recall the February experiment is more of a general denial than an assertion of fact, and the regulations make clear that a general denial is not sufficient to establish a genuine dispute. 42 C.F.R. § 93.503. So it was not arbitrary and capricious for the ALJ to determine that the undisputed facts overcame this conclusory assertion of an honest mistake defense. *See* AR 26–27 (ALJ Am. Decision at 7–8).

Counsel argued at the motions hearing in this case that the ALJ had to accept as true for purposes of her opinion the statement that Dr. Bois forgot about the earlier results. But *Singleton* indicates that the ALJ does not have to accept the implausible. Moreover, Dr. Bois, who has the burden of coming forward with evidence to establish an affirmative defense, points to nothing that would make his claimed failure to recall an experiment that undermined his hypothesis plausible. But in the end, any dispute surrounding his assertion is immaterial because the ALJ made clear in her opinion that she would have found misconduct even if the statement was true. *Id.* The Amended Opinion makes note of the fact that the results of the February experiment were reflected in Dr. Bois's laboratory notebooks, and the ALJ concludes that it was at least

reckless to fail to review them before reporting on the research.⁵ *Id.* at 26 (ALJ Am. Decision at 7). And, when the mistake of omission (failing to report the contrary results from February) is combined with the mistake of commission (reporting on the results of the December experiment when that experiment lacked a control and did not in fact produce the reported results), the Court cannot find that it was arbitrary or unreasonable for the ALJ to conclude that ORI overcame the rather thin honest mistake defense by a preponderance of the evidence, and that Dr. Bois's conduct was at least reckless. *Id.*

The key "evidence" Dr. Bois proffers to contest the finding regarding the JCB article is the testimony of Dr. Cleveland that he did not "believe" that Dr. Bois would engage in the alleged misconduct. AR 726–27, 768–69 (Pl.'s Hr'g Req. at 3–4, 45–46). There is considerable emphasis placed on this in the briefing. *See* Pl.'s P.I. Mot. at 14–16. But this is not "admissible evidence" as called for by the HHS regulations; it is an opinion. *See* 42 C.F.R. § 93.519(b) (ALJs are not bound by the Federal Rules of Evidence, but they may apply the rules where appropriate, *e.g.*, to exclude unreliable evidence). Moreover, it is merely an opinion offered by someone who admits that he does not know all of the facts. AR 787. So, even though Dr. Cleveland posited reasons why he thought that it would not make sense for Dr. Bois to falsify his results, his testimony is simply argument or conjecture, and it does not give rise to a genuine dispute of material fact. In any event, the ALJ did specifically consider Dr. Cleveland's opinion and explain in a reasonable manner why she ultimately rejected it. AR 29–30 (ALJ Am. Decision at 10–11).

⁵ Dr. Bois argued that he did not have access to his laboratory notebooks, but the ALJ concludes that this argument was disproved because he initially drafted the article that eventually became his publication while he was still in Dr. Grosveld's lab and he composed Figure 1A while still at Dr. Grosveld's lab. AR 27 (ALJ Am. Decision at 8).

Dr. Bois's claim that he repeated the successful experiment in December or January is more factual, but it is still not sufficient to raise a genuine dispute. And given the deferential standard with which the Court reviews the ALJ's decision, the Court cannot find the ALJ's decision on this point to be unreasonable. At the hearing, counsel pointed to a January 23, 2004 email from Dr. Bois to Peter Houghton, AR 794 (Ex. E to Pl.'s Hr'g Req.), which he argued provided evidence that Dr. Bois did in fact do some experiments that supported the conclusion reported in the article and that he shared them with others in his lab.⁶ But the email is not a "record of regularly recorded activity," *see* FRE 803(6), it is simply a self-serving email from Dr. Bois himself trumpeting the results. It is not clear that it would be "admissible" as evidence if offered by Dr. Bois at a hearing. *See* 42 C.F.R. § 93.519(b).

Furthermore, the ALJ's determination that Dr. Bois's defense was implausible is reasonable. Her opinion states that there were no notes of any such experiments in the lab notebooks, and that the lab was unable to reproduce them. AR 26 (ALJ Am. Decision at 7). Indeed, Dr. Bois's claim raises the question: if the researchers really did obtain the reported results, and the only error in the article was that they were obtained in January and not in December, why did they retract the article in its entirety? After all, Dr. Bois admits that "a

6 The letter states:

Dear Peter,
 Just wanted to show you the WB results from the primary tumor. The differences between ARMS and ERMS are pretty obvious!!! I had to redo the FOXOs WB 3 times to convince myself that there was no mess up. . . (100ug protein loaded in each lane, FOXOs exposure is 15min for the ERMS, over 2 hrs for MIXED and ARMS). Interesting to see the Myosin heavy chain really expressed in ERMS and not in ARMS. These 2 subtype [sic] are really 2 different beasts . . .
 Have a good week end,
 Philippe

conclusion set forth in the JCB [article] was incorrect.” AR 734 (Pl.’s Hr’g Req. at 11). So, it was not unreasonable for the ALJ to conclude that the defense was implausible.

Finally, there is a question as to whether the factual allegation, even if it were true, is material: the claimed results do not necessarily cure the problem that a representation was made in the article that a particular experiment performed at a particular point in December yielded results that it did not in fact yield, and that a figure – found on Dr. Bois’s computer – was created and included in a scientific publication, which falsely depicted those results. Even after the ALJ considered the evidence that Dr. Bois proffers here, and even though she dismissed his argument in part as implausible, she also found that his failure to review his lab notebooks before reporting the results of the December test was sufficient to support a finding of reckless research misconduct *on its own*. AR 26 (ALJ Am. Decision at 7).

According to the ALJ the required level of deference, the Court therefore cannot find that it was arbitrary and capricious to deny the hearing request on the grounds that plaintiff failed to raise a genuine dispute over facts material to the finding of research misconduct in the JCB article.

E. It was arbitrary and capricious for the ALJ to find that Dr. Bois did not raise a genuine dispute over facts material to the finding of research misconduct regarding Figure 4B in the MCB article.

The MCB article reported the results of research conducted in the laboratory of Dr. Bois’s wife, Tina Izard, Ph.D. AR 746 (Pl.’s Hr’g Req. at 23); AR 824 (ORI Report at 7). While in his hearing request, Dr. Bois did not admit to having any substantive role in the research or analysis of the work presented in the MCB article, he did admit to being asked to assist in the presentation of the figure that ultimately became Figure 4B. *Id.* at 746–47 (Pl.’s Hr’g Req. at 23–24). Notwithstanding his claim of limited involvement in the research, Dr.

Bois's name appeared first on the list of authors for the article. *Id.* at 747 (Pl.'s Hr'g Req. at 24); AR 825 (ORI Report at 8).

The Izard laboratory studied a protein called vinculin. *Id.* In particular, it studied how changing the shape of vinculin between active and inactive forms changes the ability of a cell to remain stationary or move through its environment. This has implications for understanding the development patterns of tissues and organs and also how cells move away from tumors in the spread of cancer. The MCB article focused on the binding of two different proteins – talin and α -actinin – to vinculin. The researchers' hypothesis was that the vinculin would change shape in different ways depending on whether talin or α -actinin was bound to it. To test this, the Izard laboratory took different compounds of full-length human vinculin bound to pieces of either talin or α -actinin, and put them together with an enzyme. To ensure that the vinculin would bind to the pieces of talin or α -actinin, the mixtures contained vinculin binding sites (“VBS”). The article reported that the tests supported the scientists' hypothesis. In the article, the results were recorded as Figure 4A.

ORI found that the Izard lab first submitted the MCB article manuscript for publication on or about October 7, 2004. AR 825 (ORI Report at 8). That version did not include Figure 4B. On or about October 28, 2004, a reviewer of the transcript commented that the authors had overstated the conclusion of the test. *Id.* The reviewer found that the test was carried out in the presence of different VBS peptides, which might affect the results of the test. *Id.* He recommended that the authors either add supporting data or tone down their conclusions. *Id.*

In response, a graduate student in the Izard lab, Robert Borgon, conducted a control experiment to see if the different VBS peptides affected the way that the vinculin changed shape. *Id.* at 825–26 (ORI Report at 8–9). In the experiment, Borgon put different combinations of

VBS peptides and enzyme in different lanes of a gel. *Id.* at 826 (ORI Report at 9). The image that appeared as Figure 4B showed that the different VBS peptides did not affect the enzymatic activity and were not digested by the enzyme. *Id.* This again supported the researchers' hypothesis. *Id.*

However, ORI found that the image that appeared as Figure 4B in the MCB article was significantly different than the actual image of the gel stain from the experiment Borgon conducted, and it found evidence that Dr. Bois had falsified the image so that it appeared to support the researchers' hypothesis.⁷ *Id.* at 826–27 (ORI Report at 9–10).

ORI's findings, which were undisputed by Dr. Bois in his hearing request, were:

- Dr. Bois received an electronic version of the single-stained gel and another file from Borgon on January 7, 2005. AR 804 (Ex. H to Pl.'s Hr'g Req.).
- On February 1, 2005, Dr. Izard asked Dr. Bois to compose Figure 4B via an email that read: "Dearest, can you please create a figure to show that [the enzyme] does not affect the peptides? Thanks!" AR 750–52 (Pl.'s Hr'g Req. at 27–30); AR 827 (ORI Report at 10).
- On February 11, 2005, Dr. Bois sent three different e-mails to Dr. Izard at 12:21 pm, 12:59 pm, and 1:07 pm, each of which had a progressively falsified version of Figure 4B attached. AR 750–52 (Pl.'s Hr'g Req. at 27–30); AR 828–29 (ORI Report at 11–12).
- The 12:59 pm email from Dr. Bois to Dr. Izard also contains the text: "Et violá!" AR 750–52 (Pl.'s Hr'g Req. at 27–30); AR 828 (ORI Report at 11).
- On February 11, 2005 at 1:17 pm, the graduate student sent an unaltered version of the double-stained gel to Dr. Bois. AR 750–52 (Pl.'s Hr'g Req. at 27–30); AR 829 (ORI Report at 12).
- On February 11, 2005, at 1:35 pm, Dr. Bois responded to Borgon with an email containing the falsified image and the statement, "No, too dirty for a figure. This will do." AR 750–52 (Pl.'s Hr'g Req. at 27–30); AR 830 (ORI Report at 13).
- Several electronic versions of the falsified figure appeared on Dr. Bois's computer on February 11, 2005. AR 750–52 (Pl.'s Hr'g Req. at 27–30); AR 827–29 (ORI Report at 10–12).

⁷ The authors published a correction to the MCB article in August 2007, which stated that: "Page 6118, top right panel: Lanes 1, 3, and 5 were inadvertently erroneous. The α VBS peptide was not always detectable with the silver stain used to produce this figure, which resulted in wrong images for these lanes. This error does not affect the results or conclusions of the study." See AR 757 (Pl.'s Hr'g Req. at 34); AR 831 (ORI Report at 14).

Rather than dispute these facts, Dr. Bois's hearing request argued that ORI failed to consider other "facts" which supported his claim that *he* did not falsify the figure. *Id.* at 746–58, 765, 771–72 (Pl.'s Hr'g Req. at 23–35, 42, 48–49). As the ALJ pointed out, Dr. Bois's version of these events is "confusing" at the very least. *See id.* at 28 (ALJ Am. Decision at 9). But the ALJ was required to at least acknowledge his version and explain her reasons for rejecting it. And it is here that the ALJ stumbled.

At the hearing in this case, the attorney for Dr. Bois argued that the ALJ ignored testimony from Borgon, contained in Exhibit H to the hearing request, which indicated that Borgon was present with Dr. Bois for the 10 minute period when the figure was changed on a public computer. Draft Tr. at 18. The attorney argued that that since Dr. Bois did not do the experiment and did not know what the figure was supposed to look like, it was reasonable for Dr. Bois to rely on Borgon to tell him. *Id.* at 19; *see also* AR 750–69 (Pl.'s Hr'g Req. at 27–46). The attorney further pointed out that Borgon – whom Dr. Bois claims had a motivation to lie – failed to speak up and point out the error when he read the proofs for the article. *Id.* at 19.

There are several problems with relying on this argument as grounds for reversing the agency. First, the ALJ's decision is based on the fact that the figure was saved on, altered on, and emailed from Dr. Bois's computer, not the public computer, and Borgon testified that he was not present in Dr. Bois's office for the PhotoShop session and, indeed, that he was never present in Dr. Bois's office. *See* AR 805 (Pl.'s Hr'g Req. at Ex. H). Second, this argument is not clearly supported by the exhibit. While the testimony describes an occasion when Borgon and Dr. Bois looked at an image on the computer together, the short excerpt provided in the exhibit does not indicate when this event occurred. Indeed, a review of the exhibit and the context of the quoted statements suggests that the session when Dr. Bois and the student were

standing around the lab computer could have related to the creation of the original image on January 7th, and not the modification of the image that became Figure 4B in February. AR 804–05 (Ex. H to Pl.’s Hr’g Req.).⁸ Moreover, this scenario is a different factual argument than the one advanced in Dr. Bois’s hearing request, which itself varied from prior arguments advanced by Dr. Bois. Since the inquiry before the Court is whether it was arbitrary for the ALJ to dismiss the hearing request, the Court must look to whether the hearing request itself created a genuine dispute of material fact as opposed to whether disputed factual theories were advanced at oral argument.

In the hearing request, Dr. Bois argues that the figure ORI refers to as the gel from the experiment that Borgon conducted (“experiment gel”), which it compares to the allegedly falsified Figure 4B, is not actually found in Borgon’s lab notebook. “Instead, a very different looking double-stained gel was included with a key.” AR 748 (Pl.’s Hr’g Req. at 25). He

8 Interviewer: So the blot that’s on the inquiry page 16 was E-mailed on the 7th of January, but not with a key. The key that’s on inquiry page 16 is taken from here. Are you confident that the loading matches the key that’s here?

Borgon: Yes, I can look at it again and see to make sure. Let me look at my book. It will be easier.

Dr. Conley: So he’s looking at his notebook, page 77, to make sure that the key matches the loading.

B: Yes, that’s exactly accurate.

I: Then you said in your response to the inquiry, “Under Dr. Bois’ guidance we pieced together the figure shown in Figure 4B, using different bands for various gels and here I E-mailed him the file for further editing.” We’re not sure exactly what you mean by that.

B: I remember when this figure came out, when we were working on it, I remember messing with these bars. That’s why I said with the lines that were dividing the figure up. And so I remember being involved and I remember Phil was there and he was like, well, you know you can use this clone-stamp tool and he was doing that type of thing to like clone stamp another band or copy bands. And after we got it set up he said, well, just E-mail me the file. We just had the picture. He said, just E-mail it to me and then he added everything else to it or, I don’t know what further editing he did.”

AR 804–05 (Ex. H to Pl.’s Hr’g Req.).

attaches a photo of the figure from the lab notebook as Exhibit G to the hearing request, and it certainly appears to the Court that this image does not look like the experiment gel. He also states that if you look at the gel image contained in Borgon's notebook, the α VBS peptide is actually visible, as opposed to in the experiment gel. *Id.* at 749 (Pl.'s Hr'g Req. at 26). This is important because ORI pointed to the visible spot in the α VBS peptide lane in Figure 4B, which did not appear in experiment gel, as one of the ways that Figure 4B was falsified. *Id.* at 826 (ORI Report at 9).

Given the undisputed facts that are laid out in the ORI report, this unexplained variance between the photo in Borgon's notebook and the photo ORI used to depict his test results may not be enough by itself to give rise to a material dispute or to support an affirmative defense by a preponderance of the evidence. But it does raise serious factual questions that are not answered on this record about what the figure in the lab notebook is supposed to be, and how the figure that was manipulated to end up as Figure 4B was derived.

In the hearing request, Dr. Bois also responds to the incriminating timeline of email correspondence between Drs. IZARD and Bois that ORI presents in paragraph 43 of its report. Without conceding that the lanes in Figure 4B were altered, Dr. Bois argues that they were simply mislabeled because Borgon gave him the wrong information. *See* AR 751–52 (Pl.'s Hr'g Req. at 28–29).

On February 11, 2005, Dr. Bois opened a connection between one of the shared computers in Dr. IZARD's laboratory and his own office computer. The same day Borgon was asked to assemble the image that would become Figure 4B. Borgon opened a PhotoShop session on the shared IZARD laboratory computer and cut four lanes and placed them together in a single image. Borgon thereafter misinformed Dr. Bois concerning the identity of these lanes. For example, in an email at 1:17 pm, Borgon sent Dr. Bois an eight-laned image and stated, incorrectly, that lane 7 and lane 8 were α VBS. Lane 7, that Borgon had incorrectly identified to Dr. Bois as α VBS, eventually became the mislabeled, as such, lane 5 in the final Figure 4B. After receiving the four-lane image from Borgon, Dr. Bois placed it into a

different PhotoShop session titled "Peptide+Papain.psd" and Dr. Bois added the labeling according to what Borgon had incorrectly told him. At 12:21 pm Dr. Bois emailed this four lane figure with labeling, titled "Paptide+Papain.pdf," [sic] to Dr. Izard.

AR 752 (Pl.'s Hr'g Req. at 29).

It is not disputed that the lane numbering in the image that Borgon sent to Dr. Bois at 1:17 p.m. on February 11, 2005 was incorrect. But Borgon sent the mislabeled image to Dr. Bois after Dr. Bois had already completed the figure and sent it Izard: the undisputed ORI findings establish that Dr. Bois sent the final image that was published as Figure 4B to his wife as 1:07 p.m. So the Court cannot find that it was unreasonable for the ALJ to reject Bois's argument that he made an error based on the information he received from Borgon when that claim does not comport with the undisputed chronology of events.

But Dr. Bois also seems to suggest that it was Borgon who actually manipulated the image in PhotoShop:

After the four-lane image was emailed to Dr. Izard, Borgon was asked to add a missing lane showing α VBS alone. At this time, Borgon was left unsupervised in Dr. Izard's laboratory. Borgon assembled a five-lane figure (adding the α VBS lane) and again misinformed Dr. Bois of the correct identity of the lanes that only Borgon knew. On the shared Izard laboratory computer, Dr. Bois added the labeling as instructed by Borgon by placing the five-lane figure into a new PhotoShop session. At 12:59 pm Dr. Bois emailed this figure, again titled "Peptide+Papain.pdf," to Dr. Izard.

Id. So, Dr. Bois claims both that Borgon was working alone and unattended – but still somehow manipulating images on Dr. Bois's own computer through the shared lab computer – and that he was at Dr. Bois's elbow, providing instruction on how to manipulate the images when Dr. Bois was labeling and emailing them himself.

Dr. Bois's story lacks coherence, and he provided little that would enable the ALJ to find it to be particularly plausible or persuasive. He points to no records, computer entries, or

statements of others that substantiate his claim. The defense is internally inconsistent, and in places, it is inconsistent with the known facts. For example, the suggestion that Dr. Bois based his lane numbers on the incorrect email from Borgon is undermined by the fact that the Borgon email arrived after Dr. Bois was done, and the suggestion that Borgon must have been the one manipulating the images because they were saved using Borgon's typical file-naming conventions is contradicted by the evidence that the altered file names do not use these conventions. *See* AR 756 (Pl.'s Hr'g Req. at 33). Furthermore, the story is difficult to square with such key undisputed facts as: (1) Dr. Izard emailed Dr. Bois, not Borgon, at the outset asking him to create a figure ("Dearest, can you please create a figure to show that [the enzyme] does not affect the peptides? Thanks!"); (2) Dr. Bois sent multiple images back to her with his own comments ("Et viola!") and with no acknowledgment of Borgon's participation; and (3) in the end, Dr. Bois told Borgon by email that Borgon's image was unsuitable and sent Borgon the alternative new version. *See* AR 827–30 (ORI Report at 10–13).

But, the lack of clarity on both sides of this factual presentation leaves certain questions that might be material to the findings of research misconduct unanswered, and the ALJ does not address them:

- Is it even possible to access Dr. Bois's personal computer from the shared lab computer?
- Did Borgon log on to the shared lab computer at the time in question? Did Dr. Bois?
- Dr. Bois says that Borgon opened a session of PhotoShop on the lab computer. Did he? When? Is there any indication that any of this work was performed on the public computer?
- Do the facts that Borgon was undisputedly working on the same image at approximately the same time as Dr. Bois, and that he seems to have been engaged in a dialogue with Dr. Bois about it, lend some credibility to Dr. Bois's version of the story?
- Given the lack of clarity in Borgon's testimony about the dates that he worked on an image alongside Dr. Bois, is there a possibility that Borgon was indeed talking about February 11, and not January 7?

All of these questions are questions about facts. Rejecting Dr. Bois’s version of the story requires drawing inferences and making conclusions about what is the most probable, persuasive, and credible rendition of events. And while a general denial of ORI’s findings is not sufficient to defeat summary disposition, Dr. Bois presented more than the general “I didn’t do it” denial here. Notwithstanding the lack of corroboration, he offers a specific account of the events. And although the ALJ acknowledges that Dr. Bois offered an “alternative chronology,” she dismisses it as “a confusing but ultimately irrelevant series of accusations,” without seriously parsing or considering the factual questions that it raises. *See* AR 28 (ALJ Am. Decision at 9).

Based on these facts, Dr. Bois advances the affirmative defense that he lacked the requisite level of intent to commit research misconduct. *See* AR 764–65 (Pl.’s Hr’g Req. at 41–42). But in dispensing with the arguments on state of mind, the ALJ does not set out her grounds for rejecting Dr. Bois’s account. AR 30 (ALJ Am. Decision at 11). She correctly explains that there is no “conscious intent to deceive” element to research misconduct, and she correctly points out that it is the respondent who bears the burden of going forward on the affirmative defense of honest mistake. But she stops there.⁹ She moves onto the next issue without clearly stating why the affirmative defense fails: did Dr. Bois fail to meet his burden to come forward

⁹ The Amended Decision states:

[C]ontrary to Respondent’s implication, establishing honest error is an affirmative defense, for which *Respondent* bears the burden of going forward and the burden of proving by a preponderance of evidence. 42 C.F.R. § 93.516(b)(2). The drafters of Part 93 (which are the regulations that govern these proceedings) recognized an overlap between a respondent’s responsibility to prove an affirmative defense and the agency’s responsibility to prove that research misconduct was committed intentionally, knowingly or recklessly. So, as ORI has done here, the agency must show that the research misconduct was intentional, knowing, or reckless. . . . The drafters explicitly retained ‘honest error or difference of opinion’ as an affirmative defense that the respondent has the burden of proving by a preponderance of the evidence. 42 C.F.R. § 93.106; *see* 70 *Fed. Reg.* at 28,372.

AR 30 (ALJ Am. Decision at 11).

with admissible credible evidence or did ORI overcome Dr. Bois's showing with undisputed evidence? The ALJ's failure to explain the basis for her reasoning reduces the amount of deference that the Court need accord her decision. *See Fed. Election Commis. v. Democratic Senatorial Campaign Comm.*, 454 U.S. 27, 37 (1981) (“[T]he thoroughness, validity, and consistency of an agency’s reasoning are factors that bear upon the amount of deference to be given an agency’s ruling.”).

So, according the ALJ some deference, the Court finds that while it may not have been unreasonable for the ALJ to conclude that the evidence was sufficient for ORI to meet its burden of proving misconduct by a preponderance of the evidence, Dr. Bois made factual allegations in support of his defense that were specific enough to warrant a hearing. Particularly when the Court looks at the dismissal of the hearing request together with the agency’s denial to Dr. Bois of access to his laboratory notebooks for purposes of testing ORI’s allegations,¹⁰ and the ALJ’s failure to explain the grounds for rejecting Dr. Bois’s affirmative defenses, it must reach the conclusion that the dismissal of the hearing request was unreasonable. This is not intended to suggest that ORI will not be able to meet its burden at a hearing; it just means that there should be a hearing.

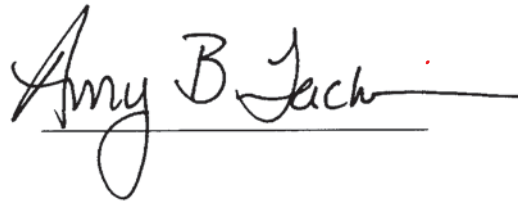
Because the Court will deny defendant’s motion for summary judgment and reverse the ALJ’s decision on that basis, it will not reach the issues of whether a summary dismissal is a “ruling on the merits” for the purposes of 42 C.F.R. 93.500(c), whether ORI engaged in

¹⁰ Documents proffered by the government indicate that Dr. Bois had supervised access to his notebooks during the course of the St. Jude investigation and he obtained scanned copies of the pages that he requested in order to respond to the misconduct allegations. *See* AR 326–29, 617–18, 622–33. However, there is no evidence, and the government does not argue, that Dr. Bois was able to revisit his laboratory notebooks – other than the scanned copies of pages in his possession – at any point after ORI released its findings.

inappropriate *ex parte* communications with the ALJ, or whether the ALJ's decision violated the Fifth Amendment.

CONCLUSION

Because the Court finds that the ALJ's dismissal of Dr. Bois's hearing request was arbitrary and capricious, it will deny defendant's motion for summary judgment, reverse the ALJ's decision dismissing the hearing request, vacate the HHS debarment of Dr. Bois, and remand to the agency for further proceedings consistent with this opinion.

A handwritten signature in black ink that reads "Amy B. Jackson". The signature is written in a cursive style with a horizontal line underneath the name.

AMY BERMAN JACKSON
United States District Judge

DATE: March 2, 2012