

The Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Office of Research Integrity,

Petitioner

v.

Frank Sauer, Ph.D.

Docket No. C-16-708

Decision No. CR4858

Date: May 22, 2017

RECOMMENDED DECISION GRANTING SUMMARY JUDGMENT

Pursuant to 42 C.F.R. § 93.523(b), I recommend that the Assistant Secretary for Health, Department of Health and Human Services (HHS), grant summary judgment to the Office of Research Integrity (ORI). The undisputed material facts establish that Respondent, Frank Sauer, Ph.D., committed research misconduct over a period of years. The extent of misconduct engaged in by Respondent justifies the administrative remedies sought by ORI, which consist of a prohibition on Respondent's service in any advisory capacity to the U.S. Public Health Service (PHS) for a period of five (5) years, and notice to a journal, *PLoS One*, that retraction or correction of a paper published in 2010 is warranted.

I. Background

Respondent is a biochemist whose research focused on epigenetics. *See* ORI Exhibits (Exs.) 7- 13. During the relevant time period of this case, Respondent was an associate professor of biochemistry at the University of California at Riverside (UCR). ORI Ex. 7 at 13.

On June 2, 2016, ORI sent Respondent a cover letter, along with an enclosure that it identified as a "charging document," that outlined eight specifications of research

misconduct.¹ ORI charged that Respondent intentionally, knowingly, or recklessly falsified and/or fabricated images that were included in seven National Institutes of Health (NIH) grant applications and three publications.² Charging document, at 3-4. The charging document proposed administrative actions against Respondent, which consisted of a five-year ban, to coincide with the five-year period of debarment previously imposed by the National Science Foundation (NSF), on Respondent being allowed to serve in any advisory capacity to PHS, and that ORI would send notice to *PLoS One* that a paper should be retracted or corrected pursuant to 42 C.F.R. § 93.411(b).³ Charging document, at 18. ORI, in its charging document, explained that its charge of research misconduct had been preceded by separate investigations by UCR and the National Science Foundation (NSF) Office of the Inspector General (OIG) that stemmed from an October 3, 2011 anonymous report of research misconduct. Charging document, at 5-8; *see* ORI Exs. 17, 27, and 30. UCR's Investigation Committee determined that Respondent had committed 21 instances of research misconduct, and that Respondent "alone was responsible for these multiple instances of research misconduct in which he falsified and fabricated research data," to include instances of the reuse and relabeling of images. ORI Ex. 27 at 6-7. After a subsequent investigation by NSF OIG, NSF's chief operating officer, in a letter dated April 6, 2016, informed Respondent that he had found that he committed research misconduct pursuant to 45 C.F.R. § 689.2(c). ORI Ex. 31 at 1- 3. The NSF chief operating officer informed Respondent that he had imposed a five-year bar on Respondent's participation as a peer reviewer, advisor, or consultant for NSF, and that Respondent must complete a comprehensive training course on the responsible conduct of research. ORI Ex. 31 at 3. On July 28, 2015, NSF sent Respondent a notice informing him of his debarment for a period of five years. ORI Ex. 32

Following receipt of ORI's June 2, 2016 letter and charging document, Respondent requested a hearing before an administrative law judge (ALJ) on July 8, 2016. The case

¹ Neither party submitted these documents as exhibits, and therefore, I will refer to the documents as the cover letter and charging document.

² ORI notes on page 6 of its memorandum of points and authorities that "the questioned research was supported by PHS funding, specifically NIH grants RO1 GM073776, "RNA-mediated recruitment of epigenetic regulators," and R01 GM066204, "Mechanism of transcription control by *Drosophila* TAF250." (ORI Exs. 1-2)." ORI noted that the remaining grant applications were submitted, but unfunded. *See* ORI Exs. 7-13. Respondent has not disputed that ORI has the authority, pursuant to 42 C.F.R. § 93.404(a), to propose the administrative actions that are discussed herein.

³ The cover letter informed Respondent that the proposed notice will state that retraction of the paper is required, but page 18 of the charging document indicates that the notice will inform *PLoS One* that the paper "requires retraction or correction in accordance with 42 C.F.R. § 93.411(b)."

was assigned to me, and on August 3, 2016, I convened a pre-hearing conference pursuant to 42 C.F.R. § 93.511. In compliance with 42 C.F.R. § 93.511(d), the Civil Remedies Division made a recording of the pre-hearing conference available to the parties via the DAB E-File system. At the time of the pre-hearing conference, I scheduled a hearing for May 1 through 5, 2017, and set deadlines for the parties' discovery requests and exchanges, submission of evidence, and the filing of briefs and motions for summary judgment. ORI thereafter filed a motion for summary judgment (ORI Motion), a memorandum of points and authorities (ORI Memorandum), and a statement of undisputed material facts. Respondent then filed a cross-motion for summary judgment (R. Cross-Motion), a memorandum in opposition to ORI's motion for summary judgment and in support of Respondent's motion (R. Memorandum), a statement of undisputed material facts (R. Statement of Facts), and a response to ORI's statement of undisputed material facts (R. Response). ORI subsequently filed a response to Respondent's cross-motion for summary judgment and a response to Respondent's statement of undisputed facts.

ORI has submitted a total of 51 exhibits, and Respondent has submitted 16 exhibits. ORI submitted objections to Respondent Exhibits (R. Exs.) 6, 7, and 14, to include evidence and argument calling into question the authenticity of a declaration submitted for a witness of Respondent, Mr. Rune Dreser. *See* R. Exs. 6, 7. Because I have issued a recommended decision based on ORI's motion for summary judgment, I will admit R. Exs. 6, 7, and 14 despite ORI's objections so that I can consider those exhibits, along with all other evidence, in the light most favorable to Respondent. While ORI has presented evidence that may cast doubt on the authenticity of R. Exs. 6 and 7 (see ORI Exs. 41 to 50), I accept R. Exs. 6 and 7 as true, for purposes of summary judgment. I therefore admit into the record all exhibits submitted by the parties.

II. Issues

The issues raised by ORI's charging document include:

1. Whether Respondent intentionally, knowingly, or recklessly falsified and/or fabricated images that were included in seven submitted NIH grant applications and three published papers;
2. Whether Respondent committed acts that constitute a significant departure from accepted practices of the relevant research community; and
3. Whether the administrative actions proposed by ORI, a five-year prohibition from serving in any advisory capacity to PHS and notice to *PLoS One* that a paper should be retracted or corrected, are reasonable.

III. Findings of Fact, Conclusions of Law, and Analysis⁴

1. Summary disposition is appropriate in a case involving allegations of research misconduct where there are no disputed issues of material fact and where the moving party is entitled to a favorable decision as a matter of law.

Summary judgment is appropriate and no hearing is required if there are no disputed issues of material fact and the only questions that must be decided involve the application of law to undisputed facts or if the moving party must prevail as a matter of law even when all factual disputes are resolved in favor of the party against whom the motion is made. The movant bears the initial burden of demonstrating that there are no genuine issues of material fact for trial and that the movant is entitled to judgment as a matter of law. When confronted with a properly supported motion for summary judgment, the nonmoving party “may not rest upon the mere allegations or denials of his pleading, but . . . must set forth specific facts showing that there is a genuine issue for trial.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986) (quoting Fed. R. Civ. P. 56(e)); *see also* Fed. R. Civ. P. 56(c).

A nonmovant, in opposition to a motion for summary judgment, bears the burden of showing that there are material facts that are disputed either affecting the movant’s prima facie case or that might establish a defense. It is insufficient for the nonmovant to rely upon mere allegations or denials to defeat the motion and proceed to hearing. The nonmovant must, by affidavits or other evidence that sets forth specific facts, show that there is a genuine issue for trial. If the nonmovant cannot show by some credible evidence that there exists some genuine issue for trial, then summary judgment is appropriate and the movant prevails as a matter of law. *Anderson*, 477 U.S. at 250. A test for whether an issue is regarded as genuine is if “the evidence [as to that issue] is such that a reasonable jury could return a verdict for the nonmoving party.” *Id.* at 248. In evaluating whether there is a genuine issue as to a material fact, an ALJ must view the facts and the inferences to be drawn from the facts in the light most favorable to the nonmoving party. *Pollock v. Am. Tel. & Tel. Long Lines*, 794 F.2d 860, 864 (3rd Cir. 1986).

The standard for deciding a case on summary judgment and an ALJ’s decision-making in deciding a summary judgment motion differ from resolving a case after a hearing. On summary judgment, the ALJ does not make credibility determinations, weigh the evidence, or decide which inferences to draw from the evidence, as would be done when finding facts after a hearing on the record. Rather, on summary judgment “[t]he evidence of the nonmovant is to be believed, and all justifiable inferences are to be drawn in his favor.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986).

⁴ Findings of fact and conclusions of law are in italics and bold font.

The regulations governing research misconduct cases provide for summary judgment. 42 C.F.R § 93.506(b)(15) (stating that an ALJ may, “[u]pon motion of a party, decide cases, in whole or in part, by summary judgment where there is no disputed issue of material fact”); *see Scott J. Brodie*, DAB CR2056 (2010), *aff’d*, *Brodie v. Dept. of HHS*, 796 F. Supp. 2d 145 (D.D.C. 2011) (upholding ALJ finding that HHS was entitled to summary judgment).

ORI contends that summary judgment is warranted, and Respondent counters, arguing that he did not create falsified and fabricated images, but rather, was himself the victim of “cyber sabotage.” R. Cross Motion, at 19. However, Respondent admits that the grant applications and papers cited in the charging document contain falsified and fabricated images. R. Response, *passim*. Although Respondent argues that another person (or persons) was responsible for the publication of false and fabricated images, he ultimately does not challenge the facts underlying this case, namely that slide images he submitted with grant applications and published in scholarly journals were falsified and fabricated. *Id.*

Respondent, in his defense, has identified *issues of law* that relate to the interpretation and application of the regulations for scientific misconduct and how those regulations are applied to the undisputed facts of this case. The issues in this case must be resolved against Respondent as a matter of law, and summary judgment is appropriate such that an oral hearing is unnecessary.

2. Respondent admits that the seven grant applications and three journal articles addressed in the charging document contain flawed images, that he assembled the images into figures for submission to journals, was the principal investigator and the only listed personnel common to all of the NIH grant applications, and is the only common author for the three journal papers at issue.

Respondent “does not dispute that he was the principal investigator” on the NIH grant applications and manuscripts cited in the charging document. R. Response, at 2. Respondent further admits that he is the only common author of the three publications and seven grant applications discussed in the charging document. R. Response, at 26. Respondent also acknowledges that he was an author and “group leader” of the three published manuscripts. R. Response, at 26. In addition, Respondent admits that he included and assembled the figures in the manuscripts. R. Memorandum, at 16, 18.

Respondent concedes that “the manuscripts and NIH applications contained falsified, reused, and falsely labeled images.” R. Memorandum, at 18. Respondent unambiguously explained: “Yes, manuscripts and NIH applications were submitted; yes, the submitted manuscripts and NIH applications contained manipulated images, and yes,

the Respondent assembled the figures for manuscripts Science 2004, Science 2006, and Nature 2005 Manuscript.” R. Memorandum, at 4.

The ORI charging document included the following list of journal articles and grant applications that involved research misconduct:

Gou, D., Rubalcava, M., Sauer, S., Mora-Bermudez, F., Erdjument-Bromage, H., Tempst, P., Kremmer, E., & Sauer, F. “SETDB1 is involved in postembryonic DNA methylation and gene silencing in *Drosophila*.” *PLoS One* 5(5):e10581, 2010 (herein referred to as “*PLoS One* 2010”).⁵

Sanchez-Eisner, T., Gou, D., Kremmer, E., & Sauer, F. “Noncoding RNAs of trithorax response elements recruit *Drosophila* Ash1 to Ultrabithorax.” *Science* 311 (5764):1118-1123, 2006 (herein referred to as “*Science* 2006”) (Retraction in: McNutt M. *Science* 344(6187):981, 2014).⁶

Maile, T., Kwoczynski, S., Katzenberger, R.J., Wassarman, D.A., & Sauer, F. “TAF1 activates transcription by phosphorylation of serine 33 in histone H2B.” *Science* 304(5673):1010-1014, 2004 (herein referred to as “*Science* 2004”) (Retraction in: McNutt M. *Science* 344(6187): 981, 2014).⁷

1 R21 DA025703-01, “Dissection of epigenetic protein landscape via DNA-RNA capture assay,” Frank Sauer, Ph.D., P.I., submitted to the National Institute on Drug Abuse, NIH, on February 12, 2008 (herein referred to as “R21 DA025703-01”).

1 R21 DK082631-01, “Role of regulators of non-coding RNA transcription in marking epigenetic chromatin structures,” Frank Sauer, Ph.D., P.I., submitted to the National Institute of Diabetes and Digestive and Kidney

⁵ ORI’s proposed administrative actions include notice that this journal article should be retracted or corrected.

⁶ This journal article was later retracted after the UCR Committee on Privilege and Tenure’s investigation determined that “image manipulations . . . constituted a significant departure from the accepted practices of Dr. Sauer’s research community,” and “the data, results, and conclusions in the papers are clearly not reliable.” ORI Ex. 6.

⁷ This journal article was later retracted after the UCR Committee on Privilege and Tenure’s investigation determined that “image manipulations . . . constituted a significant departure from the accepted practices of Dr. Sauer’s research community,” and the “data, results, and conclusions in the papers are clearly not reliable.” ORI Ex. 6.

Diseases, NIH, on February 13, 2008 (herein referred to as “R21 DK082631-01”).

1 R01 DK082675-01, “Role of non-coding RNA as epigenetic mark,” Frank Sauer, Ph.D., P.I., submitted to National Institute for Diabetes and Digestive and Kidney Diseases, NIH, on February 13, 2008 (herein referred to as “R01 DK082675-01”).

2 R01 GM073776-06A1, “RNA-mediated recruitment of epigenetic regulators,” Frank Sauer, Ph.D., P.I., submitted to National Institute of General Medical Services, NIH, on November 3, 2009 (herein referred to as “R01 GM073776-06A1”).

1 R01 GM085229-01, “Role of non-coding RNA in gene expression,” Frank Sauer, Ph.D., P.I., submitted to National Institute of General Medical Services, NIH, on October 5, 2007 (herein referred to as “R01 GM085229-01”).

1 R01 GM085303-01, “Role of MBD/SET proteins in epigenetic silencing and de novo DNA methylation,” Frank Sauer, Ph.D., P.I., submitted to National Institute of General Medical Services, NIH, on October 5, 2007 (herein referred to as “R01 GM085303-01”).

1 R01 GM085303-01A1, “Role of MBD/SET proteins in de novo DNA methylation and epigenetic silencing in development and disease,” Frank Sauer, Ph.D., P.I., submitted to National Institute of General Medical Services, NIH, on March 5, 2009 (herein referred to as “R01 GM085303-01A1”).

ORI, in the charging document, found that Respondent had committed research misconduct when he “falsified and/or fabricated images in . . . publications and grant applications to represent falsely the results of different co-immunoprecipitation (“co-IP”) assays, histone methyltransferase (“HMT”) assays, kinase assays, and reverse transcription-polymerase chain reaction (“RT-PCR”) assays” Charging document, at 15. ORI found that Respondent “engaged in research misconduct by intentionally, knowingly or recklessly falsifying and/or fabricating images” by “manipulating, reusing, and falsely labeling images of autoradiograms and gels to represent falsely the results of different experiments on the epigenetic regulation of gene expression.”⁸ Charging document, at 15 (emphasis omitted).

⁸ The falsified and falsely labeled images were listed in the preliminary results to the grant applications, and were published in the three journal papers at issue. *See* ORI Exs. 3-5, 7-13.

In support of its finding of research misconduct, ORI outlined the following specifications, which were detailed in “Issues” 1.1 through 1.8 of the charging document:

The image in Figure S4 of *Science* 2006, representing the *in vitro* interaction between the Ash 1 protein and RNA transcripts from the trithorax response elements (TREs) of the *Ultrabithorax (Ubx)* gene, was manipulated and used in Figure 9 of R21 DA025703-01, Figure 9 of R21 DK082631-01, Figure 9 of R01 DK082675-01, and Figure 11C of R01 GM085229-01 to represent the *in vitro* interactions between a segment of the MLL protein and the ncRNAs derived from HOXa2, HOXa4, and HOXa7 TREs. [See Issue 1.1, Charging document, at 10].

The image in Figure 1A of R01 GM085303-01, representing a co-immunoprecipitation assay of endogenous Mdu from the *Drosophila* [embryonic extracts], was manipulated and used in Figure 1B of the same grant application to represent a co-immunoprecipitation assay of exogenously expressed Flag-Mdu from *Drosophila* [cell line S2]. [See Issue 1.2, Charging document, at 10-11].

The left panel of the image in Figure 1d of the *Nature* 2005 manuscript, representing the total amount of histones present in a ubiquitination assay with the protein TAF 1, was used in the left panel of Figure 8A of R01 GM085303-01A1 to represent the total amount of histones present in an HMT assay with the protein SETDB2. [See Issue 1.3, Charging document, at 11].

The left panel of the image in Figure 1b of *Nature* 2002, representing the total amount of histones present in an HMT assay with two versions of the protein Ash1, was manipulated and used in the left panel of the image in Figure 1E of R01 GM085303-01 and Figure 1D of R01 GM085303-01A1 to represent the total amount histones present in an HMT assay with the protein Flag-Mdu, and also used in lanes 3 and 4 of the image in Figure 1B of *Science* 2004 to represent the total amount of histones present in an *in vitro* kinase assay with the protein TAF1. [See Issue 1.4, Charging document, at 11-12].

Lane 2 of the image in Figure 1C of R01 GM085303-01 and Figure 1B of R01 GM085303-01A1, representing an HMT assay demonstrating the ability of endogenous Mdu to methylate [nucleosomes], was manipulated and used in lane 4 of the image in Figure 1E of R01 GM085303-01 and Figure 1D of R01 GM085303-01A1 to represent an HMT assay demonstrating the ability of exogenously expressed Flag-Mdu to methylate polynucleosomes, and also used in lane 6 (third “Oct” lane) of the image in Figure 2 (right panel) of R01 GM085303-01 to represent an HMT assay demonstrating the ability of endogenous Mdu to methylate octamers. [See Issue 1.5, Charging document, at 12-13].

The right-most lane of the image in Figure 2 (right panel) of R01 GM085303-01, demonstrating the methyltransferase activity of Mdu, was manipulated and used in lane 3 of the image in Figure 1B of *PLoS One* 2010 to represent the methyltransferase activity of dSETB1. [See Issue 1.6, Charging document, at 13].

Lanes 1-5 of the image in Figure 68 of R21 DA025703-01, Figure 11B of R01 GM085229-01, Figure 6B of R01 DK082675-01, and Figure 6B of R21 DK082631-01, representing ncRNAs transcribed from the regulatory region of the HOX genes, was manipulated and used in Figure 13 of R21 DK082631-01 and Figure 13 of R21 DA025703-01 to represent ncRNAs transcribed from the regulatory regions of the *Ultrabithorax* gene and ultrabithorax and actin transcripts. [See Issue 1.7, Charging document, at 14].

The image in Figure 10C (right half) of R01 GM073776-06A1, representing the transcription of endodermal genes from embryoid bodies, was manipulated and used in Figure 10C (left half) of the same grant application to represent the transcription of mesodermal and ectodermal genes. [See Issue 1.8, Charging document at 14].

Charging document, at 15-16.⁹

Respondent has not disputed the specifications detailed above, and has conceded the following:

Respondent does not dispute that the image in Figure 9 of R21 DA025703, Figure 9 of R21 DK082631, Figure 9 of R01 DK082675, and Figure 11C of R01 GM085229 was reported as showing a different experiment than in *Science* 2006. The respondent does not dispute that he reported the image in Figure 9 of R21 DA025703, Figure 9 of R21 DK082631, Figure 9 of R01 DK082675, and Figure 11C of R01 GM085229, with reported meaning that he submitted the NIH grant proposals containing the image present in Figure 9 of R21 DA025703, Figure 9 of R21 DK082631, Figure 9 of R01 DK082675, and Figure 11C of R01 GM08522.

R. Response at 5; see Issue 1.1, Charging document, at 10.

The respondent does not dispute that he reported (meaning submitted) R01 GM085303-01 contained the images present in Figure 1A of R01 GM085303-01 and that the image was reported as immunoprecipitation assay using naturally expressed Mdu protein from the nuclei of *Drosophila* embryonic cells . . . The respondent does not dispute that he reported (meaning submitted) R01

⁹ The specifications listed herein include corrections to the errata identified by ORI's witness. ORI Ex. 37 at 6.

GM085303-01 which contained the image present in Figure 1B and that the image was reported as immunoprecipitation assay, using artificially expressed Mdu protein tagged with “Flag” (“Flag-Mdu”) extracted from cells from the *Drosophila* S2 cell line.

R. Response at 7-8; *see* Issue 1.2, Charging document, at 10-11.

The respondent does not dispute that the *Nature* 2005 manuscript and R01GM085303-01A1 were submitted and contained the same image in Figure 1d and Figure 8A, respectively. The respondent does not dispute that Figure 8A describes methyltransferase rather than ubiquitination assays.

R. Response at 10; *see* Issue 1.3, Charging document, at 11.

The images present in Figure 1b in “*Nature* 2002”, Figure 1B of *Science* 2004 and in Figure 1E of R01 GM085303-01 (and Figure 1D of R01 GM085303-01A1) were derived from the same digital image . . . Respondent does not dispute that Figure 1b in *Nature* 2002 describes HMT assays. Respondent does not dispute that he submitted *Nature* 2002, which contains Figure 1b describing HMT assays . . . Respondent does not dispute that Figure 1B of *Science* 2004 does not represent HMT assay, but rather a kinase assay.

R. Response at 11-12; *see* Issue 1.4, Charging document, at 11-12.

Respondent does not dispute that Figure 1E of R01 GM085303-01 (and Figure 1D of R01 GM085303-01A1) describe the results of HMT assays. Respondent does not dispute that he submitted R01 GM085303-01 and R01 GM085303-01A1, which contain Figure 1E and Figure 1D, respectively, describing an HMT assay . . . The respondent does not dispute that the same image is present in Figure 1C of R01 GM085303-01 (and Figure 1B of R01 GM085303-01A1), Figure 1E of R01GM085303-01 (and Figure 1D of R01 GM085303-01A1), and Figure 2 of R01 GM085303-01.

R. Response at 13-14; *see* Issue 1.5, Charging document, at 12-13.

Respondent does not dispute that he submitted [*PLoS One*] 2010, which contains Figure 1B describing methyltransferase assays testing the methyltransferase activity of the protein dSETDB1. Respondent does not dispute that Figure 2 of R01 GM085303-01 and the right panel of Figure 1B of *PLoS One* 2010 contain the same image.

R. Response at 18; *see* Issue 1.6, Charging document, at 13.

The respondent does not dispute that the submitted Figure 6B of R21 DA025703 (and in Figure 11B of R01 GM085229, Figure 6B of R01 DK082675, and Figure 6B of R21 DK082631) and the image in Figure 13 of R21 DK082631 (and Figure 13 of R21 DA025703) were derived from the same image . . . The respondent does not dispute that the submitted Figure 6B of R21 DA025703 (and Figure 11B of R01 GM085229, Figure 6B of R01 DK082675, and Figure 6B of R21 DK082631) describe the transcription of ncRNAs from Hox clusters in murine cells. The respondent does not dispute that he reported R21 DA025703, R01 GM085229, R01DK082675, and R21 DK082631 that contain the image present in Figure 6B of R21 DA025703 (and Figure 11B of R01 GM085229, Figure 6B of R01 DK082675, and Figure 6B of R21 DK082631).

R. Response at 19-21; *see* Issue 1.7, Charging document, at 14.

The respondent does not dispute that the right half of Figure 10C of R01 GM073776 describes endodermal gene transcripts. The respondent does not dispute that he reported (submitted) R01 GM073776 that contains the images present in Figure 10C . . . The respondent does not dispute that the left half of Figure 10C of R01 GM073776 described mesodermal and ectodermal gene transcripts . . . The respondent does not dispute that he reported (submitted) R01 GM073776 that contains the images present in Figure 10C.

R. Response at 23-24; *see* Issue 1.8, Charging document, at 14.¹⁰

Therefore, as a *factual matter*, Respondent does not challenge the factual basis underpinning ORI's finding of research misconduct, namely that journal publications and grant applications contained falsified, reused, and falsely labeled images, and he has presented no evidence that the publications and grant applications did not contain falsified, reused, and falsely labeled images. *See* R. Memorandum, at 18. I therefore sustain ORI's determination that the seven grant applications and three publications at issue contained falsified, reused, or falsely labeled images.

Respondent has offered no facts that call into dispute the facts offered by ORI demonstrating that the data included in the grant applications and publications had been falsified and fabricated, as discussed in Issues 1.1 through 1.8. Respondent does not deny

¹⁰ By making these admissions, it appears that Respondent does not dispute the findings of ORI's witness, a senior scientist investigator, who submitted a declaration outlining her investigation, along with her findings relating to Respondent's scientific misconduct. *See* ORI Ex. 37.

the facts that ORI presented, but rather, admits to the facts detailed above, limiting his arguments to essentially *who* falsified and fabricated the data that he submitted.

3. *Summary judgment is warranted because the undisputed material facts establish, by a preponderance of the evidence, that Respondent intentionally, knowingly or recklessly reported falsified and/or fabricated images that were included in seven NIH grant applications and three published papers, and in doing so, Respondent significantly departed from accepted practices of the relevant research community.*

As I previously explained, I have determined that this case should be decided in favor of ORI's motion for summary judgment. Even assuming all facts in the light most favorable to Respondent, including those facts that push the extreme limits of plausibility and credibility, the only reasonable inference that can be drawn from the undisputed material facts of this case is that Respondent committed research misconduct by *intentionally, knowingly, or recklessly* falsifying and fabricating data.

Respondent admits that the falsified and fabricated images were the product of intentional, knowing, or reckless action, but that the action was taken by other(s), and not him. Respondent's explanation of the reasons behind the false and fabricated images has been an evolving and inconsistent tale. In the UCR scientific misconduct proceedings, Respondent argued that the allegations against him were "in fact hyper-technical, and none of the alleged instances of image manipulation caused the papers in which they appear to be anything other than an accurate and honest reflection of Dr. Sauer's scientific work." Ex. B to Request for Hearing (Closing Statement, submitted August 5, 2013), at 5. In defending himself against allegations of scientific misconduct by UCR, Respondent did not allege that he was the victim of any sabotage, but rather, explained that there were legitimate reasons to explain the images contained in his grant applications and papers. Ex. B to Request for Hearing; *see* ORI Ex. 28. In fact, Respondent argued that a forensic expert "was able to ascertain that the images [the forensic expert] analyzed were not falsified or fabricated; instead, some images were merely a visual distortion caused by the normal process of image conversation [sic] required for publication." Ex. B to Request for Hearing, at 17. Respondent also blamed "honest error" for some of the alleged misconduct." Exhibit B to Request for Hearing, at 17. Respondent also claimed that his notebooks and original data had been stolen in the past, and the loss of this data prevented him from producing the original images and digital images from that period to support his claims that the images were not falsified and fabricated. Ex. B to Request for Hearing, at 25.

At the time of the NSF OIG investigation in 2014, Respondent did not allege that he had been the victim of any sabotage. ORI Ex. 30. In fact, NSF OIG reported that Respondent did not address the manipulation of images. ORI Ex. 30 at 9.

At the time Respondent filed his request for hearing, he submitted a February 2016 letter, written in the German language and translated by Respondent, from an unidentified individual who claimed to have sabotaged his research, giving the following reason: “An eye for an eye, a tooth for a tooth. I have lost my job, you yours.” Ex. A to Request for Hearing, at 10. Petitioner described this document as “a confession by the unknown individual(s) that they and not the respondent are responsible for image manipulations that have been observed in the respondent’s manuscripts and grant applications.” Request for Hearing, at 3. Respondent added that the letter “establishes a clear motive (revenge).” Request for Hearing, at 4.

Later in the course of this appeal. Respondent advanced an entirely new theory for the image manipulation through the submitted testimony of an individual, Mr. Rune Dreser. R. Exs. 6, 7. Mr. Dreser claimed, in written testimony submitted by Respondent, that his group “systematically sabotaged the work of German scientists” in order to “achieve the discontinuation of all gene-technological work in Germany with all available methods.” R. Ex. 7 at 1. Mr. Dreser stated that his group “manipulated all scientific data, which Dr. Sauer published in research grants and journal articles,” and that Mr. Dreser had “regret” because he “wasted [his] life with this ‘task.’” R. Ex. 7 at 2.

Respondent’s inconsistent arguments, to include a drastic shift during the months since he filed his request for hearing, raise significant doubts about the veracity of his explanations about how his data came to be fabricated and falsely reported. On the one hand, Respondent has previously alleged honest mistakes and the editing process as causes for the misreporting of his images. Ex. B to Request for Hearing. Yet, Respondent has also alleged two different theories of sabotage based on the separate motives of “revenge” by someone who apparently lost his job due to Respondent, and a crusade by an anti-gene technology group to systematically sabotage the work of German scientists.

ORI presents compelling objections to Respondent’s submission of Mr. Dreser’s statement, to include that it submitted evidence from the notarial company that purportedly notarized Mr. Dreser’s statement that “[t]here is a high probability that the [notary] seal used was forged” and “[t]here is also a high probability that the signature was forged.” ORI Ex. 45.

Despite ORI’s objections and the concerns it has raised regarding the authenticity of the evidence supporting Respondent’s arguments, summary judgment is nonetheless appropriate, as there are no disputed issues of material fact and the only questions that I must decide involve the application of law to undisputed facts. The only disputed facts, for purposes of this decision, involve *who* fabricated and falsified the images in the seven grant applications and three journal articles. However, the question of *who* fabricated and falsified the images is not material. Even assuming the disputed facts in Respondent’s favor, and accepting as true Respondent’s dubious allegation that he was

the victim of sabotage either due to revenge or the acts of an anti-gene technology crusade, Respondent has still committed research misconduct by *reporting* false and fabricated data when *he* submitted this information in grant applications and papers. The regulations governing scientific misconduct are found at 42 C.F.R. pt. 93 and became effective on June 15, 2005. 70 Fed. Reg. 28370 (2005). HHS will apply the version of the regulation that is in effect at the time of a respondent's conduct. *See, e.g.*, 70 Fed. Reg. 28370, 28380 (2005). Further, there is a six-year statute of limitations, with exceptions, to include if a respondent "continues or renews any incident of alleged misconduct that occurred before the six-year limitation through the citation, republication or other use for the potential benefit of the respondent of the research record that is alleged to have been fabricated, falsified, or plagiarized."¹¹ 42 C.F.R. § 93.105(b)(1). Pursuant to 42 C.F.R. § 93.103, research misconduct is defined as "fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results." The regulation further defines that fabrication means "making up data or results and recording or reporting them." 42 C.F.R. § 93.103(a). The definitions of fabrication and falsification clearly contemplate the *reporting* of research results, even if the individual reporting the research results did not *create* the data. Even if Respondent believes that others somehow manipulated the data in his grant applications and publications, *he* ultimately *reported* that data, thereby adopting the data, and its flaws, as his own.

Likewise, pursuant to 42 C.F.R. 93.103(b), 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." Research misconduct, according to 42 C.F.R. § 93.103(b), does not include honest error or differences of opinion. In order to sustain the finding of research misconduct, I must find, by a preponderance of the evidence, that Respondent "intentionally, knowingly, or recklessly" significantly departed from accepted practices of the relevant research community. 42 C.F.R. § 93.104.

The evidence is overwhelming and undisputed: Respondent was the principal investigator or primary author in the seven grant applications and three papers cited in the charging document. Even assuming, to the degree most favorable to Respondent, that another person or persons somehow manipulated his final grant applications and papers in order to include false data, that still does not negate that Respondent reported and submitted fabricated and false information. 42 C.F.R. § 93.103(a), (b).

¹¹ ORI notes that the *Science* 2004 is subject to the "subsequent use exception" discussed by 42 C.F.R. § 93.105(b)(1), and Respondent poses no opposition. As Respondent cited to *Science* 2004 in two of the grant applications at issue, that publication is excepted from the six-year statute of limitations. *See* ORI Exs. 12, 13.

Other than allegations made in the form of a letter and notarized statement, Respondent does not offer any specific detail regarding how a saboteur or saboteurs caused his images to be fabricated and falsely reported when he submitted grant applications and papers. In fact, Respondent has not shown how a saboteur accessed the documents prior to their submission as grant applications or for publication. More importantly, even if saboteurs had access to his computers and the files prior to their submission, such actions, if accepted as true for purposes of summary judgment, do not shield Respondent from research misconduct, as he did not ensure that his papers and grant applications were without fabrication and falsification when *he* submitted them. I need not determine whether Respondent, himself, personally created the documents he readily admits were false and fabricated. Rather, Respondent fails to appreciate that he has committed research misconduct, even if he did not *create* the false and fabricated data. Respondent admits that he was responsible for the grant applications and publications, and therefore, he is the person responsible for publication of the fabricated and false information. As a matter of law, even if Respondent did not create the false and fabricated data, at best case, he caused the journal articles to be published and submitted the grant applications without regard for whether the content was true. Respondent's repeated publication and submission of applications containing utterly false information shows, at minimum, indifference to the truth. By permitting numerous papers to be published and grant applications to be filed, all of which contained falsified and fabricated images, Respondent, at a minimum, acted *recklessly* and without regard for the truth of the information he reported. Respondent has asserted that he is the victim of "revenge," or alternatively, sabotage by an anti-gene technology entity; I have given Respondent the benefit of the doubt, consistent with summary judgment, and even assuming he did not personally create any of the fabricated or false images, he still committed scientific misconduct pursuant to 42 C.F.R. §§ 93.103 and 93.104.

In order to constitute research misconduct, there "must be a significant departure from accepted practices of the relevant research community." 42 C.F.R. § 93.104. Respondent, in response to the charging document and ORI's briefing, has not refuted ORI's allegations that the publication and submission of multiple grant applications and papers containing falsified and fabricated data is a departure from the accepted practices of the relevant research community. ORI has submitted evidence, in the form of articles (ORI Exs. 33, 34, 35), that establish the accepted practices of his research community. For example, an article cited by ORI addresses that the deletion of a band from a plot, "even if you believe it to be an irrelevant background band, is a misrepresentation of your data." ORI Ex. 33 at 2. An editorial cited by ORI addresses that "[m]oving, adding, removing, enhancing or obscuring features or sections of an image" can constitute data manipulation. ORI Ex. 35 at 1. ORI notes, in addition, that the journal *Science* retracted Respondent's *Science* 2004 and *Science* 2006 publications based on UCR's determination, in pertinent part, that Respondent's "image manipulations . . . constituted a significant departure from the accepted practices of Dr. Sauer's research community."

ORI Motion at 22, citing ORI Ex. 6. Regardless of the reason why Respondent's publications and grant applications contained fabricated and falsified information, Respondent repeatedly *reported* the flawed data without confirming its accuracy. ORI has demonstrated, without any rebuttal by Respondent, that Respondent departed from the accepted practices of the relevant research community by reporting false and fabricated images.

Research misconduct is shown by preponderance of the evidence; in fact, the evidence is overwhelming and undisputed by Respondent. *See* 42 C.F.R. § 93.103(c). Accepting Respondent's claims of sabotage, at face value and for purposes of summary judgment, Respondent nonetheless acted "intentionally, knowingly, or recklessly" in committing research misconduct. Over and over, on numerous occasions, Respondent submitted grant applications and publications that contained false and fabricated data. This is not an isolated instance of false or fabricated data, amounting to an honest mistake. *See* 42 C.F.R. § 93.103(d). Rather, this conduct occurred on an ongoing basis, and pervaded numerous publications and grant applications. Respondent simply has not disputed the overwhelming evidence that he repeatedly *submitted* false images and data; rather, he only challenges who created the images and data. The data flaws in Respondent's grant applications and journal articles were significant and should have been apparent, had Respondent taken care to review his data prior to reporting the data in his submissions. Even if, assuming for summary judgment, Respondent did not create the falsified and fabricated images, Respondent was *reckless* in repeatedly adopting those flawed images as his own and reporting them in grant applications and journal articles.

Respondent has admitted that the false and fabricated data contained such significant flaws as altered versions of images, manipulated images, reports of the same image as two different experimental results, images that were derived from the same digital image, and misreported images. R. Response, *passim*. Respondent has undeniably admitted these flaws. In reporting this flawed data in publications and grant applications, Respondent did not commit an honest error, but rather (and at best case), failed to review and oversee the accuracy of the publications and grant applications that he authored.

4. The undisputed material facts support that the proposed HHS administrative actions are reasonable.

ORI proposed that Respondent, who was already debarred by NSF (ORI Exs. 30-32), be prohibited from serving in any advisory capacity to PHS, including, but not limited, to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant for a period of five years to coincide with his NSF debarment, and that HHS would send a notice to *PLoS One* that a paper published in that journal in 2010 should be retracted or corrected. Charging document, at 18; *see* ORI Ex. 3. Respondent has not argued that the administrative actions are unreasonable, or that ORI improperly considered aggravating and mitigating factors pursuant to 42 C.F.R. § 93.408.

I have considered this proposal in light of the undisputed facts relating to the seriousness of Respondent's misconduct and the aggravating and mitigating factors governing HHS administrative actions that are set forth at 42 C.F.R. § 93.408. ORI determined that there were several aggravating factors, to include: Respondent's "knowing and intentional falsification and/or fabrication include manipulating and reusing falsely relabeling images," that his misconduct was not isolated and was part of a continuing pattern, that his fabrications and falsifications had a "significant impact on the scientific record because they led to retractions of publications in the high-impact journal *Science*," and that he failed to accept responsibility. Charging document, at 17. ORI did not find that any mitigating factors were present. Charging document, at 15; *see* 42 C.F.R. § 93.408. Despite the finding of multiple aggravating factors, the proposed administrative actions are nonetheless restrained and do not, in reality, reflect a severity of administrative action that shows significant influence by multiple aggravating factors pursuant to 42 C.F.R. § 93.408. In fact, Respondent has already been debarred through a separate action by NSF, which is a more severe penalty than the administrative actions proposed by ORI. The primary administrative action proposed by HHS, a prohibition in serving in any advisory capacity to PHS, coincides with the previously imposed debarment and would not involve any additional period of time. Charging document, at 18. Further, the administrative action of sending a notice to *PLoS One* that retraction or correction is warranted pursuant to 42 C.F.R. § 93.411(b) is reasonable, as Respondent has admitted that the journal article contained fabricated or falsified images. R. Response at 19-21. I therefore find the proposal of administrative remedies to be reasonable.

The undisputed facts establish that this case involves serious scientific misconduct. Respondent's misconduct was repeated, and involved numerous grant applications and publications. Further, ORI has shown that Respondent's misconduct has had significant impact, in that his *Science* 2006 paper, alone, has been cited 185 times in scientific literature. ORI Memorandum at 23, citing ORI Exs. 36, 37. ORI has supported its charge of scientific misconduct with eight specifications, and ORI has established that the scientific misconduct occurred repeatedly over a period of years. This further supports that Respondent should not be permitted to serve in any advisory capacity to PHS for a period of five years and that *PLoS One* should be notified that a specific article should be retracted or corrected.

I have carefully reviewed Respondent's submissions in order to determine whether he has offered facts that dispute those facts demonstrated by ORI, and to the contrary, Respondent's admissions support ORI's charge. ORI has proposed reasonable administrative actions that, based on the scale of the misconduct, are restrained and appropriate. The large scale of false and fabricated data warrants no less than a five-year bar to serving in an advisory capacity to PHS. Further, the notification to *PLoS One* that an article should be retracted or corrected because it relies on admittedly altered and manipulated images is entirely reasonable. *See* R. Response at 3-6. I therefore recommend that the proposed administrative actions be upheld.

IV. Conclusion

I recommend that the Assistant Secretary for Health uphold the administrative actions proposed by ORI based on the scientific misconduct committed by Respondent.



Leslie C. Rogall
Administrative Law Judge