# IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, ex rel.	:	CIVIL ACTION
ROBERT BAUCHWITZ, M.D., Ph.D.	:	
	:	NO. 04-2892
ν.	:	
	:	
WILLIAM K. HOLLOMAN, Ph.D., et al.	:	

### **MEMORANDUM OPINION**

## Savage, J.

## **December 1, 2009**

In this action presenting issues relating to the False Claims Act ("FCA")<sup>1</sup> statute of limitations that have not been decided by the Third Circuit Court of Appeals and have divided other circuit and district courts, we hold that the tolling provision in § 3731(b)(2) does not apply to a relator when the government has not intervened, and the limitations period in 31 U.S.C. § 3731(b)(1) is triggered by the earlier filing of the claim rather than the later payment. The decision with respect to the triggering point is confined to the peculiar framework of the federal grant program.

Plaintiff Robert P. Bauchwitz ("Bauchwitz") alleges that the defendants William K. Holloman ("Holloman"), Eric B. Kmiec ("Kmiec"), Cornell University Medical College ("Cornell University"), and Thomas Jefferson University ("Thomas Jefferson"), misrepresented the findings of their DNA research when they applied for National Institute of Health ("NIH")<sup>2</sup> research grants and did not correct the misrepresentations on

<sup>&</sup>lt;sup>1</sup> 31 U.S.C. §§ 3729-3733 (2003).

<sup>&</sup>lt;sup>2</sup> NIH is a division of the U.S. Public Health Service ("PHS"), which is part of the Department of Health and Human Services ("HHS"). HHS is the largest grant awarding agency in the Federal government.

subsequent progress reports and renewal applications. These misrepresentations, Bauchwitz asserts, resulted in false claims in violation of the FCA.

#### Background

Central to this case is scientific research performed by Holloman and Kmiec involving the identity of the gene, protein and activity within the cell of the fungus *Ustilago maydis* ("*U. maydis*"). Holloman is a scientific researcher in Cornell University's Department of Microbiology. Kmiec had collaborated with Holloman as a graduate student from 1979-1984 at the University of Florida where he worked under Holloman's supervision, and as a scientific researcher in Thomas Jefferson University's Department of Pharmacology and at the Kimmel Cancer Center where he assisted Holloman on research partly funded by NIH grants from 1991 to 1999. When he was a student in the early 1980's, he and Holloman co-authored several articles in which they claimed to be the first to isolate a protein associated with nucleated cells from the eucaryotic fungus *U. maydis*.<sup>3</sup> They called the protein "Rec1," and claimed that the Rec1 protein was derived from the *REC1* gene and had activity that allowed for the specific recombination of strands of DNA, called recombinase.<sup>4</sup> In the DNA research field, this was a significant revelation.

Bauchwitz worked in Holloman's lab from 1987-1990 as a graduate student. At that time, Bauchwitz and others working at Holloman's lab isolated the genes for *REC1* and *REC2*, and obtained sequences from them. The results were that the *REC1* DNA

<sup>&</sup>lt;sup>3</sup> Previously, proteins had been isolated only from bacterial cells, which are prokaryotic, or non-nucleated.

<sup>&</sup>lt;sup>4</sup> This was similar to the activity found in the recA protein isolated from the *Escherichia Coli* bacterium.

sequence would not specify the protein elements common to known DNA recombinases, but the *REC2* gene had a sequence consistent with a recombinase.

After Kmiec left Holloman's lab, they continued to collaborate and co-author articles. One of those articles, "The *Rec2* gene encodes the homologous pairing protein of *Ustilago maydis*" ("the 1994 Article"), was published in the November 1994 issue of *Molecular and Cellular Biology*.<sup>5</sup> The authors claimed that the protein they had isolated from *Ustilago maydis* was a Rec2 protein, not a Rec1 protein, which was derived from the *REC2* gene.

After reading the 1994 article sometime around November 28, 1994, Bauchwitz had suspicions about the reported findings. He had already been dubious of Holloman and Kmiec's research. His doubts dated back to when he had worked in Holloman's lab in the late 1980s. At that time, Bauchwitz suspected, for several reasons, that Holloman was engaging in scientific misconduct. First, no one else in Holloman's lab was able to replicate Kmiec and Holloman's findings that the Rec1 protein was derived from the *REC1* gene and had recombinase activity. Second, when Holloman was having difficulty obtaining approval of grant applications, another graduate student in his lab was able to achieve results<sup>6</sup> that were contradicted by prior results in other labs as well as Bauchwitz's own sequencing results obtained in the late 1980's on the *REC1* and *REC2* genes were not consistent with Holloman and Kmiec's earlier findings linking the Rec1 protein activity to

<sup>&</sup>lt;sup>5</sup> Kmiec, E.B., Cole, A., and Holloman, W.K. *Molecular and Cellular Biology* 14(11):7163-72 (1994). *Molecular and Cellular Biology* is a journal published by the American Society for Microbiology. http://mcb.asm.org (last visited Nov. 30, 2009).

<sup>&</sup>lt;sup>6</sup> Namely, that the Rec1 protein and its recombinase activities were found in a mutated *REC2* gene.

the *REC1* gene, and instead supported a link between the Rec1 protein and the *REC2* gene.

His suspicions were so profound that after he left the lab, he continued to follow Holloman's work. In late 1990, he informed Dr. Ken Berns, Chairman of the Cornell University Graduate School of Medical Sciences' Department of Microbiology, that, over his objections, Holloman had removed unfavorable data from a manuscript that they had co-authored and that Holloman had forged Bauchwitz's initials indicating that he had approved the manuscript. Also, in 1990, he urged the Office of Scientific Integrity ("OSI")<sup>7</sup> to investigate the accuracy of Holloman's reported findings regarding the Rec1 protein activity.

After reading the 1994 article, in which the individual defendants claimed that the protein they had isolated from *U. maydis* was derived from the *REC2*, not *REC1* gene, Bauchwitz suspected, even more strongly than he had previously, that Holloman and Kmiec had falsified their findings. He believed that the irreproducibility of the Rec1 protein research in the 1980s, as well as Bauchwitz's sequencing results, which were inconsistent with Holloman and Kmiec's findings linking the Rec1 protein activity to the *REC1* gene, motivated Holloman and Kmiec to find a way to transform the disputed Rec1 protein activity into Rec2 protein activity. Bauchwitz alleges that the 1994 article contained two false statements to support the authors' new "Rec1 is Rec2" theory. Between December of 1994 and February of 1995, he pursued his own investigation by contacting current and

<sup>&</sup>lt;sup>7</sup> OSI is now the Office of Research and Integrity ("ORI"), a division of the PHS. It "monitors institutional investigations of research misconduct and facilitates the responsible conduct of research through educational, preventive, and regulatory activities." <u>http://ori.dhhs.gov</u> (last visited Nov. 30, 2009).

former colleagues of Holloman, and current and former graduate students who worked in Holloman's lab.

As part of his investigation, Bauchwitz contacted ORI on February 6, 1995 to learn the status of the government's investigation of the defendants instigated by his first call to ORI in 1990, and to give ORI additional information based on his December 1994 phone call with Brian Rubin, a graduate student who succeeded Bauchwitz at Holloman's lab. The parties do not agree whether Bauchwitz identified himself on this call and whether he provided ORI with any details regarding alleged fraud at Holloman's laboratory.<sup>8</sup>

Bauchwitz's own research, which he began in 1991 and completed in 1999, failed to replicate Kmiec and Holloman's results. He concluded that the "Rec1 is Rec2" *U. maydis* research was false and the defendants used it to obtain NIH grants. But, he argues that he did not reach this conclusion until 2002, after he read another article authored by Holloman<sup>9</sup> ("the 2001 article") that he believed falsified the rec2-1 mutant gene sequence to appear capable of producing protein. Bauchwitz maintains that he did not learn that the defendants obtained any of the specific grant funding at issue in this case<sup>10</sup> until

<sup>&</sup>lt;sup>8</sup> Bauchwitz again contacted ORI on March 6, 2002. He admits that he provided ORI with no details or documentation of the alleged fraud during this phone call or any other previous time despite numerous requests from the Division of Investigative Oversight ("DIO") from 2002-2004 that he do so. *See* PI's Memo Addressing Issues Raised in 1/27/09 Order (Doc. No. 106-2) at 14 ("PI.'s 1/27 Memo") ("plaintiff never gave the ORI any information concerning the specific allegations at issue in this case prior to filing the Original Complaint" on June 30, 2004); Exs. to PI.'s Statement of Disputed Facts and Additional Facts (Doc. No. 90), Ex. 10.

<sup>&</sup>lt;sup>9</sup> See Kojic, M., Thompson, C.W. and Holloman, W.K. 2001, "Disruptions of the *Ustilago maydis REC2* gene identify a protein domain important in directing recombinational repair of DNA," *Molecular Microbiology* 40(6): 1415-1428 (2001).

<sup>&</sup>lt;sup>10</sup> There are three grants involved, two awarded to Holloman and Cornell University ("Cornell defendants") and one to Kmiec and Thomas Jefferson University ("Thomas Jefferson defendants"). The NIH grants are described in more detail later.

September 23 and November 8, 2002, when he received responses to his FOIA requests that his counsel had submitted on June 10, 2002.<sup>11</sup>

## The NIH Grants at Issue and the False Statements

Bauchwitz is alleging that grant applications, progress reports and financial status reports ("FSRs") submitted to NIH by the defendants between October 31, 1991 and September 19, 2006 contained false<sup>12</sup> or misleading statements pertaining to three categories of false statements.<sup>13</sup> Specifically, he accuses the defendants of (1) fabrication and/or falsification of the amino acid sequence of the Rec1 protein; (2) falsification of the DNA sequence of the *rec2-1* mutant gene; and (3) falsification of data images relating to Rec2 protein activity. With respect to all defendants, he contends that the false statements were published in, or based in substantial part upon, conclusions or findings reported in the 1994 article (categories 1 and 3). With respect to the Cornell defendants only, he contends that grant 2 RO1 GM42482-12A2 contains false statements by citing the 2001 article (category 2).<sup>14</sup> These false statements, according to Bauchwitz, were material to

<sup>&</sup>lt;sup>11</sup> See Pl's 1/27 Memo (Doc. No. 106-2) at 16-17.

<sup>&</sup>lt;sup>12</sup> With respect to the progress reports and FSRs, he contends that they contained impliedly false statements based on their relation to the grant applications.

<sup>&</sup>lt;sup>13</sup> Specifically, he contends that the Cornell defendants submitted grant applications, progress reports and FSRs containing false or misleading statements on October 31, 1991, April 29, 1993, September 30, 1993, April 26, 1994, September 29, 1994, January 24, 1995, April 24, 1995, September 14, 1995, September 27, 1996, December 31, 1996, October 31, 1995, April 28, 1997, December 15, 1997, April 28, 1998, April 27, 1999, May 21, 1999, September 5, 2001, October 30, 2001, April 25, 2003, April 28, 2004, April 21, 2005 and September 19, 2006. He contends that the Thomas Jefferson defendants submitted grant material containing false statements on May 31, 1995, January 30, 1997 and January 28, 1998. For a list of the grants at issue, *see* Appendix A to this Opinion.

<sup>&</sup>lt;sup>14</sup> See First Amended Compl. ("FAC") **¶¶** 27-42; Pl.'s Second Decl. (Doc. No. 110) **¶¶** 6-10.

the NIH grants at issue in this case.<sup>15</sup>

# The NIH Grant Process

A grant, a form of federal assistance, is an exercise of Congress' spending power.

31 U.S.C. § 6501(4)(A)-(B) (2003). A grant is defined as money paid or provided by the United States to an entity for a specified purpose. 31 U.S.C.A. § 6501(4)(A). Unlike a contract where the government pays for goods or services, a grant is monetary assistance to a non-federal entity authorized by statute to meet needs that Congress deems in the public interest. *Id.* 

The grants in this case are discretionary ones that were awarded on a competitive basis.<sup>16</sup> NIH announces opportunities for funding for specific topics or research goals. To obtain these funds, entities submit "competing new applications."<sup>17</sup> The applications must

<sup>16</sup> Grants are mandatory or discretionary. Mandatory grants, known as formula grants, are made to one or more classes of persons who meet specific criteria for eligibility in specified amounts, usually based on a statutory formula. Unlike discretionary grants that are awarded on a competitive basis, mandatory grants are given to all who qualify for them. *See* http://www.hhs.gov.asrt/og/grantinformation/grantsnet.html (last visited Nov. 30, 2009); http://www.ed.gov/fund/grant/about/discgrant.html (last visited Nov. 30, 2009).

<sup>&</sup>lt;sup>15</sup> Examples of false statements that the defendants allegedly made in grant application 1 R01 GM53732 based on false statements made in the 1994 article include: (a)"The structural gene responsible for the activity has been identified as REC2"; (b) "There is strong evidence that the 70kDa protein is responsible for the DNA renaturation activity." (and citing the 1994 article); (c) "We obtained amino acid sequence of peptides derived from the 70kDa protein purified from U. maydis. . . [T]he sequence information obtained corresponded precisely to REC2. . ." (and citing the 1994 article); and (d) "N-terminal sequence analysis of homologous pairing protein purified from U. maydis was found to correspond to an internal region within the REC2 sequence." See FAC ¶¶ 28-29. Examples of false statements that defendants allegedly made in grant application 2 R01 GM42482-12A2 based on citation to the 2001 article include the following statements and figures published in the 2001 article: (a) "Inspection of the rec2-1 DNA sequence on both sides of the deletion indicated that a novel ORF could be generated through conjunction of the flanking sequences. This ORF would be predicted to encode a 613 amino acid Rec2 protein variant with a novel 19residue leader sequence derived from upstream of the wild-type Rec2 protein;" (b) "The small open box on the left in Rec2-1 is a stretch of 19 residues brought into frame by conjunction of the DNA sequences flanking the deletion underlying the rec2-1 allele;" and (c) Schematic drawings in Figure 1 purporting to show a 5' extension of the rec2-1 open reading frame. See FAC ¶ 38.

<sup>&</sup>lt;sup>17</sup> See NIH Grants Policy Statement, U.S. Dep't Health & Human Services (Rev. Dec. 1, 2003) ("NIH Grants Policy Stmt.") at 20, *available at* http://grants.nih.gov/grants/policy/nihgps\_2003/index.htm. Competing new applications typically include a project description, detailed budget and budget justification, biographical sketches of key personnel, and other information specified in the funding opportunity announcement. *Id.* 

meet legislative and regulatory requirements, and published selection criteria established for the particular program. After conducting a formal review process that includes peer review of the competing applications, the agency determines which applications best address the program requirements and are most worthy of funding.<sup>18</sup>

When an agency awards a grant, it issues a Notice of Grant Award ("NGA"). The NGA sets out the terms, the project period,<sup>19</sup> the total project amount, the amount authorized for each year, the annual budget, and the budget period.<sup>20</sup> To accept the grant, the recipient either signs and returns the NGA, or draws funds from the designated Department of Health and Human Services ("HHS") payment system. Funds are committed and available on the day the grant is awarded. Once the NGA is signed or money is drawn, the NGA and the grant terms are binding on the grantee and the government.<sup>21</sup>

A grant may be approved for a multi-year period, known as the project period. Under the project period system of funding, when an initial NGA is awarded, the project is programmatically approved for support in its entirety, but is funded in annual increments known as budget periods. Funds for each subsequent budget period are paid on a noncompetitive basis provided funds are available, the grantee has achieved satisfactory progress and the grant continues to be in the best interests of the government.<sup>22</sup> An NGA

<sup>&</sup>lt;sup>18</sup> NIH Grants Policy Stmt. at 26.

<sup>&</sup>lt;sup>19</sup> *Id.* at 14. A project period may cover more than one year and consist of several budget (fiscal) periods. *Id.* at 6, 75.

<sup>&</sup>lt;sup>20</sup> Id. 12, 74-75.

<sup>&</sup>lt;sup>21</sup> *Id.* at 74.

<sup>&</sup>lt;sup>22</sup> *Id.* at 74-75.

constitutes an "obligation,"<sup>23</sup> and the agency is required to submit its annual budget proposal to Congress, which includes the agency's "obligations."<sup>24</sup> Thus, the agency is only committed to funding the grant for the current budget period due to dependency upon the annual Congressional appropriations process. In this way, although the initial NGA declares the granting agency's intention to "provide continued financial support throughout the life of the grant," the projections of future funding levels are not guarantees that the project will be funded beyond the end date of the current budget period as shown in the NGA.<sup>25</sup>

To obtain an NGA for a subsequent budget period under a multi-year grant, a grantee must submit an annual progress report known as a "non-competing continuation application"<sup>26</sup> The progress report, which must be submitted two months before the beginning date of the next budget period, requires a description of: (1) the progress made over the past year; (2) any significant balance of funds to be carried over to the next budget period and how they will be spent if permitted to be carried forward; and (3) any significant

<sup>25</sup> NIH Grants Policy Stmt. at 74-75; HHS Grants Policy Statement (Rev. Jan. 1, 2007), at I-34-37, *available at* http://www.hhs.gov/grantsnet/docs/HHSGPS\_107.doc (last visited Nov. 30, 2009).

<sup>&</sup>lt;sup>23</sup> B-289801 (Dec. 30, 2002); B-126652 (Aug. 30, 1977).

<sup>&</sup>lt;sup>24</sup> An obligation is defined as "a definite commitment which creates a legal liability of the Government for the payment of appropriated funds for goods and services." 42 Comp. Gen. 733, 734 (1963); §§ 20.3, 20.5 OMB Circular No. A-11. An obligation must be supported by documentary evidence. 31 U.S.C.A. § 1501(a). For grants, an amount is an obligation when it is supported by documentary evidence that it is payable: (A) from appropriations made for payment of, or contributions to, amounts required to be paid in specific amounts fixed by law or under formulas prescribed by law; (B) under an agreement authorized by law; or (C) under plans approved consistent with and authorized by law. 31 U.S.C.A. § 1501(a)(5) (2003).

<sup>&</sup>lt;sup>26</sup> Both NIH and HHS's policy statements define a non-competing continuation application as "a request for funding . . . for the second or subsequent budget period within an approved competitive segment." According to HHS, after the first year and for the remaining project on an annual basis, HHS will "*non-competitively* fund the project during the approved project period as long as required information is submitted, funds are available, and certain criteria are met." (emphasis added). HHS Grants Policy Stmt. atl-15-16; NIH Grants Policy Stmt. at 20.

changes in key personnel expected during the next budget period. For a non-SNAP grant,<sup>27</sup> it must also contain a detailed budget for the next budget period.<sup>28</sup> Once funds for a subsequent budget period are awarded, a new NGA will be issued setting the new budget period and the amount of new funding that the government is obligated to provide.

In addition, a Financial Status Report ("FSR") must be submitted at the end of each twelve-month budget period in the case of certain grants, and at the end of a competitive segment in a project period in non-SNAP grants.<sup>29</sup> The FSR is a budget reconciliation form submitted to the government sixty to ninety days after the end of the report period and is an accounting of how the grantee spent the funds it received during the report period. It is not a report of results of the research project and is not a request for payment.<sup>30</sup>

Once the project period has ended, the grant is either renewed or closed. 45 C.F.R. §§ 74.71-74.73. To renew grants, grantees must submit a "competing continuation application." Renewal applications compete in the same manner as initial grant applications.<sup>31</sup> If the grantee chooses not to renew or the grant is terminated, the grantee must file a final FSR<sup>32</sup> and a final progress report. The final FSR covers the entire project

<sup>31</sup> *Id.* at 20.

<sup>&</sup>lt;sup>27</sup> All of the grants at issue are Streamlined Non-Competing Award Process ("SNAP") grants. Under SNAP, NIH negotiates the direct costs for the entire competitive segment at the time of the competing award, which eliminates the need for annual budget submissions, and reduces the amount of information NIH has to review to approve non-competing continuation awards. NIH Grants Policy Stmt. at 130.

<sup>&</sup>lt;sup>28</sup> NIH Grants Policy Stmt. at 75, 129-30; U.S. Dep't H.H.S., Public Health Service, Instructions for Non-Competing Continuation Progress Report (PHS 2590) at 3, 7, 11, 15.

<sup>&</sup>lt;sup>29</sup> NIH Grants Policy Stmt. at 131.

<sup>&</sup>lt;sup>30</sup> *Id.* at 131-32, 139-40.

<sup>&</sup>lt;sup>32</sup> Bauchwitz contends that because only SNAP grants are at issue, there are no annual FSRs, only final FSRs. This is contradicted by the record, which shows the Cornell defendants submitted annual FSRs for grant 42482-04 through 07. See PI.'s Second Decl. ¶¶ 48-50 and exhibits thereto. However, as we

period. Like the annual one, the final FSR is a budget reconciliation form submitted after the end of the project period that does not report results and does not request payment. The final progress report includes, at a minimum, a summary of progress in light of the originally stated goals, a list of significant results and a list of publications.<sup>33</sup>

### **Procedural History**

Bauchwitz filed his original complaint under seal on June 30, 2004. The government investigated the case while the complaint remained under seal. At the request of the United States Attorney's Office, ORI conducted a scientific review of the allegations set forth in Bauchwitz's complaint. Because the research at issue had taken place so many years earlier and because it did not view the statements at issue as intentionally false, ORI concluded that it did "not believe that evidence is available" to prove that any of the three claims alleged by Bauchwitz are false.<sup>34</sup> On August 31, 2005, after its fourth motion for an extension was denied, the government elected not to intervene.

On April 19, 2006, because Bauchwitz did not prosecute the action for over seven months after the government had declined to intervene, the action was dismissed. On April 19, 2007, the dismissal was vacated upon Bauchwitz's motion. An amended complaint was filed on May 16, 2007, adding claims based on allegedly false statements made in connection with a third federal grant submitted by the Thomas Jefferson defendants. It

discuss *infra*, whether the FSRs were submitted annually or only at the end of each project period is not relevant to our determination.

<sup>&</sup>lt;sup>33</sup> NIH Grants Policy Stmt. at 131-32, 139-40; U.S. Dep't H.H.S., Public Health Service, Instructions for Non-Competing Continuation Progress Report (PHS 2590) at 22.

<sup>&</sup>lt;sup>34</sup> Letters from ORI dated November 23, 2004 and June 28, 2005 at 9 and 2, Defs.' Jt. Stmt. of Undisputed Facts (Doc. No. 86), Exs. TTT and UUU, respectively .

also "identifie[d] . . . the specific statements made by each . . . defendant[] that the Relator contends were false or fraudulent, as well as the specific grant applications and progress reports in which such false or fraudulent statements were made."<sup>35</sup>

The defendants moved to dismiss the amended complaint. The grounds included plaintiff's failure to state a claim pursuant to Rule 12(b)(6) because he is alleging a scientific dispute and not a fraud, lack of subject matter jurisdiction because plaintiff is not an "original source" of the support for his allegations, and the claims are barred by the statute of limitations. Pursuant to notice, the motion to dismiss was converted to a motion for summary judgment. The parties then conducted discovery limited to the issue of the statute of limitations.

## **Summary Judgment Standard**

Summary judgment is appropriate if there is no genuine issue as to any material fact and "if, viewing the facts in the light most favorable to the non-moving party, the moving party is entitled to judgment as a matter of law." *Ebbert v. DaimlerChrysler Corp.*, 319 F.3d 103, 108 (3d Cir. 2003) (citing Fed. R. Civ. P. 56(c)). Because the statute of limitations is an affirmative defense, the defendants bear the burden of proving that the statute of limitations bars Bauchwitz's claims. *Richard B. Roush, Inc. Profit Sharing Plan v. New England Mut. Life Ins. Co.*, 311 F.3d 581, 585 (3d Cir. 2002). Thus, because the defendants are moving for summary judgment on statute of limitations grounds, the burden of demonstrating that there are no genuine issues of material fact begins and remains with them. *Ebbert*, 319 F.3d at 108.

<sup>&</sup>lt;sup>35</sup> Pl.'s Consolidated Mem. of Law in Opposition to Defs.' Mots. for Sum. J. (Doc. No. 88) at 4, 7.

Although all reasonable inferences are drawn in the nonmovant's favor, *Intervest, Inc. v. Bloomberg, L.P.*, 340 F.3d 144, 159-60 (3d Cir. 2003), an inference based upon speculation or conjecture does not create a material fact. *Robertson v. Allied Signal, Inc.*, 914 F.2d 360, 382 n.12 (3d Cir. 1990). Thus, "[w]here the record taken as a whole could not lead a rational trier of fact to find for the non-moving party, there is no 'genuine issue for trial." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986) (citation omitted).

#### The False Claims Act Statute of Limitations

The FCA prohibits "any person from making false or fraudulent claims for payment to the United States." *Graham County Soil & Water Conservation Dist. v. United States ex rel. Wilson*, 545 U.S. 409, 411 (2005); 31 U.S.C. § 3729(a). Any person found liable for violating the FCA is subject to a civil penalty of \$5,000 to \$10,000 per violation and treble damages. 31 U.S.C.A. § 3729(a) (West Supp. 2008); *Hutchins v. Wilentz, Goldman & Spitzer*, 253 F.3d 176, 181 (3d Cir. 2001).

An action under the FCA may be commenced in one of two ways. The attorney general may sue on behalf of the United States government; or, a private individual, known as a relator, can bring a *qui tam* action. 31 U.S.C.A. § 3730(a), (b)(1); *Graham County*, 545 U.S. at 411-12 (citing *Vermont Agency of Natural Res. v. United States ex rel. Stevens*, 529 U.S. 765, 769-72 (2000)). Because the relator brings the action on behalf of the government, he must give the government notice of the action. The government has sixty days from the filing of a *qui tam* complaint to elect to intervene in the action, and,

for good cause shown, can petition the court to permit it to intervene at a later date. *Graham County*, 545 U.S. at 412; § 3730(b)(2) and (c)(3).

A civil action under the FCA must be brought within six years of the violation or within three years of the date when the government learned or should have learned the facts material to the violation, whichever is later. *Id.* §§ (b)(1), (2). In no event may an action be brought after ten years of a violation. *Id.* Specifically, the FCA statute of limitations provides:

(b) A civil action under [the False Claims Act] may not be brought -

(1) more than 6 years after the date on which the violation of [the False Claims Act] is committed, or

(2) more than 3 years after the date when facts material to the right of action are known or reasonably should have been known by the official of the United States charged with responsibility to act in the circumstances, but in no event more than 10 years after the date on which the violation is committed,

whichever occurs last.

# 31 U.S.C.A. § 3731(b) (2003).

The critical difference between  $\S(b)(1)$  and (b)(2) is that under  $\S(b)(1)$ , the statute of limitations begins to run when the violation occurs, whereas under  $\S(b)(2)$ , it begins to run when the appropriate person learned or should have learned facts putting him on notice that a violation occurred. A conflict arises from the interplay between the unusual procedure allowing a private party to bring a *qui tam* action on behalf of the government and the language of the tolling provision, which appears to relate only to the government. It is this conflict that raises the issues confronting us in this case.

## The Tolling Provision - 31 U.S.C. § 3731(b)(2)

The three-year tolling provision permits suit to be brought after the six-year period where the fraud was not discovered during or until late in that period. In most cases, the three-year discovery period expires within six years of the violation. In that event, subsection (b)(1), with its longer limitations period, applies. If the fraud is discovered early in the six-year period, subsection (b)(2) will not be implicated. For example, if the fraud is discovered within one year of the violation, the three-year tolling period does not come into play because the six-year period in § (b)(1) would apply. Where the fraud is not discovered until after six years or late in the six-year period, subsection (b)(2) extends the limitations period. If the fraud is not discovered until seven years after the violation, the limitations period is extended for three years after the discovery. If it is discovered five years afterwards, the period is extended three years, effectively moving the limitations bar to eight years after the violation.

In determining whether Bauchwitz's claims are timely, we must answer three questions. First, when did the violation occur with respect to each grant to trigger the running of the applicable limitations period under § 3731(b)(1)? Second, does § 3731(b)(2), the tolling provision, apply to private relators when the government has not intervened? Third, if it does, when does the limitation period start running - when the relator learned of the violation or when the government did?

## Accrual of Action Under § 3731(b)(1)

In applying § 3731(b)(1), the FCA speaks of a "violation." Is the violation the filing of the claim or is it the payment? There is a lack of unanimity as to whether the statute of limitations begins to run when the false claim is filed or when the government pays the

claim. *Compare United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 225 (1st Cir. 2004) (stating that the "statute attaches liability, not to the underlying fraudulent activity or to the government's wrongful payment, but to the 'claim for payment'") (quoting *United States v. Rivera*, 55 F.3d 703, 709 (1st Cir. 1995)), *with Jana, Inc. v. United States*, 41 Fed. Cl. 735, 742-43 (Fed. Cl. 1998) (stating that if the government makes payment on a submitted false claim, the FCA violation occurs on the date payment was made, rather than on the date the claim was submitted).<sup>36</sup>

Section 3729 does not define the words "false claim." It does define "claim" as "any request or demand . . . for money." 31 U.S.C. § 3729(c). Setting out what constitutes a violation of the FCA, it reads: "any person who . . . (1) knowingly presents, or causes to be presented, to an officer . . . of the United States Government . . . a false or fraudulent claim for payment or approval; (2) knowingly makes, uses or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government...." 31 U.S.C. § 3729(a).

Bauchwitz argues that the six-year statute of limitations period begins to run on the date the government paid the claim. He contends that is when the final payment was made, which, he asserts, was at the end of each project period after the grantees

<sup>&</sup>lt;sup>36</sup> See also these lower court cases concluding that the FCA statute of limitations starts running on the date of the false claim submission rather than of its payment: *United States v. Vanoosterhout*, 898 F.Supp. 25, 29 (D.D.C.1995), aff'd, 96 F.3d 1491 (D.C. Cir.1996); *United States ex rel. Condie v. Board of Regents of Univ. of Cal.*, No. C89-3550-FMS, 1993 WL 740185, at \*3 (N.D. Cal. Sept. 7, 1993), as compared to those holding that the statute of limitations starts running on the date payment was made: *United States v. The Incorporated Village of Island Park*, 888 F. Supp. 419, 441 (E.D. N.Y.1995); *United States ex rel. Kreindler & Kreindler v. United Technologies Corp.*, 985 F.2d 1148, 1157 (2d Cir.1993); *United States ex rel. Duvall v. Scott Aviation*, 733 F. Supp. 159, 161 (W.D. N.Y.1990); *United States v. Klein*, 230 F. Supp. 426, 441 (W.D. Pa.1964), aff'd, 356 F.2d 983 (3d Cir.1966).

submitted their final FSRs.<sup>37</sup> The defendants, on the other hand, argue that the statute of limitations begins to run at the time the grantees submitted the request for a grant<sup>38</sup> containing a false statement, not when the grant applications were approved and paid by government. According to the defendants, their position is consistent with the language of the FCA and the FCA's purpose of preventing fraud on the government by "attacking the activity that presents the risk of wrongful payment."<sup>39</sup>

Both the plain language of § 3729(a) and statements made by the Supreme Court and the Third Circuit support the principle that the application for payment, rather than payment of the claim, triggers the accrual of an action. The language of § 3729(a) focuses on the means and not the end. Liability arises from the use of fraudulent submissions intended to cause the government to issue payment. The statute does not fix liability on the receipt of payment. In fact, payment is not a prerequisite to liability. Payment need only be sought or approved in reliance on the false representations. In other words, liability begins with the false statement that is intended to induce payment. *See United States v. Neifert-White Co.*, 390 U.S. 228, 230 (1968).

The Supreme Court, in analyzing the applicability of § 3731(b)(1) to retaliation claims under § 3730(h) of the FCA, made clear that federal statutes of limitations start

<sup>&</sup>lt;sup>37</sup> Bauchwitz argues, in the alternative, that the six-year limitations period is triggered by the date the progress reports and continuation applications, which contained false express and implied certifications, were submitted. Pl.'s Mem. of Law in Opp'n to Defs.' Mot. for Summ. J. (Doc. No. 88) ("Pl.'s SJ Br.") at 33. See infra.

<sup>&</sup>lt;sup>38</sup> The defendants argue that grant requests include the initial and renewal grant applications, progress reports and continuation applications.

<sup>&</sup>lt;sup>39</sup> See Cornell Defs.' Mem. of Law in support of MSJ (Doc. No. 85) at 21 (quoting *Rivera*, 55 F.3d at 709).

running when the cause of action accrues. *Graham County*, 545 U.S. at 418. Although it did not address the issue of whether the application for payment or the actual payment itself triggers the running of the limitations, it did use language that suggests that the period starts when the claim is made rather than when payment is issued. It said, "the language in § 3731(b)(1) [ties] the start of the time limit to 'the date on which the violation of section 3729 is committed.' In other words, the time limit begins to run on the date the defendant submitted a false claim for payment." *Id.* at 415. This language imparts that the cause of action accrues before payment and is keyed to the "claim for payment."

Although the Third Circuit has not ruled on the issue, it has intimated that the trigger date is when the claim is made. In United States ex rel. Malloy v. Telephonics Corp., 68 F. App'x 270, 273 (3d Cir. 2003), when applying the six-year limitation period under § 3731(b)(1), the court treated the date that the defendant made the claim, not the date of payment, as the start date for calculating the limitations period. The court noted, "Malloy concedes that the claim accrued when Telephonics filed the original false claim. . . ." Id. The government attempts to minimize the import of the court's language by characterizing the statement as the relator's concession and not the court's position. Contrary to the government's argument, the court's analysis cannot be reduced to meaningless verbiage. Although it was not the court's holding, it is meaningful because the court would not have used that starting point in its analysis of the applicability of the statute of limitations merely because the relator did not challenge it. In other words, it would not have misapplied a legal principle even if the parties had. Otherwise, its entire analysis and the result would have been flawed. Therefore, the Malloy court's approach endorses, albeit implicitly, the principle that a § 3729 action accrues when the claim is made.

Prior to *Malloy*, the Third Circuit in *Hutchins v. Wilentz, Goldman & Spitzer*, 253 F.3d 176 (3d Cir. 2001), signaled that an FCA violation is complete at the time the claim is made. In considering what constitutes a false claim, it did not decide what established a violation for purposes of applying the statute of limitations. Nor did it rule out that submissions of false statements for approval of payment were false claims under the FCA. Indeed, the court held that the FCA "prohibits fraudulent claims that cause or *would cause* economic loss to the government." *Hutchins*, 253 F.3d at 179 (emphasis added).<sup>40</sup> *See also United States ex rel. Sanders v. American-Amicable Life Ins. Co.*, 545 F.3d 256, 259 (3d Cir. 2008) (stating that the FCA "cover[s] instances of fraud 'that *might* result in financial loss to the Government,' " but finding the FCA inapplicable because no claim was made to the government) (quoting *Hutchins*, 253 F.3d at 183) (emphasis added).

In reaching its decision, the *Hutchins* court explained that the FCA covers all fraudulent attempts to cause the government to pay money and actual payment is not necessary. *Id.* at 183, 184. *See also Neifert-White*, 390 U.S. at 233 (a "claim" under the FCA consists of "all fraudulent attempts to cause the government to pay out sums of money."); *Sanders*, 545 F.3d at 259 ("[R]ecovery under the [FCA] is not dependent upon the government's sustaining monetary damages.") (quoting *Hutchins*, 253 F.3d at 183). *Hutchins* cited the statutory definition of "claim," which includes "any request or demand," and does not mention "paid." *Id.* at 183. It observed that "the conception of a claim

<sup>&</sup>lt;sup>40</sup> The result in *Hutchins* turned on whether the government suffered or could have suffered an economic loss. The inflated legal bills the relator contended were fraudulent were submitted to the United States Bankruptcy Court for approval of payment by the bankruptcy estate, not the court. Acknowledging that the bankruptcy court was a government agency, the Third Circuit concluded that the court neither made nor was expected to make payment and, thus, suffered no economic loss. Therefore, because the government (the Bankruptcy Court) suffered no loss, the relator failed to make out a cause of action under the FCA. *Id.* at 184.

against the government normally connotes a demand for money or for some transfer of public property." *Id.* at 184 (quoting *United States v. McNinch*, 356 U.S. 595, 599 (1958)).

The Federal Court of Claims, which the relator and the government urge us to follow, has held that payment of the claim is what starts the limitations period. *See Jana,* 41 Fed. Cl. 735. Though it acknowledged that the submission of the fake claim itself is a violation of the FCA even when it is not paid, the *Jana* court concluded that the statute of limitations in the case before it did not begin to run until the claim was paid. It reasoned that the FCA cause of action accrues only when all events necessary to state a claim have occurred. *Id.* at 743. The last event, in its view, is payment.

The Jana court relied on dictum in United States ex rel. Kreindler & Kreindler v. United Technologies, Corp., 985 F.2d 1148, 1157 (2d Cir. 1993). In a discussion that was not necessary to its decision in Kreindler, the Second Circuit sought to correct the district court's comments with respect to the relator's continuing fraud theory. It pointed out that where there are multiple false claims in connection with a single contract, the statute of limitations for each claim runs from the date each claim accrued. Then, without analysis, it quoted the district court's holding that "the six-year limitation period of § 3731(b)(1) 'begins to run on the date the claim is made, or, if the claim is paid, on the date of payment.'" *Id.* at 1157 (quoting *Blusal Meats, Inc. v. United States*, 638 F. Supp. 824, 829 (S.D.N.Y. 1986), *aff'd*, 817 F.2d 1007 (2d Cir. 1987)).

To reconcile its conclusion with the fact that it is the false claim itself that constitutes the violation of the FCA, the *Jana* court distinguished between cases seeking civil penalties and those seeking damages. It concluded that in the former cases, the cause of action accrues upon presentation of the false claim; and, in the latter, it occurs upon payment because it is not until then that the government suffers damage. *Id.* at 743. In effect, it established two statutes of limitations, one for civil penalty cases and another for damages cases.

There is no justification for importing an optional statute of limitations into the statute. Nowhere in the FCA is there a distinction between civil penalty and damages cases for purposes of applying the statute of limitations. Both types of cases are treated the same. Nor is there anything in the legislative history that suggests that Congress intended two different statutes of limitations depending on whether the cause of action was for civil penalties or for damages. Thus, the foundation of the *Jana* court's reasoning cannot support its holding that the limitations period in *qui tam* actions is not triggered until payment is made.

Relying on the Jana decision, the government and Bauchwitz argue that until payment is made, there are no damages. Consequently, so they reason, the cause of action cannot accrue until then. This argument ignores the language of § 3731(b)(1) that refers to "the date on which the violation is committed" as the trigger date. Waiting for damages to start accumulating before starting the FCA clock ticking is inconsistent with established legal principles and the purpose of the FCA.

In the federal grant context, the government suffers harm at the time the false application is made. The government relies upon the false statements in determining whether the applicant's contributions will benefit the public interest. When it awards a grant to the applicant on the basis of the false representations, it excludes other applicants, thus losing the benefits of their contributions. At the same time, it commits public monies to an undeserving applicant at the expense of the public. Additionally, it expends time and resources during the evaluation of the application. Thus, the government is harmed by the false claim even before payment is made, giving rise to a cause of action.

If a private relator knows a claim is false when it is made, he cannot wait until payment is made to blow the whistle. In a case where payment is not due for years or a substantial period of time after the false claim is made, the government will suffer increased harm while losses increase. The government will have paid monies that it would not have had to pay had it been aware of the fraud, and it would not have to surrender a portion of the recovered monies with the relator. In effect, by waiting until the claim is paid, the relator gets a benefit at the expense of the government that was not intended by Congress.

To summarize, the Third Circuit's analysis of what constitutes a false claim in *Hutchins* and followed in *Sanders* shows that the violation is complete when the claim is made and not when paid. Where the defendant has put in motion the payment process and payment is a matter of mere ministerial procedure, the violation is complete. Here, the funds were committed after the defendants' applications had been submitted and approved. Thus, the false claim occurs at the time the grant application is submitted, not at the time the government releases the funds.

#### **Do Progress Reports Constitute False Claims for Payment?**

Because there are differences between an initial grant application and a progress report or non-competing continuation application, we must determine whether the submission of a progress report is a claim or demand for payment under the FCA.

Unlike an initial grant application, a progress report is not submitted on a competitive basis with other applicants, but is a prerequisite to the release of funding for the next

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budget period. It is not nearly as extensive as a grant application, particularly in the case of SNAP grants. Because it measures activity during the prior budget period, it merely contains a description of the progress the grantee has made over the past year and a certification that the "statements herein are true."

Like a grant application, a progress report is a prerequisite to the NIH releasing funds for a subsequent budget period. Although the initial NGA is considered an obligation for the entire project period, the agency does not guarantee funding for the entire project period, and is "committed" to funding the grant for only the current one-year budget period. As a prerequisite to obtaining funding for each subsequent annual budget period, the grantee must submit an annual progress report to NIH. Funds are released only if the grantee has achieved satisfactory progress toward meeting the objectives of the project and Congress appropriates the funds. Therefore, because approval of a progress report is a prerequisite to the release of funds for a subsequent budget period, a progress report is a claim or demand for payment under the FCA.

We next examine whether the progress reports contained false statements. If they did, they would constitute separate false claims under the FCA. If they did not, the question is whether the progress reports related back to the original false statements contained in the grant application, rendering them false claims. Bauchwitz does not contend that the information contained in the progress reports is false. On the contrary, he concedes there were no false statements in the progress reports themselves.<sup>41</sup> There is no dispute that the progress reports truthfully recite what the researchers had done and

<sup>&</sup>lt;sup>41</sup> See Tr. Oral Arg., Feb. 23, 2009, at 83, 97; Pl's 1/27 Memo (Doc. No. 106-2) at 8.

what results had been achieved during the reporting period. It is also agreed that the certifications in the progress reports signed by the defendants certified that the information in the actual progress report was true and that they acknowledged that they would be liable for any false claims and statements in them.

The question then becomes whether, in the grant context, a progress report that contains no false statements constitutes a false statement for FCA purposes when the grant was awarded on the basis of a false statement made in the original grant application. Bauchwitz argues that each progress report constitutes a separate false claim because the "written certifications [in the reports] . . . amounted to false express or implied ratifications and certifications of the continued truth and accuracy" of the misrepresentation in the initial application.<sup>42</sup> Relying on the "false certification theory of liability,"<sup>43</sup> he argues that the certification on each progress report signed by the defendants obligated them to correct the original false statements made in the grant application that preceded the progress report. Bauchwitz contends that because the defendants in the progress reports did not correct or retract the prior alleged false statements made in the grant application, each progress report should be considered a separate false claim continuing the fraud made in the initial application.

<sup>&</sup>lt;sup>42</sup> See Pl.'s Mem. (Doc. No. 106-2) at 8. Bauchwitz calls this argument an "alternative" to his theory that the six-year statute of limitations period is triggered by the date that each defendant received its last payment on a grant from the government. Pl.'s SJ Br. (Doc. No. 88) at 33.

<sup>&</sup>lt;sup>43</sup> The false certification theory of liability is premised on a defendant's false certification of compliance with a contract term, statute or regulation where payment by the government is conditioned on compliance with that requirement or the defendant's violation of the applicable regulation was relevant to the government's decision to disperse the funds. *Rodriguez v. Our Lady of Lourdes Medical Ctr.*, 552 F.3d 297, 303-04 (3d Cir. 2008); *United States ex rel. Quinn v. Omnicare Inc.*, 382 F.3d 432, 441 (3d Cir. 2004) (citing *United States ex rel. Siewick v. Jamieson Science and Eng'g, Inc.*, 214 F.3d 1372, 1376 (D.C. Cir. 2000)).

The defendants agree that each progress report constitutes a separate claim or demand for payment from the government. They disagree, however, that the false certification theory of liability applies, or that each progress report constitutes a separate *false* claim. Instead, they argue that the language in the certification in the progress report that "the statements herein are true" is limited to the truth and accuracy of the progress reports themselves, and cannot refer back to the alleged false statements in the initial grant application. Because, by Bauchwitz's admission, each progress report contains no express false statement, they argue that the progress reports cannot be viewed as false claims.

Contrary to Bauchwitz's argument that the signed certification implicitly guarantees that the information in the original grant application was true, the progress reports do not constitute false claims. The Third Circuit has not adopted the false certification theory of FCA liability on which Bauchwitz relies. The court recently declined to adopt the theory in *Rodriguez v. Our Lady of Lourdes Medical Center*, 552 F.3d 297, 303-04 (3d Cir. 2008) (stating that it has "yet to adopt in a holding the false certification theory, either in its express or implied version," and that "yet again we can avoid this issue . . ." (citing *United States ex rel. Quinn v. Omnicare Inc.*, 382 F.3d 432, 441 (3d Cir. 2004)). Therefore, the certification theory of liability will not be applied here.

Even if a false certification theory were available to him, Bauchwitz failed to plead the elements of an FCA claim based on this theory. The false certification theory of liability is premised on a defendant's false certification of compliance with a contract term, statute or regulation, and payment is conditioned on compliance with that requirement, or the defendant's violation of the applicable regulation was relevant to the government's decision to disperse the funds. *Rodriguez*, 552 F.2d at 303-04; *Quinn*, 382 F.3d at 441 (citing *United States ex rel. Siewick v. Jamieson Science and Eng'g, Inc.,* 214 F.3d 1372, 1376 (D.C. Cir. 2000)).<sup>44</sup>

Although it is unclear whether he is proceeding on an express or implied false certification theory,<sup>45</sup> Bauchwitz argues that he has pled the required elements of a false certification claim. Specifically, he contends that because the NIH grant programs at issue "were established and are operated under an extensive network of interrelated statutes and regulations which contain numerous provisions expressly requiring grantee compliance," this satisfies the requirement of a false certification claim that a defendant's compliance with the allegedly violated regulations was a condition of the government's payment of funds to the defendants. He also notes that the defendants signed the certifications in the progress reports, which stated: "I certify that the statements herein are true, complete and accurate," but fails to explain how this supports a false certification claim.

Bauchwitz has not made out a false certification claim. He fails to point to any specific regulation that the defendants violated. Nor has he articulated how payment by NIH was conditioned on the defendants' compliance with the unidentified regulation or how the defendants' purported non-compliance was relevant to NIH's decision to award the funds.

<sup>&</sup>lt;sup>44</sup> Specifically, there are three elements to a false certification claim: (1) the defendant received federal funds; (2) the defendant failed to comply with applicable regulations; and (3) the defendant's compliance with those regulations was a condition of, or at least "relevant to," the government's payment of the federal funds. *Rodriguez*, 552 F.3d at 304.

<sup>&</sup>lt;sup>45</sup> The false certification theory can encompass two types of claims: express and implied. The primary difference between the two approaches is that to state an express false certification claim, the defendant grantee must have expressly certified that he complied with the applicable regulation; whereas in an implied false certification claim, the grantee's act of submitting the claim for payment itself implicitly certified compliance with the regulation. *Rodriguez*, 552 F.3d at 303; *Quinn*, 382 F.3d at 441-42.

Under the circumstances, the certification language in the progress report that "the statements herein are true" refers only to the accurate statements made in the progress reports themselves, and not to the alleged false statements in the initial grant application. Therefore, the progress reports, in this case, do not constitute false claims.

## Do Financial Status Reports Constitute False Claims for Payment?

Similar to his argument that each progress report, despite its accuracy, constitutes a separate false claim, Bauchwitz argues that each final FSR, even though it does not contain any false statements, is a false claim. He contends that because the person who signs each FSR certifies that the information in it is complete and accurate, and that "the outlays and unliquidated obligations are for the specific purposes set forth in the grant documents," and the final FSR refers to all funds in the preceding competitive segment, "the FSR is intended to provide a clawback mechanism as a means to recover ALL improperly or fraudulently used funds in a particular competitive segment." On this basis, he argues that the submission of the final FSR is the trigger for the running of the statute of limitations.<sup>46</sup>

Unlike a progress report, an FSR, whether final or annual, is not a claim for payment from the government. It is a budget reconciliation form submitted to the government sixty to ninety days after the end of the preceding report period and is an accounting of how the grantee spent the funds it received during the report period.<sup>47</sup> Because there is no payment received after its submission, an FSR does not constitute a *claim* under the FCA.

<sup>&</sup>lt;sup>46</sup> Pl.'s Second Decl. ¶¶ 48-57; Pl.'s Stmt. of Add'l Facts Precluding Summ. J. (Doc. No. 89-2) ¶¶ 5-17.

<sup>&</sup>lt;sup>47</sup> Pl.'s Second Decl. ¶¶ 54-55; NIH Grants Policy Stmt. at 131-32.

In addition, even if the defendants could receive money after submitting an FSR, there is no *false* claim because Bauchwitz does not contend that any of the FSRs inaccurately state how the funds were spent. Therefore, the FSRs do not constitute false claims, and they cannot act as a trigger for the statute of limitations period.

# The Six-Year Limitations Period Under § 3731(b)(1)

Having determined that the six-year statute of limitations under § 3731(b)(1) was triggered when an initial grant application or a progress report containing an express false statement was submitted to the government, and that no false statement was made in connection with the submission of the progress reports or the FSRs, we now calculate when the six-year statute of limitations under § 3731(b)(1) was triggered for the grants at issue.

In applying the statute of limitations, we start counting backwards from the date of the filing of the complaint, June 30, 2004. The six-year limitation bars any cause of action relating to claims submitted prior to June 30, 1998.

With respect to the Thomas Jefferson defendants, the initial grant application (AR 44092-01) was submitted on May 31, 1995. To come within the six-year statute of limitations period, the complaint had to have been filed on or before May 31, 2001. Because the original complaint was not filed until June 30, 2004,<sup>48</sup> the claims against the

<sup>&</sup>lt;sup>48</sup> Because claims involving this grant were not alleged in the original complaint, the Thomas Jefferson defendants argue that the claims regarding this grant in the amended complaint, which was filed on May 16, 2007, should not relate back to that time. Bauchwitz argues that the claims first alleged in the first amended complaint relate back to the conspiracy claim in the original complaint. These arguments need not be addressed because even if the claims did relate back to the June 30, 2004 complaint, they cannot be saved and remain stale.

Thomas Jefferson defendants are barred by the statute of limitations, unless the tolling provision saves them. *See infra*.

With respect to the Cornell University grants, which were submitted on October 31, 1991 (2 R01 GM42482-04),<sup>49</sup> January 24, 1995 (1 R01 GM53732-01), October 31, 1995 (2 R01 42482-08), and October 30, 2001 (2 R01 42482-12A2), only the claim relating to the last grant falls within the six-year statute of limitations, and the claims as to the earlier grants can survive only if the tolling provision applies.<sup>50</sup> Accordingly, Bauchwitz's claims against the Cornell defendants, except the one relating to the grant 2 R01 42482-12A2, are barred by the six-year statute of limitations.<sup>51</sup>

## Applicability of the FCA's Tolling Provision to Relators

Before we can apply the tolling provision to the claims barred by the six-year limitations period, we must determine whether § 3731(b)(2), which states that the statute of limitations does not begin running until an official of the United States knew or reasonably should have known of the material facts, applies to *qui tam* actions where the government has not intervened. 31 U.S.C.A. § 3731(b)(2). Bauchwitz contends that it does apply; and, for purposes of applying it, the relevant "United States official" is a Department of Justice ("DOJ") official charged with the responsibility to act. The defendants argue that § 3731(b)(2) does not apply to private relators; but, if it does, the

<sup>&</sup>lt;sup>49</sup> This grant is also outside the ten-year tolling period.

<sup>&</sup>lt;sup>50</sup> Specifically, the statute of limitations expired with respect to these grant applications on October 31, 1997, January 24, 2001, October 31, 2001, and October 30, 2007, respectively.

<sup>&</sup>lt;sup>51</sup> Even if the progress reports were considered false claims, the six-year limitations period precludes any claims against the Thomas Jefferson defendants because the last progress report was submitted on January 28, 1998, and the original complaint was filed on June 30, 2004, more than five months after the sixyear statute of limitations expired. With respect to the Cornell University defendants, progress report 5 R01 GM 42482-11, which was submitted on April 27, 1999, if considered a false claim, would still be timely.

statute of limitations started running when Bauchwitz, not a government official, knew of the material facts.<sup>52</sup>

The circuits and district courts that have considered the issue are split as to whether § 3731(b)(2) applies to private relators in actions where the government has not intervened. The Courts of Appeals for the Fourth, Fifth and Tenth Circuits have held that the tolling provision does not apply to *gui tam* actions where the government has not intervened. United States ex rel. Sanders v. N. Am. Bus Indus., 546 F.3d 288 (4th Cir. 2008), cert. denied, 129 S. Ct. 2793 (2009); United States ex rel. Erskine v. Baker, 213 F.3d 638, No. 99-50034, 2000 WL 554644 (5th Cir. 2000) (unpublished table opinion); United States ex rel. Sikkenga v. Regence Bluecross Blueshield of Utah, 472 F.3d 702, 725 (10th Cir. 2006). In contrast, the Ninth Circuit, as well as district courts in Massachusetts, Georgia and Illinois, apply § 3731(b)(2) to private actions even where the government has not intervened. United States ex rel. Hyatt v. Northrop Corp., 91 F.3d 1211, 1214, 1217 (9th Cir. 1996); United States ex rel. Ven-A-Care v. Actavis Mid Atlantic LLC, F. Supp. 2d , 2009 WL 3171798 (D. Mass. 2009); United States ex rel. Lewis v. Walker, No. 3:06-CV-16, 2007 WL 2713018 (M.D. Ga. Sept. 14, 2007); United States ex rel. Bidani v. Lewis, No. 97 C 6502, 1999 WL163053 (N.D. III. Mar. 12, 1999). The Third Circuit has not decided the issue.

Those courts not allowing private relators to invoke the tolling provision absent government intervention reason that the reference in the subsection to "the government

<sup>&</sup>lt;sup>52</sup> Assuming that the three-year tolling provision did apply, the next question we would ask is whose knowledge – the relator's or the government's – triggers the running of the tolling period. But because, as we shall see later, the government and Bauchwitz knew or should have known the relevant material facts at about the same time, whose knowledge we use as the measure does not affect the outcome in this case.

official charged with responsibility to act in the circumstances" evidences that Congress intended the provision to apply only to the government and not to private parties. *Sanders*, 546 F.3d at 293-94; *Sikkenga*, 472 F.3d at 723-725; *Erskine*, 213 F.3d 638, No. 99-50034, 2000 WL 554644 at \*1. They note that the provision was borrowed from a similar tolling provision, 28 U.S.C. §2416(c), that is part of a statute that deals with actions brought by the United States to recover monetary damages. *Sanders*, 546 F.3d at 294; *Sikkenga*, 472 F.3d at 723-25. Declaring the statutory language ambiguous and examining the legislative history, they conclude that Congress intended to afford only the government the benefit of tolling.

Courts holding that § 3731(b)(2) applies to relators regardless of the government's lack of participation rest on the principle that a relator "stands in the shoes" of the United States government. *Hyatt*, 91 F.3d at 1214-16; *Ven-A-Care*, 2009 WL 3171798, at \*10; *Lewis*, 2007 WL 2713018, at \*6; *Bidani*, 1999 WL 163053, at \*8. So, they reason, the term "United States official" in subsection (b)(2) is considered synonymous with relator. Accordingly, they conclude that the "government official" language does not exclude the relator from the benefit of the tolling provision. *Hyatt*, 91 F.3d at 1216.

The Third Circuit has not taken a precedential position. However, its rationale in deciding related issues in two FCA cases reveals an expansive view of the relator's status where the government has not intervened. *See Rodriguez*, 552 F.3d 297 (3d Cir. 2008); *Malloy*, 68 F. App'x 270.

In *Rodriguez*, acknowledging a circuit split, the Third Circuit sided with the Fifth, Seventh and Ninth Circuits,<sup>53</sup> holding that the sixty-day deadline for filing a notice of appeal under Fed. R. App. P. 4(a)(1)(B) where the United States is a party, rather than the thirtyday deadline for private parties under Rule 4(a)(1)(A), applies in *qui tam* actions even when the government has declined to intervene. *Id.* at 301-02. The court reasoned that the government always retains an interest in the case, noting that when it declines to intervene, the United States still "remains a party to a *qui tam* action in the literal sense, *i.e.*, its name is on the caption." *Id.* at 302. Consequently, as the *Rodriguez* court saw it, the extended deadline intended for the government inures to the benefit of a relator as the government's surrogate. *Id.* at 301. Applying the *Rodriguez* rationale, the tolling provision of the FCA, like the appellate filing deadline, would apply to both private relators and the government.

The Third Circuit's view of the relator's status vis-a-vis the government is no longer viable in light of the Supreme Court's recent holding in *United States ex rel. Eisenstein v. City of New York*, 129 S. Ct. 2230 (2009). There, the Supreme Court held that the relator in a non-intervened FCA case cannot invoke the sixty-day deadline applicable to the United States as a party for filing a notice of appeal under Fed. R. App. P. 4(a)(1)(B). Resolving the circuit split, the Supreme Court determined that the government's retaining an interest in an FCA case in which it has not intervened does not make it a "party." 129 S. Ct. at 2233. It concluded that this interest does not convert the government's status as a real party in interest to that of a "party" in the litigation in which it has declined to intervene. *Id.* 

<sup>&</sup>lt;sup>53</sup> United States ex rel. Lu v. Ou, 368 F. 3d 773 (7th Cir. 2004); United States ex rel. Russell v. Epic Healthcare Mgmt. Group, 193 F.3d 304 (5th Cir. 1999); United States ex rel. Haycock v. Hughes Aircraft Co., 98 F.3d 1100 (9th Cir. 1996). The Second and Tenth Circuits took the contrary position. See United States ex rel. Eisenstein v. City of New York, 530 F.3d 94 (2d Cir. 2008); United States ex rel. Petrofsky v. Van Cott, Bagley, Cornwall, McCarthy, 588 F.2d 1327 (10th Cir. 1978).

at 2235. Consequently, the relator cannot be deemed to have the same status as the government.

Because the Third Circuit's rationale regarding the relator's status in *Rodriguez* has been rejected, it cannot support a holding that would permit a relator to take advantage of a tolling provision applicable only to the government.<sup>54</sup> It has been replaced by the reasoning of the Supreme Court in *Eisenstein*. Therefore, following that reasoning, we conclude that the three-year tolling period in § 3731(b)(2) does not apply in cases where the government does not intervene.

Even if the tolling provision applies, as Bauchwitz argues it does, the result would be the same. Because Bauchwitz possessed knowledge of the facts underpinning his allegations regarding all three areas of the defendants' fraudulent statements by 1999 and their probable connection to grants, the claims that are barred by the six-year limitations period would also be barred by the three-year tolling period.

The FCA tolling provision incorporates both actual and constructive notice standards. The "should have been known" language imposes the constructive notice standard. Actual knowledge of the material facts that a false statement (fraudulent scientific results) was made and that the statement was made as part of a claim for

<sup>&</sup>lt;sup>54</sup> Similarly, in a non-precedential opinion involving a *qui tam* action without the government's intervention, the Third Circuit appears, in dictum, to follow the Ninth Circuit on the tolling provision's application to private relators. *United States ex rel. Malloy v. Telephonics Corp.*, 68 F. App'x 270 (3d Cir. 2003). The issues in *Malloy* were whether a second complaint related back to the first complaint, which was filed and dismissed in a different district, and whether the FCA statute of limitations should have been equitably tolled during the pendency of the earlier action. Although the court did not directly decide whether the tolling provision applies to *qui tam* actions where the government does not intervene, in discussing the factual background of the case necessary to reach its decision on equitable tolling, the court applied both the six-year and the three-year limitation periods to the *qui tam* plaintiff. The court also indicated that it is the relator's, not a government official's, knowledge that triggers the running of the three-year limitation period in such a case. *Id.* at 273.

payment from the government (grant application) - is not necessary to trigger the running of the § 3731(b)(2) three-year period. Rather, the start date is when the plaintiff possesses enough knowledge that would lead a reasonable person to investigate whether a false claim was made. See *Zeleznik v. United States*, 770 F.2d 20, 24 (3d Cir. 1985).

To balance a defendant's right to be free from stale claims and a plaintiff's right to pursue claims where the facts have been concealed, a due diligence standard is imposed upon the plaintiff who invokes the equitable tolling doctrine. The FCA statute of limitations under the tolling provision begins running when the facts underlying the fraud should have been discovered. Hyatt, 91 F.3d at 1216; United States ex rel. Purcell v. MWI Corp., 520 F. Supp. 2d 158, 170 (D.D.C. 2007) (the limitations period begins at the time that the basis of the lawsuit was discovered or could have been discovered through reasonable diligence). The limitations period under the tolling provision begins to run when the injured party knows "sufficient critical facts to put him on notice that a wrong has been committed and that he need[s to] investigate to determine whether he is entitled to redress." Loughlin v. United States, 230 F. Supp. 2d 26, 40 (D.D.C. 2002) (quoting Zeleznik, 770 F.2d at 23. The plaintiff need not have all the information necessary to prevail at trial, or even know that the conduct is actionable under the law. Purcell, 520 F. Supp. 2d at 170. Thus, a plaintiff's duty to investigate occurs "when the plaintiff acquires knowledge of the wrongful activity." Hyatt, 91 F.3d at 1217. See also United States v. Kensington Hosp., Civ. A. No. 90-5430, 1993 WL 21446, at \*9, \*11, \*14 (E.D. Pa. Jan. 14, 1993) (VanArtsdalen, S.D.J.) (where information in government's possession did not constitute evidence for purposes of proof in court, but provided a "large quantity of substantial" detailed facts crucial to its claims, the government knew "facts material to its right of action" to trigger both the running

of the FCA's statute of limitations and its obligation to make a reasonable inquiry into its potential claims).

Another court in this district that has construed another federal statute containing a tolling provision with language similar to that in § 3731(b)(2) has likewise concluded that a plaintiff need not have all information needed to prevail at trial to be on inquiry notice. In *United States v. Sunoco, Inc.*, 501 F. Supp. 2d 641 (E.D. Pa. 2007), Judge Brody construed 28 U.S.C. § 2416(c)'s general federal statute of limitations provision, which contains tolling language<sup>55</sup> virtually identical to that in § 3731(b)(2), to mean that the government only needs to know the "very essence of the right of action" to trigger the statute of limitations. *Id.* at 654 (quoting *United States v. Kass*, 740 F.2d 1493, 1497 (11th Cir. 1984)). The government did not need to know "every detail" of the claim before the right of action accrued. *Sunoco*, 501 F.S. 2d at 654 (government knew the facts material to the right of action when it first knew it was going to pay some amount of money to clean up defendants' pollution, not when it knew its total costs.).<sup>56</sup>

<sup>&</sup>lt;sup>55</sup> Section 2416(c) provides that the statute of limitations is tolled for the amount of time that "facts material to the right of action are not known and reasonably could not have been known by an official of the United States charged with the responsibility to act."

<sup>&</sup>lt;sup>56</sup> Similarly, in construing accrual language in 28 U.S.C. § 2401(b), which provides that a tort claim against the United States must be brought "within two years after such claim accrues," the Supreme Court has held that the statute of limitations begins to run when the plaintiff knew he had been hurt and the relevant facts about how he got hurt, not when plaintiff knew that his legal rights had been violated. *United States v. Kubrick*, 444 U.S. 111, 122 (1979). The Court instructed that if a plaintiff, "armed with the facts about the harm done to him," fails to bring suit within the limitations period because he did not realize that his legal rights had been violated, even if this occurred because of reliance on incompetent legal advice or failure to seek any legal advice, this does not delay the accrual of the claim. *Id.* at 123-24. Once his claim accrues, he is on notice to investigate his claims. *Id.* at 124. *See also Zeleznik v. United States*, 770 F.2d 20, 23 (3d Cir. 1985) (construing *Kubrick*'s holding to be that a "claim accrues when the injured party learns of his injury and its immediate cause" and that the "accrual date is not postponed until the injured party knows every fact bring his action.").

Although the facts in *Kubrick* and *Zeleznik* are not directly on point because they involved plaintiffs who were immediately aware of their injuries when they occurred, unlike Bauchwitz, who did not immediately

In summary, the statute of limitations period under § 3731(b)(2) is triggered when the relator possesses sufficient information to prompt an investigation into his claims to determine if he can legally prevail. Knowledge of the extent and precise nature of the legal violation is not required for the relator to be put on inquiry notice. He need not know that the suspect conduct constitutes an FCA violation.

In the context of this case, a violation occurs at the time the grant application or progress report containing the false statement is submitted to the government. *See supra*. A violation consists of two elements: (1) a fraudulent statement was made; and (2) a claim for funds in the grant application, or a progress or continuation report that contains the fraudulent statement, was submitted to the federal government. Consequently, if § 3731(b)(2) applied, Bauchwitz's FCA claims would have accrued when he discovered or should have discovered facts putting him on notice both that the defendants made fraudulent statements and that the defendants submitted grant requests that contained or relied upon the fraudulent statements.

The defendants argue that Bauchwitz had known about the actual scientific fraud or, at least, enough about it to spurn additional investigation in the mid-1990s. Bauchwitz counters that his knowledge was about similar but unrelated research hypotheses. It is not enough to show when he knew about the allegedly false research results. What they also must show is when he learned or should have learned that they were used to obtain federal grant money.

know the injury (the government's award of grant money based on purported fraud), the cases are nonetheless instructive because they stand for the proposition that the running of the statute of limitations is tolled only until the facts underlying the fraud are discovered or should have been discovered, not until the relator or government is aware that a legal violation has occurred.

In this case, the conduct that triggers the statute of limitations period is not the allegedly fraudulent scientific research results. It is the filing of the false claims for payment, that is, the applications for grants, that starts the running of the limitations clock. Absent any application for payment based upon the reported scientific results, there can be no false claim no matter how longstanding or how serious the scientific misconduct was. The cause of action can only accrue upon submission of a false claim. Accordingly, for purposes of determining when the statute of limitations period under § 3731(b)(2) would have started running, the inquiry focuses on the dates that Bauchwitz learned or should have learned that the defendants had submitted the grant applications that relied upon the allegedly false scientific research. In short, the cause of action did not ripen until a claim was made, not when Bauchwitz knew of prior misconduct.

There is no dispute about what Bauchwitz knew and when he knew it. Nor is there any dispute about what he did with his information. The dispute is over what he should have done with the facts he knew and when he should have done it. The dispute involves a legal, not a factual, question. Resolving it requires a legal analysis of what Bauchwitz's obligation was, given the facts he knew at the time.

#### The First Element - Knowledge of False Statements

The analysis begins with a determination from the undisputed facts of when Bauchwitz learned the facts underlying the alleged fraudulent statements at issue in this case - the facts relating to the first element of his FCA claim. Once these dates are established, the inquiry turns to when he knew or should have known that the statements were made in connection with grant funding, the facts relevant to the second element. Bauchwitz asserts that the fraudulent statements fall into three categories: The defendants' falsification of: (1) the Rec1 protein sequence; (2) the *rec2-1* DNA sequence; and (3) data images purporting to show active Rec2 protein.<sup>57</sup>

## The First Category of Fraud

The fraud alleged in the first category refers to statements and findings made in the 1994 article regarding characteristics of the Rec1 protein sequence. Specifically, in the article, the authors claimed that when an outside lab sequenced their purified Rec1 protein preparation from *U. maydis*, peptide sequences were identical to a portion of the Rec2 protein sequence. These results supported their theory that "Rec1 is Rec2." In his complaint, Bauchwitz contends that the defendants either fabricated the sequencing results because they never actually sent the peptides to an outside lab for sequencing, or they falsely stated what product they were sequencing because the product they sent to the lab was recombinant Rec2 protein derived from a bacterial source rather than Rec1 protein purified from a fungal source.

Bauchwitz knew the facts material to this first category of fraud as early as December of 1994, when he spoke with Rubin, a graduate student who succeeded Bauchwitz at Holloman's lab. After Bauchwitz read the 1994 article in late November of 1994, he was "highly suspicious" of Holloman and Kmiec's findings and conclusions. Because he was surprised and "disturbed" that Rubin was not listed as an author on the article, he initiated a telephone call to Rubin, which he surreptitiously tape recorded. Rubin told him that he removed his name from the 1994 article because the conclusions were

 $<sup>^{57}</sup>$  PI.'s Second Decl.  $\P$  6.

contrary to and inconsistent with his own research and that of another student working in the lab, in that neither could show that Rec2 was a strand exchange protein. Rubin also told him that Holloman had sent Rubin's overexpression strain to Kmiec, who:

came up with this incredible result that, he purified Rec1 protein from *Ustilago* and sent it to Harvard for sequencing, and several of the peptides were identical to Rec2 sequence. I was very skeptical about all this.

\* \* \*

I think they purified epsilon from *E. Coli* . . . They never had a very pure prep on that.<sup>58</sup>

Bauchwitz argues that he did not have actual notice that the statements in this first category of fraud were false until 2002 or even 2003. He asserts that the information Rubin gave him in December of 1994 was not enough to alert him that the defendants falsified the Rec1 protein sequence in the 1994 article.<sup>59</sup> He characterizes his concerns about the results reported in the 1994 article as just "skepticism."<sup>60</sup> Yet, he concedes that after his call with Rubin, he was more than "highly suspicious" that Holloman and Kmiec's published findings were based on scientific misconduct and fraudulent activity.<sup>61</sup> It is also undisputed that Rubin told him that he was "very skeptical" about the defendants' reported

<sup>&</sup>lt;sup>58</sup> See Tr. of Dec. 27, 1994 phone call with Rubin ("12/94 Rubin call"), RPG 00009-00011, 00019.

<sup>&</sup>lt;sup>59</sup> PI.'s Second Decl. ¶ 21 (stating that "Rubin did not say anything to me to suggest that any of the defendants had sought or obtained funding based on the 1994 article," and there "was no basis for me to be watching for future grant applications containing false statements based on the 1994 article since I did not have adequate knowledge that they were false.")

<sup>&</sup>lt;sup>60</sup> Pl.'s Second Decl. ¶ 32.

<sup>&</sup>lt;sup>61</sup> See 12/94 Rubin call, RPG 00010. Specifically, prior to his call with Rubin, Bauchwitz's "index of suspicion was high" that the defendants had engaged in scientific misconduct, and he was "highly suspicious" that they had engaged in "fraudulent activity." See Tr. of Bauchwitz's dep. ("Pl.'s dep.") at 101-102, 106, 215-16. After speaking with Rubin, his "suspicion was heightened." *Id.* at 112.

results.<sup>62</sup> Additionally, by that time, Rubin and Bauchwitz believed the defendants had a "prior pattern of dishonest behavior."<sup>63</sup>

Bauchwitz concluded that the tenuous conclusions and findings in the 1994 article merited government investigation. On that basis, he called ORI. Using the excuse that he was waiting for ORI to investigate the anonymous "tips" he gave them in 1995, he contends that he did not need to do any more at that time. Instead, he simply "got on with his life."<sup>64</sup>

Bauchwitz argues that he did not know of this first category of fraud until a series of events, beginning in February of 2002 when he read the statement made in the 2001 article (which is at the heart of the claim of the second category of fraud) falsifying the sequence of the *rec2-1* mutant gene version to show that it is capable of producing protein.

Apparently, upon reading that article, he

decid[ed] to investigate further . . and to reconsider and analyze the circumstances of the Rec1 protein sequence in more detail. . . . [He] then reexamined the [1994 article] . . . [and i]t occurred to [him] that for the Rec1 protein sequence to have been as the defendants claimed (identical to that expected for Rec2), data might have been available at a laboratory external to theirs which had performed part of the work claimed.

\* \*

To pursue this possibility, on April 30, 2003, [he] contacted the Harvard Microchemistry laboratory, the outside laboratory defendants claimed to have employed. . . .<sup>65</sup>

<sup>&</sup>lt;sup>62</sup> See 12/94 Rubin call, RPG 00010.

<sup>&</sup>lt;sup>63</sup> Pl.'s Second Decl. ¶ 17.

 $<sup>^{64}</sup>$  Pl.'s Second Decl.  $\P\P$  15-21, 32; Tr. of Oral Argument at 21-22.

<sup>&</sup>lt;sup>65</sup> Pl.'s Second Decl. ¶¶ 22-23, 32, 38; Pl.'s First Decl. ¶¶ 26-27.

When his call to the Harvard lab uncovered no record of use of the facility by any of the authors of the 1994 article at the relevant time, he concluded "that there was a very high likelihood that the defendants had never sent anything at all to that laboratory in the relevant time frame," which information he "felt . . .was obviously consistent with the amino acid data having been fabricated."<sup>66</sup> For these reasons, Bauchwitz claims that he was not on notice that the defendants potentially falsified the Rec1 protein sequence in the 1994 article until April 30, 2003.

Bauchwitz learned nothing new in 2002 about this first category of fraud involving the purported falsified Rec1 protein sequence reported in the 1994 article. Although he contends that reading the 2001 article in 2002 caused him to "decid[e] to investigate further ... and to reconsider and analyze the circumstances of the Rec1 protein sequence in more detail," the only reason he gives for why the 2001 article prompted an investigation is that it "occurred to him" that the lab that performed the sequencing for the 1994 article might have the actual protein preparation the defendants sent, which would confirm or contradict the defendants' claim that the product sent was derived from a fungal and not bacterial source.<sup>67</sup> He provides no explanation as to *how* reading anything new in the 2001 article made him realize that there had been a fraudulent statement in an article published seven years earlier.

Even if he had provided an explanation as to why the 2001 article prompted him to investigate fraud in the 1994 article, the 2001 article did not provide Bauchwitz with any

<sup>&</sup>lt;sup>66</sup> PI.'s Second Decl. ¶¶ 23-24; PI.'s First Decl. ¶ 27. Bauchwitz then transcribed recordings of his conversations with Rubin, which he completed January 27, 2004.

<sup>&</sup>lt;sup>67</sup> Pl.'s Second Decl. ¶ 22.

new information to investigate. His investigation consisted of: (1) *re-reading* the 1994 article, which he had read and discussed with Rubin in 1994 and 1995; (2) "reconsider[ing] and analyz[ing] the circumstances of the Rec1 protein sequence in more detail"<sup>68</sup>; and (3) calling the Harvard laboratory, which was disclosed in the 1994 article and mentioned by Rubin in 1994 as the place where the defendants sent the protein for sequencing. He could have performed an investigation involving all three of these steps back in 1994.

What Bauchwitz knew in February of 2002 regarding the falsified Rec1 protein sequence reported in the 1994 article was no more than what he knew regarding the falsified report when he spoke to Rubin in December of 1994. His font of knowledge did not change during these intervening years. He learned no more facts. He merely decided to take a new tact. He offers no explanation other than he had gotten "on with his life," for waiting to do what he could have done years earlier to test his theory.

In addition, Bauchwitz states that it was not until December of 2003, when he finally attempted to transcribe his 1994 and 1995 telephone conversation recordings, that the transcriptions "revealed" that "falsified data were published in [the 1994 article] and thereby were introduced into federal grants."<sup>69</sup> Bauchwitz had initiated, recorded and participated in those calls. The content of those conversations were not new to him in 2003. He knew the substance of those calls when they took place in 1994 and 1995. He did nothing with this knowledge for nine years.

<sup>&</sup>lt;sup>68</sup> Id.

<sup>&</sup>lt;sup>69</sup> Pl.'s Second Decl. p. 24 note ii.

It is indisputable that the information Rubin gave him in December of 1994 about Kmiec's "incredible result that, he purified Rec1 protein from *Ustilago* and sent it to Harvard for sequencing, and several of the peptides were identical to Rec2 sequence," put Bauchwitz on notice that the defendants likely falsified the Rec1 protein sequence in the 1994 article, and to conduct an investigation into their falsity. He could have called the Harvard lab at that time, instead of waiting seven years.

#### The Second Category of Fraud

The fraud alleged in the second category refers to statements and findings made in the 2001 article that the sequence of the *rec2* mutant gene version (*rec2-1*) showed that it is capable of producing protein because there is a novel ATG start site upstream of the deletion in the *rec2-1* mutant.<sup>70</sup> Bauchwitz contends that this conclusion is false because: (a) Rubin never observed a novel ATG start site *upstream* of the *rec2-1* deletion in his thesis work as Bauchwitz's own *rec2-1* sequencing research confirms; (b) in a 1994 article that he authored with Rubin,<sup>71</sup> Holloman removed the relevant *REC2* gene sequence, thereby omitting the purported novel ATG; and (c) Holloman never published the sequence *data* for the purported novel ATG start codon.

Bauchwitz knew the facts material to this second category of fraud as early as February of 1995, when he spoke with Rubin for a second time, and later, in 1999, when he published the results of his own *rec2-1* sequencing. On February 13, 1995, Bauchwitz

<sup>&</sup>lt;sup>70</sup> In the 1994 article, the authors claimed that peptide sequences of purified Rec1 protein preparation from the fungus *U. maydis* were identical to a portion of the sequence of the bacterial Rec2 protein.

<sup>&</sup>lt;sup>71</sup> This article is different from the 1994 article written by Kmiec, *et al. See* Rubin, B.R., Ferguson, D.O., and Holloman, W.K. "Structure of *REC2*:, a recombinational repair gene of *Ustilago maydis*, and its function in homologous recombination between plasmid and chromosomal sequences," *Molecular Cell Biology*, 14: 6287-6296 (1994).

called Rubin<sup>72</sup> to discuss the 1994 article again. When Bauchwitz asked him about the location of ATG start codons for methionine in the *rec2-1* deletion, Rubin told him that he had observed no ATG start codons for methionine upstream of the *rec2-1* deletion, and that *the rec2-1* mutation truncated on its own. Rubin also said that Holloman knew this information because Rubin had published it in his thesis. During the call, Rubin realized that Holloman had removed the *rec2-1* mutant sequence from a different 1994 article that he authored with Rubin.<sup>73</sup> Just five days later, on February 18, 1995, Bauchwitz made the same allegations of fraud that he is now raising when he drafted a letter to his former employer, Dr. Gilbert. Specifically, in the letter, Bauchwitz stated that Holloman omitted this relevant rec2-1 sequence from the 1994 article so that he could report that the rec2-1 gene produced an active protein.<sup>74</sup>

Bauchwitz argues that he was not on notice of the false statement in the second category of fraud until he read it in the 2001 article in February of 2002. He admits that talking to Rubin in 1995 made him suspicious that Holloman was falsifying the *rec2-1* mutant DNA sequence. Yet, he now claims that because Rubin considered Holloman's actions merely "an oddity," he was not certain that Holloman was committing a fraud. He was motivated only to try to produce his own relevant rec2-1 sequence to test his suspicions, which test results confirmed his suspicions by 1999. Nevertheless, he still contends that he was not on notice of claims based on this second category until the spring

 $<sup>^{72}</sup>$  See Tr. of Feb. 13, 1995 phone call with Rubin ("2/95 Rubin call"), RPG 00001-0008. Bauchwitz also recorded this telephone call.

<sup>&</sup>lt;sup>73</sup> *Id.* at RPG 00001-00003.

<sup>&</sup>lt;sup>74</sup> See letter to Walter Gilbert, Defs.' Jt. Stmt. of Undisputed Facts (Doc. No. 86), Ex. Q, at RPG 000094-95.

of 2002, when he "developed solid evidence of lies - of frauds" when he read the 2001 article and was able to "perceive" that it was "a patent lie." He argues that his mere "skepticism" and "suspicion" of defendants' fraud after speaking with Rubin in 1994 and 1995, and publishing his own relevant rec2-1 sequence in 1999, was "not the equivalent of knowledge that a fraud occurred, or even evidence of such."<sup>75</sup>

Bauchwitz's assertions that he did not "perceive" Holloman's actions to amount to fraud in 1995 are not supported by the undisputed facts. He was on notice of the facts underlying this second category of fraud by 1999 at the latest, when he published the results of his own rec2-1 sequencing.

### The Third Category of Fraud

The fraud alleged in the third category refers to a data image in Figure 3 of the 1994 article showing bands of active Rec2 protein when it was actually an inactive purification. Figure 3 depicted gel images of a purified fraction of protein that Rubin had produced in his thesis.

Bauchwitz learned the facts material to this third category of fraud in December of 1994. At that time, Rubin told Bauchwitz that "there are figures [in the 1994 article] straight from my thesis that have totally nothing to do, really, with what was published. . . [H]e used my purification gel . . . and then he claims that this protein is active. And he would rationalize it by saying, 'Well, it's just a better looking gel than [Kmiec's].' Of course, we are using the same strain, but that prep wasn't active. . . . [My gel] really isn't of the same prep that [Holloman] used to show activity."<sup>76</sup>

<sup>&</sup>lt;sup>75</sup> Pl.'s Second Decl. ¶¶ 16, 25-34, 38.

<sup>&</sup>lt;sup>76</sup> 12/94 Rubin call, RPG 00011-12.

Bauchwitz concedes that during his December 1994 conversation with Rubin, he learned that Holloman had falsified Rubin's images in the 1994 article. In fact, he acknowledges that in 1994 he had "potential knowledge of" this false statement "had I realized its potential significance and noted it at the time." Nevertheless, he argues that because Rubin "did not say anything to [him] to suggest that any of the defendants had sought or obtained funding based on the 1994 article," he was not put on notice of his claims relating to this category.<sup>77</sup> Bauchwitz does not offer any date or event that put him on notice of this category of claim. Thus, just as with the false claims based on category one, the December 1994 phone call with Rubin put Bauchwitz on notice that Holloman had falsified Rubin's gel images in the 1994 article.

As the undisputed facts demonstrate, Bauchwitz possessed knowledge of the facts underpinning his allegations regarding all three areas of the defendants' fraudulent statements by February of 1995, or, in the case of category two, no later than 1999. Next, we must examine when Bauchwitz had actual or constructive knowledge of enough relevant facts to cause him to investigate whether the defendants submitted grant applications containing the three categories of fraudulent statements.

#### The Second Element - Knowledge of Grant Funding

From the time he began working in Holloman's lab in the late 1980's, Bauchwitz was aware of the essential role NIH grants played in funding the defendants' labs.<sup>78</sup> In mid-1990, Bauchwitz described to OSI, ORI's predecessor, dishonest and fraudulent conduct Holloman and Kmiec used to receive "high scores and funding on two NIH grants which

<sup>&</sup>lt;sup>77</sup> Pl.'s Second Decl. ¶ 21.

<sup>&</sup>lt;sup>78</sup> Pl.'s dep. at 29.

had not received adequate scores for funding previously."<sup>79</sup> In November of 1990, Bauchwitz called the NIH Division of Research Grants, where, in his words, "the grant officer and program officer for Holloman's NIH grant GM 42482 could be found." He asked for NIH's rules of conduct for grant-funded research, procedures for making complaints, penalties for violations and how NIH defines "misconduct."<sup>80</sup> In November of 1994, he read in the 1994 article that the research for the article was supported by "federal grant GM42482.<sup>81</sup>" Finally, in his call to ORI in 2002, Bauchwitz assured Alan Price, the Director of ORI's Division of Investigational Oversight, that when he had first called ORI (then OSI) in 1990, he had learned how to obtain information about funded (approved) grant applications using the Freedom of Information Act ("FOIA").<sup>82</sup>

On September 21, 2000, when he wrote science journalist Gary Taubes, Bauchwitz demonstrated his full understanding of how grants work. At that time, in order to help Taubes determine "what Holloman knew and when he knew it relative to what he wrote in grants or publications," Bauchwitz "looked up the grants [Holloman] obtained in [the relevant time period]" and found a specific grant on CRISP that was awarded to Holloman that he thought would be "most useful" for Taubes. Based upon his knowledge of how the grant system worked, he then explained to Taubes: "This means that it probably was submitted more than 6 months prior to that, which would have been not long after the

<sup>&</sup>lt;sup>79</sup> Pl.'s dep. at 38-41; RPG 0024-25.

<sup>&</sup>lt;sup>80</sup> Pl.'s dep. at 67-69; RPG 0087-93

<sup>&</sup>lt;sup>81</sup> Compl. ¶ 38b.

<sup>&</sup>lt;sup>82</sup> Even if he had not learned about the FOIA process from OSI, Bauchwitz consulted with two attorneys that same year regarding his concerns about the defendants. Either of these attorneys could have aided him in using FOIA. See PI.'s dep. at 45, 192-93; RPG 00086.

phenomenon was observed." In his own words, Bauchwitz displayed his working knowledge of the federal grant system.

Of course, because Bauchwitz was not involved in drafting or submitting the grant applications at issue, he cannot be expected to have known precisely when they were submitted. However, in light of his understanding of the integral role that grant applications and awards played in sustaining the research activities of scientists in this field, particularly Holloman and Kmiec, and his awareness by 1995 of the facts underpinning his allegations regarding all three areas of the defendants' fraudulent statements, he knew enough to identify or to go about identifying the defendants' fraudulent grant applications soon after their submission dates. For more than a decade prior to filing his complaint, Bauchwitz knew that Holloman and Kmiec, like himself and other microbiologists, were regularly applying for research grants, and that one's prior research findings and publications of those findings are frequently and repeatedly cited in future grant applications. He knew that scientific research builds on prior research. He also knew how to access the grants through CRISP; and, as early as 1990, he was told that he could obtain copies of approved grant applications through a FOIA request. Indeed, as demonstrated by his communication with Taubes in September of 2000, he understood: (1) there was likely a grant at the heart of Holloman's alleged fraudulent conduct; (2) how to access a grant online and through FOIA; and (3) how the timing on grants works.

Because he knew grants were essential to Holloman and Kmiec's research careers and projects, Bauchwitz was aware that the defendants were likely to cite these allegedly false or misleading statements in future grant applications. Consequently, when Bauchwitz became "highly suspicious" after reading statements and representations made in the 1994 article and after speaking with Rubin in December of 1994 and February 1995, he knew these scientific findings were more than likely involved in ongoing research projects that were funded by NIH. Under the circumstances, he should have investigated whether Holloman and Kmiec submitted any grants containing these false statements. Given his understanding of the CRISP system and what he had been told about FOIA in 1990, he knew how to obtain copies of grants that were awarded to Holloman or Kmiec. Similarly, because of his longstanding suspicions of the veracity of Holloman and Kmiec's research and publications, and his own ongoing personal sequencing research, he should have been aware of the defendants' newly published articles on issues related to the fraudulent claims soon after they were published.

With respect to grants containing category one false statements, Bauchwitz was on notice, in 1994, to investigate whether any false statement was submitted as part of a grant application because the information Rubin had given him in December of 1994 alerted him that the defendants likely falsified the Rec1 protein sequence in the 1994 article and he was familiar with the grant and publication systems. At that time, he could have checked CRISP and made FOIA requests to get information about newly approved grant applications submitted by the defendants that relied on the falsified Rec1 protein sequence claim made in the 1994 article. That Rubin did not tell him that the defendants had sought or obtained funding based on the 1994 article does not excuse Bauchwitz's having waited seven years to conduct an investigation that revealed nothing more than was available to him in 1994.

With respect to grant applications containing category two false statements, although Bauchwitz was on notice of the facts underlying this category of fraud by 1999,

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the applications that allegedly contained these false statements were not submitted until October 30, 2001. Because an FCA violation can only occur in connection with a grant application after the grant application has been submitted, he could not have been on actual notice that the defendants had submitted a fraudulent statement in a grant application based on the false findings in the 2001 article until: (1) the 2001 article containing the false statement was published; and (2) the grant applications containing or relying on the false statements made in the 2001 article were submitted. Because the FCA statute of limitations is six years, and Bauchwitz filed his complaint in 2004, any claim based on this category of fraud falls within the statute of limitations period.

With respect to grants containing category three false statements, the phone call with Rubin put Bauchwitz on notice to investigate whether the false statement was submitted as part of a grant application. In December of 1994, he learned that the defendants had falsified a data image in Figure 3 of the 1994 article. Again, he knew how to check CRISP and make FOIA requests to seek newly approved grant applications submitted by the defendants that relied on the falsified data image.

As stated previously, inquiry or constructive notice does not require the relator to have all the information necessary to prevail at trial. *Purcell*, 520 F. Supp. 2d at 170. Rather, the limitations period begins to run when the plaintiff possesses sufficient information to prompt an investigation to determine if he can legally prevail. Knowledge of the extent and precise nature of the legal violation is not required.

Bauchwitz repeatedly contends that he did not know about the fraudulent grants at issue until 2002 or 2003 because no one told him about them. In addition, he advocates that the standard for inquiry notice of a false claim is when the plaintiff is absolutely certain

that he will prevail in a court of law. He maintains that he did not even know what a *qui tam* action was until 2002.

Bauchwitz was on inquiry notice of the claims at issue much earlier than 2002. The undisputed facts show that he worked diligently and resourcefully when he wanted. He took detailed notes of conversations he had with former Holloman employees, ORI, former employers, and Taubes, in which he noted the person's name and details about the call. He always had available the information from these conversations because he had retained the secretly recorded communications. He composed chronologies of events and conducted his own experiments. As early as 1990, he called NIH to inquire about how grants are awarded and the rules of conduct governing grant awards, called ORI to report the defendants' alleged fraudulent acts, and consulted at least two lawyers. By 1990, he had learned how to obtain copies of grant awards through a FOIA request. He also knew how integral grants were to the defendants' careers, how to access grants online, and how grant funding worked. He was familiar with the areas of science in which the defendants were involved. This extensive knowledge, understanding and resourcefulness demonstrate that Bauchwitz had constructive, if not actual, notice of grant applications containing fraudulent statements soon after they were approved by NIH.

In summary, Bauchwitz was on inquiry notice of the facts underlying fraud categories one and three by December 1994, and category two in 1999; and, on notice that the defendants submitted grant requests that contained or relied upon the fraudulent statements soon after their submission.

Ultimately in this case, if the tolling provision did apply, the question of whose knowledge triggers the running of the statute of limitations does not affect the outcome because the government and the relator knew the relevant facts at about the same time. Bauchwitz had more scientific information than OSI; and ORI had more information about the grants. Both had enough information to put them on inquiry notice of most of the suspected false claims in 1995. The government had been notified of Holloman's alleged scientific misconduct as early as November 30, 1990 and several times later during the late 1990s. ORI was aware that Holloman was a grant recipient. Using reasonable diligence, ORI could have checked its records to determine if Holloman had submitted any grant applications involving the subject matter of the research about which Bauchwitz had complained. There is no evidence that it did or did not identify the grants awarded to Holloman. Thus, in giving the benefit of the doubt to Bauchwitz, as we must, we assume it did not.

ORI was alerted by Bauchwitz of Holloman's engaging in scientific misconduct regarding a specific grant in February, 1995. ORI had a protocol for matching complaints and reports with grantees and grants.<sup>83</sup> Consequently, based upon Bauchwitz's complaints, ORI was on sufficient notice of a potential false claim to instigate further investigation. Thus, if it were the government's knowledge that triggers the tolling provision, the result would be the same.

As we determined earlier, Bauchwitz's claims against the Thomas Jefferson defendants based on the AR 44092-01 grant, which was submitted on May 31, 1995, are barred by the six-year statute of limitations. Likewise, his claims against the Cornell defendants, based on grants submitted on October 31, 1991 (2 R01 GM42482-04),

<sup>&</sup>lt;sup>83</sup> See Govt's Suppl. to Stmt. of Interest (Doc. No. 109).

January 24, 1995 (1 R01 GM53732-01) and October 31, 1995 (2 R01 42482-08) are barred by § 3731(b)(1).

These claims could survive only if the tolling provision of § 3731(b)(2) saved them. Because that provision does not apply in this case, they are time barred. Even if it did apply, they would not survive.

Bauchwitz's claims would have accrued under § 3731(b)(2) when he discovered or should have discovered facts putting him on notice both that the defendants made fraudulent statements and that the defendants submitted grant requests that contained or relied upon the fraudulent statements. Hence, the three-year tolling provision would bar claims of the material facts which he should have learned before June 30, 2001.

As explained earlier, Bauchwitz should have known the facts underlying fraud categories one and three by December 1994, and category two in 1999, and should have known that the defendants submitted grant requests that contained or relied upon the alleged fraudulent statements soon after their submission. Thus, with respect to the Thomas Jefferson defendants' grant application, which was submitted on May 31, 1995, he should have learned the facts material to claims pertaining to that grant shortly thereafter.

With respect to the Cornell defendants, Bauchwitz should have learned the facts material to claims based on: (a) grant application 2 R01 GM42482-04, which was submitted on October 31, 1991, by April 30, 1992; (b) grant application 1 R01 GM53732-01, which was submitted on January 24, 1995, by July 24, 1995; and (c) grant application 2 R01 GM42482-08, which was submitted on October 31, 1995, by April 30, 1996.

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Therefore, the three-year tolling provision would not save any of Bauchwitz's claims from the statute of limitations bar.

# Conclusion

Because all claims against the Thomas Jefferson defendants are outside the statute of limitations, judgment will be entered in their favor. Bauchwitz's claims against the Cornell defendants, except with respect to grant 2 R01 GM 42482-12A2, are untimely. Accordingly, the motion for summary judgment on behalf of the Cornell defendants will be denied.<sup>84</sup>

<sup>&</sup>lt;sup>84</sup> Because the ORI did not consider the statements at issue intentionally false and that it it could not prove otherwise, the government did not intervene. *See* letters from ORI dated November 23, 2004 and June 28, 2005 at 9 and 2, Defs.' Jt. Stmt. of Undisputed Facts (Doc. No. 86), Exs. TTT and UUU, respectively. At this point, we do not decide whether the relator can ultimately prevail on the only remaining claim. *See United States ex rel. Milam v. Regents of the University of California*, 912 F. Supp. 868, 879-80 (D. Md. 1995) (holding that ORI's findings that the defendants did not engage in scientific misconduct and that there was insufficient evidence to warrant further investigation was admissible as an admission by a party-opponent under F.R.E. 801(d)(2)A)).

## APPENDIX A: GRANTS AT ISSUE

#### Grants Submitted by Holloman and the Cornell Defendants

- <u>2 RO1 GM42482-04</u> Grant application (renewal) submitted Oct. 31, 1991
  <u>2 RO1 GM42482-05</u> Progress report submitted April 29, 1993
  <u>2 RO1 GM42482-06</u> Progress report submitted April 26, 1994
  2 RO1 GM42482-07 Progress report submitted April 24, 1995
- <u>1 RO1 GM53732-01</u> Grant application submitted Jan. 24, 1995
  <u>1 RO1 GM53732-02</u> Progress report submitted Dec. 31, 1996
  <u>1 RO1 GM53732-03</u> Progress report submitted Dec. 15, 1997
- <u>2 RO1 GM42482-08</u> Grant application (renewal) submitted Oct. 31, 1995
  <u>2 RO1 GM42482-09</u> Progress report submitted April 28, 1997
  <u>2 RO1 GM42482-10</u> Progress report submitted April 28, 1998
  <u>2 RO1 GM42482-11</u> Progress report submitted April 27, 1999
- <u>2 RO1 GM42482-12A2</u> Grant application (renewal) submitted Oct. 30, 2001
  <u>2 RO1 GM42482-13</u> Progress report submitted April 25, 2003
  <u>2 RO1 GM42482-14</u> Progress report submitted April 28, 2004
  2 RO1 GM42482-15 Progress report submitted April 21, 2005

#### Grants Submitted by Kmiec and the Thomas Jefferson Defendants

<u>1 RO1 44092-01</u> - Grant application - submitted May 31, 1995
 <u>5 RO1 44092-02</u> - Continuation report - submitted Jan. 30, 1997
 <u>5 RO1 44092-03</u> - Continuation report - submitted Jan. 28, 1998