Hill Reply Brief

MATERIALITY

In Figure 7 of his revised grant application (313a), Howell proposed to develop a cluster model that would model human tissue uptake of radioactive isotopes in nuclear medicine procedures. He modeled the non-uniform distribution of radioactivity reflecting that some cells are radioactive and some are not. Since human tissues are not hypoxic, a finding that his clusters were hypoxic would greatly affect the chances that the grant application would be accepted. Hypoxia is important because it reduces the effect of the radioactivity by as much as 3-fold pursuant to a phenomenon known as the oxygen effect. (Hill S.J. Exhibit 1: *Certified Written Disclosure*) (240a-243a).

Bishayee performed the experiment depicted in Figure 7 of the grant application. Bishayee is listed in the grant application as Research Teaching Specialist V (288a). Indeed, Bishayee was designated to and did undertake to perform all of the experiments that were recorded in the Preliminary Results section of the grant (308a). His description set forth in the grant application additionally noted that he "has three years of experience with the assays to be performed in this project. He will use this experience to immediately begin carrying out the day to day experiments described in the project. He will be responsible for generation of bio-kinetics, survival, and mutation data, as well as

their analysis". (288a). Two publications that Bishayee co-authored were referenced in the list of Literature Cited in the grant application (332a at # 66 and #71).

Figures 2 and 4 of the grant, based on other experiments performed by Bishayee also contained fabricated information as found and determined by Hill's expert, Dr. Robbins (1444a) (See also Hill's Initial Brief at 7). How then, the District Court reached the conclusion that Bishayee's work was not material to the grant application is thus bewildering and problematic. It is an unwarranted conclusion. It is a conclusion for which there is no factual evidence that, had the Study Section reviewing the grant actually known the data had been questionably produced, it would not have affected their recommendation to grant. Indeed ORI makes no mention at all in its report about the NIH decision.

31 USC § 3729(b) (4), defines materiality to mean "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property. In United States ex rel Longhi v Lithium Power Technologies, Inc., WL 1959259, at *9 (5th Cir. July 9, 2009), the "natural tendency" test was held to require only:

> "that the false or fraudulent statements either (1) make the government prone to a particular impression, thereby producing some sort of effect, or (2) have the ability to effect the Government's actions, even if this is a result of indirect or intangible actions on the part of the Defendants. All that is required under the test for materiality, therefore, is that the false or fraudulent statements have the potential to influence the Government's decisions."

HOWELL DEMONSTRATED SUFFICIENT SCIENTER FOR THE COURT BELOW TO HAVE FOUND THAT HE VIOLATED THE FCA

What did Howell know in October 1999 when he submitted the grant? He knew that Hill's experiment disagreed with Bishayee's and that Hill's said the clusters were hypoxic while Bishayee's said otherwise. (240a-243a) (401a). Howell chose to ignore Hill's experiments and to use Bishayee's results instead (888-889a). He did so because his proposal set forth a novel idea seeking to compete among many ideas for limited RO1 grant dollars. Howell did so despite the fact that Hill had advised him the dishes used by Bishayee and which were to have contained the mutant colonies were actually devoid of colonies (881a). Consequently Bishayee's results shown in Figure 7 of the grant application had to have been fabricated. Thus, in making the choice between Hill and Bishayee, Howell violated the scientific method by not resolving the difference between Hill's results and Bishayee's (1670-1671a). He chose to validate his model based on Bishayee's claimed results and argue there was a human tissue-like situation in the clusters. And he then proceeded to sign the grant application (285a); in doing so, certifying that everything was true to the best of his knowledge. Yet Howell well-knew that questions had been raised by Hill about the truth of what he was presenting. To say that the Study Section reviewing the grant would not have found this to be material is simply not the case.

In addressing the issue of whether Howell demonstrated a sufficient level of scienter to have violated the FCA, the Defendants have acknowledged that the District Court considered but four (4) elements to determine the question of whether Howell knowingly supplied false or fraudulent information to NIH. (Defendants' Brief at 16). In

doing so, it is respectfully submitted that the Defendants have committed the same error that the District Court did in focusing their attention solely on the evidence that was known to Hill at the time that Howell submitted his revised 1999 grant application.

Had the District Court and the Defendants properly confronted that evidence together with all of the additional evidence that the Defendants first disclosed pursuant to the November 2004 subpoena issued by the U.S. Attorney (1399a); and/or the evidence obtained in further discovery engaged in by Hill commencing in late March 2008 (24a), it should have been evident that there are ten (10) elements which prove that Howell knowingly supplied false or fraudulent evidence in support of the grant, periodic progress reports and a continuation grant. (Hill Brief at 69-70; and at 46-55 summarizing these elements). These very elements had been set forth and discussed in Hill's District Court summary judgment brief. (27a – Docket Entry 44, Attachment #3, pages 21-23).

These elements are: (1) the accounts of two eye-witnesses (Hill and Lenarczyk); (2) the inability of both Howell and Lenarczyk (indeed, anyone for that matter) to ever replicate Bishayee's 100% experiments; (3) the inability of both Howell and Lenarczyk (or anyone for that matter) to ever replicate Bishayee's 50% experiments; (4) the statistical analysis of an expert statistician, Dr. Pitt, that determined there is only a probability of 1 in 100 billion that Bishayee's Coulter counts were not fabricated[1]; (5) as determined by Dr. Pitt, there was a distinctive pattern in Dr. Bishayee's measurements that would lead any reasonable observer to conclude that Dr. Bishayee repeatedly invented one value in each triad of the colony count measurements he had allegedly

[1] See Hill S.J. Exhibit 104: *Expert Report of Dr. Joel Pitt* (1403a) (1408a) (Table 1).

taken to force his data to conform to the experimental results he wished to report[2]; (6) in determining the relative frequency with which the two least significant digits in Dr. Bishayee's measurements are equal, Dr. Pitt found the probability that the relative frequency of such incidents diverge from the expected frequency as much as they did in Dr. Bishayee's case is less than 0.0000001 (one in ten million); (7) the biochemical and radiobiological principles and analysis by an expert Radiation Biologist, Dr.Michael Robbins, demonstrating Tritiated Thymidine (^{3}H-TdR) blockage of the cell cycle progression; (8) that there was no deoxycytidine (dCyd) in the medium during exposure to ^{3}H-TdR, which fact would have abrogated the effect of ^{3}H-TdR blocking cell cycle progression; (9) that there was no attempt at synchronization of the cells before adding ^{3}H-TdR which would have allowed all the cells to be in S phase during the ^{3}H-TdR exposure; and (10) the strong likelihood that hypoxia prevailed in the Helena tubes during all of the experiments but most importantly in the 50% experiments. (221a)(1403a) (1443a) (Hill S.J Exhibits 1, 104 and 108).

This evidence demonstrated irrefutable biochemical, radiobiological and statistical evidence that supplemented the analysis of the issue. This evidence demonstrated that Howell knew, should have known, and/or acted in reckless disregard of the truth in submitting the original and renewal grant applications. (Hill Brief 55-68). Indeed, with all due respect to the District Court, it completely shut its eyes to the well established scientific policy that research scientists must well know and guide themselves by the principle that, in order for experimental results to be accepted as valid, the results

[2] Dr. Pitt calculated that the probability the colony terminal digits were not fabricated is 9 in 100 billion (1409a) (Table 2).

must be capable of being replicated (1670a) (Hill S.J. Exhibit 74, UMDNJ Guidelines for Conduct of Research, Section III).

Moreover, these elements become all the more compelling when viewed in the time frames of the submission of annual progress reports and the 2005 renewal grant by Howell. By confining itself to the 1999 evidence, the District Court effectively gave Howell carte blanche because he had successfully failed to disclose fully what he then knew to the two Campus Committees and to ORI. Hill's initial brief has shown the limitations of myopically reviewing the evidence in that fashion.

On the basis of the evidence then before it, ORI determined that the Committee had discounted the testimony that the bystander effect could not be repeated by Howell and Lenarczyk and, if true, would have presented a substantial motive for Bishayee to falsify the data showing such an effect (Brief at 14-16). Indeed the Committee and ORI reports are silent on the issue of the inability of Howell to repeat the results of Bishayee's experiments showing a bystander effect (Brief at 18-19). Moreover, the Second Committee was in possession of Lenarczyk's notebook but failed to recognize the significance of it (Brief at 23-24). Had it done so and had it actually undertaken a statistical analysis based on the materials presented or obtainable, it would have concluded as Hill and Pitt did. It would have discerned that:

a. In reviewing and analyzing the survival data of the experiments, Bishayee repeatedly and deliberately invented at least one value in each triad of data to force the data to comply with his desired result (1410a-1413a).

b. The probability that the terminal digits in the counts were random or uniform in the 120 coulter counts recorded during the re-plating of the samples was 0.00000000000074 (396a). [3]

The case of Boisjoly v Morton Thiokol, Inc, 706 F. Supp. 795, 809 (D. Utah 1988) is clearly distinguishable from the matter sub judice. In that case, the complaint and record evidence showed that the government had full knowledge of the facts, or was in possession of the facts, which allegedly made the claim false. In contrast to Boisljoly, the facts which support Hills claim were knowingly concealed from the government by Howell. He well knew that that Hill did not replicate the results of the Figure 7 experiment at the time the grant was submitted. He well knew that he and Lenarczyk could not replicate Bishayee's 50% and 100% experiments at the time the progress reports and renewal application were submitted (emphasis added). Nevertheless he proceeded to sign the progress reports and the renewal application certifying that everything was true to the best of his knowledge. In doing so, he deliberately chose not to disclose the information to NIH, the committees and to ORI. What Howell did is a far cry from the facts in Boisjoly. Any suggestion to the contrary or that NIH was on reasonable notice of Hill's allegations is clearly specious[4]. It was six years after ORI

[3] Utilizing all of Bishayee's Coulter counts, Dr. Pitt calculated the probablility to be <. 0.00000000001 (1408a)

[4] The fact that NIH was copied on the ORI report (1062a)(Defendant Brief at 29) has no evidential worth. There is no record evidence indicating who the individuals who were copied at NIH were. There is no evidence in the record establishing they were linked to the Study Group who reviewed Howell's annual progress reports and renewal grant. Nor

became involved in 2001 that Hill first came into the possession of the information which Howell had concealed.

See also, United States v Menominee Tribal Enterprises, 888 F.Supp. 419, 442 (E.D. N.Y. 1995) (government's knowledge is not a bar to an FCA claim if the knowledge was incomplete or acquired too late in the process); United States ex rel. Harrison v Westinghouse Savannah River Co., 352 F. 3d 908, 911 (4th Cir. 2003) (because the defendant was unable to show sufficient evidence of the government's extensive "full knowledge" of the defendant's conflict of interest, the government knowledge defense was inapplicable).

RETALIATION

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does it establish that, had the Study Section reviewing his renewal application known about the false data, it would not have affected their recommendation. The Study Sections simply had before it the preliminary studies and proposed experiments that Howell had set forth in his application, without mention of the repeated inability to replicate the data.

Hill does not appeal from the determination that she failed to make out a claim of retaliation under the FCA.