

United States District Court
Northern District of California

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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

GARY SIEBERT,
Plaintiff,
v.
GENE SECURITY NETWORK, INC,
Defendant.

Case No. 11-cv-01987-JST

**ORDER DENYING MOTION TO
DISMISS**

Re: ECF No. 28

Before the Court is the Motion to Dismiss Plaintiffs’ First Amended Complaint filed by Defendant Natera, Inc. (“Natera”), formerly known as Gene Security Network, Inc.¹ ECF No. 28.

I. BACKGROUND

The Court accepts the following allegations as true for the purpose of resolving this Rule 12(b)(6) motion. Cahill v. Liberty Mutual Ins. Co., 80 F.3d 336, 337–38 (9th Cir. 1996).

Plaintiff-relator Gary Siebert brings this qui tam action against Defendant Natera for violating the federal False Claims Act, 31 U.S.C. § 3729, et seq. ECF No. 22 (“FAC”). Natera is a privately-held, for-profit biotechnology corporation that studies and conducts molecular diagnostic tests for in vitro fertilization. FAC ¶ 15. From 2007 to 2010, Natera applied to receive three research grants from the National Institutes of Health (“NIH”) and was awarded a total of \$3,494,750. Id. ¶ 19–25. Plaintiff alleges that the NIH grant awards were conditioned on compliance with financial management system requirements, addressed in the NIH Grants Policy Statement and the Uniform Administrative Requirements for Awards and Subawards to

¹ The operative First Amended Complaint, ECF No. 22, names “Gene Security Network, Inc.” as Defendant. According to Defendant, in January 2012, subsequent to the filing of this action, Gene Security Network, Inc. changed its corporate name to Natera, Inc., and Defendant filed its motion to dismiss under that name.

1 Institutions of Higher Education, Hospitals, Other Nonprofit Organizations, and Commercial
2 Organizations, 45 C.F.R. 74 (“UAR”). Id. ¶ 18, 28. The NIH Grants Policy Statement and UAR
3 are intended to ensure that the rate and type of expenditures are consistent with the approved
4 project. Id. ¶ 17.

5 Plaintiff alleges that Natera’s affirmative statements in its applications for NIH grants and
6 its consent to program requirements contained in NIH award letters were fraudulent because
7 Natera was not in compliance with the mandatory financial monitoring provisions for
8 organizations receiving NIH grants. Id. ¶ 28–31. Plaintiff alleges that at the time of each grant
9 award, Natera was aware of its failure to monitor its finances in accordance with NIH
10 requirements — in particular, its failure to track the time employees spent on specific projects and
11 failing to track expenditures by project. Id. ¶ 28, 32.

12 **II. REQUESTS FOR JUDICIAL NOTICE**

13 Although a court’s review on a motion to dismiss is generally limited to the allegations in
14 the complaint, Lee v. City of Los Angeles, 250 F.3d 668, 688 (9th Cir. 2001), courts may properly
15 take judicial notice of material attached to the complaint, and of matters in the public record. Fed.
16 R. Evid. 201(b). See, e.g., Castillo-Villagra v. INS, 972 F.2d 1017, 1026 (9th Cir. 1992). In
17 addition, the “incorporation by reference” doctrine allows judicial notice of a document attached
18 by a defendant to a motion to dismiss when a “plaintiff’s claim depends on the contents of a
19 document” and “the parties do not dispute the authenticity of the document, even though the
20 plaintiff does not explicitly allege the contents of that document in the complaint.” Knievel v.
21 ESPN, 393 F.3d 1068, 1076 (9th Cir. 2005). Therefore, a court may take judicial notice of matters
22 of public record without converting a motion to dismiss into a motion for summary judgment;
23 however, courts may not take judicial notice of facts subject to reasonable dispute. Lee, 250 F.3d
24 at 689. A court “shall take judicial notice if requested by a party and supplied with the necessary
25 information.” Fed. R. Evid. 201(d).

26 Defendant Natera requests judicial notice of three documents: “Requirements for Financial
27 and Business Management Systems for SBIR/STTR Awardees” (“SBIR/STTR Awardee
28 Requirements”) and “Financial Questionnaire: Evaluation of Financial Management Systems”

1 (“Questionnaire”), ECF No. 29, and “Excerpt of the SF424 Application Guide for NIH and other
2 PHS Agencies” (“NIH Application Guide”), ECF No. 39-1. Plaintiff requests judicial notice of
3 excerpts of the “NIH Grants Policy Statement” (“Grants Policy”), ECF No. 37. Because each
4 submitted document is either incorporated by reference by the First Amended Complaint, or is a
5 matter of public record, the Court GRANTS Defendant and Plaintiff-relators’ unopposed requests
6 for judicial notice.

7 **III. LEGAL STANDARD**

8 On a motion to dismiss, the Court accepts the material facts alleged in the complaint,
9 together with all reasonable inferences to be drawn from those facts, as true. Navarro v. Block,
10 250 F.3d 729, 732 (9th Cir. 2001). However, “the tenet that a court must accept a complaint’s
11 allegations as true is inapplicable to threadbare recitals of a cause of action’s elements, supported
12 by mere conclusory statements.” Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009). To be entitled to
13 the presumption of truth, a complaint’s allegations “must contain sufficient allegations of
14 underlying facts to give fair notice and to enable the opposing party to defend itself effectively.”
15 Starr v. Baca, 652 F.3d 1202, 1216 (9th Cir. 2011), cert. den’d, --- U.S. ----, 132 S.Ct. 2101
16 (2012).

17 To survive a motion to dismiss, a plaintiff must plead “enough facts to state a claim to
18 relief that is plausible on its face.” Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 570 (2007).
19 Plausibility does not mean probability, but it requires “more than a sheer possibility that a
20 defendant has acted unlawfully.” Iqbal, 556 U.S. at 687. “A claim has facial plausibility when the
21 plaintiff pleads factual content that allows the court to draw the reasonable inference that the
22 defendant is liable for the misconduct alleged.” Id. In the Ninth Circuit, “[i]f there are two
23 alternative explanations, one advanced by defendant and the other advanced by plaintiff, both of
24 which are plausible, plaintiff’s complaint survives a motion to dismiss under Rule 12(b)(6).
25 Plaintiff’s complaint may be dismissed only when defendant’s plausible alternative explanation is
26 so convincing that plaintiff’s explanation is implausible.” Starr, 652 F.3d at 1216 (original
27 emphasis).

28 In addition, fraud claims are subject to a heightened pleading standard. “In alleging fraud

1 or mistake, a party must state with particularity the circumstances constituting fraud or mistake.”
2 Fed. R. Civ. P. 9(b). The allegations must be specific enough to give a defendant notice of the
3 particular misconduct alleged to constitute the fraud such that the defendant may defend against
4 the charge. Semegen v. Weidner, 780 F.2d 727, 731 (9th Cir. 1985). In general, allegations
5 sounding in fraud must contain “an account of the time, place, and specific content of the false
6 representations as well as the identities of the parties to the misrepresentations.” Swartz v. KPMG
7 LLP, 476 F.3d 756, 765 (9th Cir. 2007). However, “[m]alice, intent, knowledge, and other
8 conditions of a person's mind may be alleged generally.” Fed. R. Civ. P. 9(b).

9 **IV. ANALYSIS**

10 The False Claims Act (“FCA”) allows private citizens who have knowledge of past or
11 present fraud on the United States to sue on the government’s behalf to recover civil penalties and
12 damages. 31 U.S.C. §§ 3729–3733. Defendant Natera moves to dismiss Plaintiff’s operative First
13 Amended Complaint for violation of the FCA, subsections 31 U.S.C. § 3279(a)(1)(A) and
14 (a)(1)(B), for failure to state a legal claim and failure to plead fraud with particularity. ECF No.
15 28.

16 Plaintiff’s first cause of action for violation of subsection 3729(a)(1)(A) requires: “(1) a
17 false or fraudulent claim (2) that was material to the decision-making process, (3) which defendant
18 presented, or caused to be presented, to the United States for payment or approval (4) with
19 knowledge that the claim was false or fraudulent.” Hooper v. Lockheed Martin Corp., 688 F.3d
20 1037, 1047 (9th Cir. 2012) (citing United States v. Bourseau, 531 F.3d 1159, 1171 (9th Cir.
21 2008)). Likewise, Plaintiff’s second cause of action for violation of subsection 3729(a)(1)(B)
22 requires a showing that “defendants knowingly made, used, or caused to be made or used, a false
23 record or statement material to a false or fraudulent claim.” Id.

24 Natera moves to dismiss on the grounds that Plaintiff has failed adequately to plead the
25 falsity, materiality, and scienter requirements necessary to establish a prima facie FCA violation.
26 ECF No. 28 at 7. The Court addresses each requirement in turn.

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1 **A. Falsity**

2 Natera moves to dismiss because “Plaintiff’s failure to plead any false certification or
3 statement in the grant applications that was a condition to payment is fatal to his claims.” ECF
4 No. 28 at 7.

5 For an FCA plaintiff “to succeed on a false certification theory, some falsity must be
6 alleged.” U.S. ex rel. Hendow v. University of Phoenix, 461 F.3d 1166, 1171 (9th Cir. 2006). In
7 FCA cases, “[i]t is the false certification of compliance which creates liability when certification is
8 a prerequisite to obtaining a government benefit.” U.S. ex rel. Hopper v. Anton, 91 F.3d 1261,
9 1266 (9th Cir. 1996) (original emphasis). Plaintiff here alleges that Natera falsely certified its
10 compliance with financial system requirements during the NIH grant application process in two
11 ways. First, Plaintiff alleges that Natera falsely certified in all three grant applications that it
12 would abide by any terms and conditions included in the grant application for which it was
13 approved. FAC ¶ 26. Second, Plaintiff alleges that Natera re-certified its compliance with the
14 terms and conditions of the grant each time it accepted NIH grants through NIH Notice of Award
15 letters. These alleged false certifications stem from a complex maze of regulations, policy
16 statements, and other documents. A detailed explanation of how they relate is necessary.

17 **i. The Grant Applications**

18 Each of the three grant applications contain the following certification statements:

19 18. By signing this application, I certify (1) to the statements
20 contained in the list of certifications* and (2) That the statements
21 herein are true, complete, and accurate to the best of my knowledge.
22 I also provide the required assurances* and agree to comply with
23 any resulting terms if I accept an award. I am aware that any false,
fictitious, or fraudulent statements of claims may subject me to
criminal, civil or administrative penalties (U.S. Code Title 18,
Section 1001).

24 Id. ¶ 26. In each grant application, the asterisked portion reads: “The list of certifications and
25 assurances, or an Internet site where you may obtain this list, is contained in the announcement or
26 agency specific instructions.” Id., Ex. A p. 2 (signed Dec. 12, 2007); id., Ex. D p. 2 (signed April
27 7, 2008); id., Ex. H p. 2 (signed Aug. 5, 2009). That list is the NIH Application Guide, which
28 serves as a guide for preparing and submitting applications to NIH. “Excerpt of the SF424

1 Application Guide for NIH and other PHS Agencies” (“NIH Application Guide”), ECF No. 39-1
2 (rev. June 18, 2012). Under a section titled “Assurances and Certifications,” the NIH Application
3 Guide states that “applicants and grantees must comply with a number of additional public policy
4 requirements. Refer to the NIH Grants Policy Statement for additional information.” Id. p. III-16
5 (original emphasis).

6 The NIH Grants Policy Statement requires applicants to affirm their compliance with
7 various “Financial Management System Standards”:

8 Grantees are required to meet the standards and requirements for
9 financial management systems set forth or referenced in 45 C.F.R.
10 74.21 or 92.20, as applicable. The standards and requirements for a
11 financial management system are essential to the grant relationship.
12 NIH cannot support the research unless it has assurance that its
13 funds will be used appropriately, adequate documentation of
14 transactions will be maintained, and assets will be safeguarded. . . .
15 A grantee’s failure to establish adequate control systems constitutes
16 a material violation of the terms of the award. Under these
17 circumstances, NIH may include special conditions on awards or
18 take any of the range of actions specified in “Administrative
19 Requirements — Enforcement Actions,” as necessary and
20 appropriate.

21 ECF No. 37 (“Grants Policy”), Ex. 3 p. 10. The Department of Health and Human Services
22 (“HHS”) promulgated regulations establishing the administrative requirements for awards to
23 commercial organizations, which are known as the “Uniform Administrative Requirements for
24 Awards and Subawards to Institutions of Higher Education, Hospitals, Other Nonprofit
25 Organizations, and Commercial Organizations” (“UAR”), codified at 45 C.F.R. 74, et seq. The
26 NIH Grants Policy Statement incorporates the UAR.

27 Part 74.21 provides the post-award requirements for commercial organizations, specifying
28 the standards for financial management systems. In particular, subsection (b) requires that the
recipient’s financial management systems include “records that identify adequately the source and
application of funds for HHS-sponsored activities,” “effective control over and accountability for
all funds,” “comparison of outlays with budget amounts for each award,” and “written procedures
for determining the reasonableness, allocability, and allowability of costs in accordance with . . .
the terms and conditions of the award.” 45 C.F.R. § 74.21(b). By signing and presenting the
application to the NIH, Plaintiff alleges Natera falsely certified compliance with the NIH Grants

1 Policy and the UAR.

2 **ii. Award Letter Requirements**

3 Plaintiff also alleges that Natera violated the FCA each time it accepted NIH funds by
4 reaffirming its compliance with the terms and conditions of the grant contained in Notice of
5 Award letters. Each Notice of Award letter states:

6 “REQUIREMENT: This award is subject to the requirements
7 pertaining to the awardee’s financial and business management
8 systems, as set forth in the documents entitled, ‘SBIR/STTR
9 Financial/Management Systems Requirements’, available at [url
omitted] and which is hereby incorporated by reference.”

9 Id. ¶ 27; id. Ex. B, p. 4. The document refers to the publicly available “Requirements for
10 Financial and Business Management Systems for SBIR/STTR Awardees” (“System
11 Requirements”), located on the NIH website. ECF 29-1, Ex. A. That document states: “the
12 awardee must have records that document and reflect compliance with the following,” and lists
13 various financial and business management system requirements, including the requirement that
14 awardees track employee time spent on specific projects and expenditures by project. Id. p. 2.

15 The System Requirements document also directs awardees to the “Financial Questionnaire:
16 Evaluation of Financial Management Systems.” FAC, Ex. J. The Questionnaire “is a tool
17 designed to assist both grantee and NIH staff in assessing the grantee’s management capabilities.”
18 ECF No. 29-2, Ex. B p. 1. Section A of the questionnaire evaluates the “Accounting System” of
19 the applicant and contains the following description:

20 The grantee organization needs to incorporate an accounting system
21 that will track costs between direct and indirect costs (general
22 ledger) as well as direct costs by project (project ledger). The
23 grantee will also need to establish a time and effort reporting system
24 to track personnel costs by project. It is industry practice to require
daily reporting of effort expended on individual projects or
activities. This should be reported on an hourly basis, or in
increments of an hour.

25 Id. at 2. Plaintiff alleges that Natera violated the FCA when it filled out the questionnaire,
26 certifying that it tracked employee time spent on specific projects and expenditures by project
27 even though it had no system in place to do so. FAC ¶ 28.

28 Natera argues that Plaintiff inadequately alleges that it made any false statements. In

1 particular, Natera argues that Plaintiff has not alleged what statements were false and how they
2 were false. The Court disagrees. The First Amended Complaint: traces the above-cited authorities
3 and program requirements; attaches the subject grant applications, each of which includes signed
4 “Section 18” statements certifying compliance with the UAR and the financial management
5 systems requirements; and alleges that the signed certifications were false because Natera, at the
6 time the certifications were made, did not track hourly employee time by project and expenditures
7 by project. FAC ¶ 28. In addition, Plaintiff alleges that “each application for an NIH grant
8 requires that the applicant affirm its compliance with various financial management system
9 requirements” and that “[i]n response to the [Financial Questionnaire], GSN expressly affirmed
10 the existence of” financial systems it did not have in place — namely, the time and expenditure
11 tracking system required by the NIH. Those allegations are sufficient to satisfy the falsity
12 requirement.

13 Confusingly, Natera also argues that the Notice of Award letters, which contain terms and
14 conditions that lead to the Financial Questionnaire, cannot serve as false certifications “because
15 they are statements by the government, and not by Natera.” ECF No. 28 p. 7 (original emphasis).
16 That misconstrues Plaintiff’s allegations; Plaintiff alleges that it was Natera’s certification of
17 compliance, made in response to the Questionnaire, which constitutes a false certification.

18 **B. Materiality**

19 Natera also moves to dismiss on the grounds that the post-award certifications cannot
20 satisfy the materiality requirement because the False Claims Act only applies to false statements
21 made pre-award — that is, prior to the Government’s decision to pay the claim. The certifications
22 at issue here either came after the NIH Notice of Award letters or govern post-award program
23 requirements. Per Natera, false certifications concerning post-award requirements, or made after
24 the award letter is mailed, do not constitute a claim for payment material to the Government’s
25 decision-making process.

26 In order to plead an actionable violation of the False Claims Act, the false certification of
27 compliance must be material to the government’s payment of funds. Hendow, 461 F.3d at 1172.
28 Plaintiff alleges that NIH award payments are conditioned on compliance with the Financial

1 Systems Requirements in the NIH Grants Policy Statement and the UAR. Natera argues that all
2 the alleged certifications were merely conditions for continued post-award participation rather
3 than conditions of pre-award payment.

4 In Hendow, the qui tam plaintiffs alleged that the University of Phoenix knowingly made
5 false promises to comply with an incentive compensation ban to become eligible to receive Title
6 IV funds. The court examined the controlling statutes, regulations, and agreement, and found that
7 they were “not ambiguous exhortations of an amorphous duty,” but explicitly conditioned
8 “participation and payment on compliance with, among other things, precise requirements that
9 relators allege that the University knowingly disregarded.” Id. at 1176. The University of
10 Phoenix pressed the difference between certifications that an institution will comply with
11 requirements and certifications that it has complied with requirements. Id. (emphasis added).
12 The Hendow court found that “[t]his grammatical haggling is unmoored in the law.” Id. If
13 “conditions of participation were not conditions of payment, there would be no conditions of
14 payment at all — and thus, an education institution could flout the law at will.” Id. The court held
15 that “[t]hese conditions are also ‘prerequisites,’ and ‘the sine qua non’ of federal funding, for one
16 basic reason: if the University had not agreed to comply with them, it would not have gotten paid.”
17 Id.

18 Hendow is instructive. Here, the UAR concerns “Post-Award Performance,” but Plaintiff
19 alleges that the NIH would not have awarded Natera the grants had Natera refused to certify that it
20 would comply with the provisions of the UAR (prior to the grant), or that it was already in
21 compliance (at the Notice of Award letter stage). Though Natera is free to dispute the merit of
22 those allegations, Plaintiff adequately raises the issue for purposes of a motion to dismiss.

23 Natera does argue that Plaintiff fails to identify express language conditioning payment on
24 compliance to requirements. That argument is refuted by the text in both the Grants Policy and
25 the Questionnaire. In the Grants Policy, under a section titled “Completing The Pre-Award
26 Process,” subsection “Eligibility,” the text states that the “NIH may consider other factors relating
27 to the applicant’s ability to responsibly handle and account for Federal funds and to carry out the
28 project.” ECF No. 37 Ex. 2 p. 2. Under the subsection “Cost Analysis and Assessment of

1 Management Systems,” the Grants Policy provides that the Grants Management Officer
2 “determines the adequacy of the applicant’s financial and business management systems that will
3 support the expenditure of and accountability of NIH funds.” Id. “On the basis of the review
4 results, the [Grants Management Officer] will determine the need for any corrective action and
5 may impose special conditions on the award.” Id.

6 The Questionnaire states: “Demonstration of a grantee’s management capabilities is one of
7 the evaluative criteria used in the administrative review process prior to issuance of the award.”
8 ECF 22 Ex. J. In the same paragraph, the text states: “Concerns related to a grantee
9 organization’s management capabilities may result in the determination to withhold an award or
10 issuance of an award with special terms and conditions in accordance with 45 CFR 74.14.” Id.
11 An asterisked portion explaining the purpose of the Questionnaire states: “For use primarily with
12 new for-profit grantees (including SBIR/STTR organizations) to determine major weaknesses in
13 financial management systems. Responses may require that an in-depth review be performed.”
14 Id.

15 Finally, the Notice of Award letters make clear that, even after NIH decides to award a
16 grant, it is subject to further certifications of compliance. Each letter states: “Acceptance of this
17 award including the ‘Terms and Conditions’ is acknowledged by the grantee when funds are
18 drawn down or otherwise obtained from the grant payment system.” See, e.g., FAC, Ex. B p. 1.
19 Further, the award letters provide: “Prior to drawing down funds for this award from the Payment
20 Management System, the awardee is required to have in place written policies and procedures for
21 financial and business management systems that comply with the standards set forth in” the
22 Systems Requirements document. Id. p. 4. The Notice of Award letters are therefore offers of
23 funding, acceptance of which constitutes further certifications of compliance with and consent to
24 the terms and conditions contained and incorporated therein.

25 While Natera correctly points out that “[m]ere regulatory violations do not give rise to a
26 viable FCA action,” violations that may be conditions for payment do meet the FCA standard.
27 See Hopper, 91 F.3d at 1267; Hendow, 461 F.3d at 1172. Plaintiff adequately alleges that the
28 false certifications at issue here were material to the NIH’s decision to award (and fund) Natera’s

1 grants.

2 **C. Scierter**

3 Natera also moves to dismiss on the grounds that Plaintiff has failed adequately to plead
4 scierter, subject to the heightened fraud pleading standard.

5 The False Claims Act defines “knowing” to include a defendant who, with respect to false
6 information, “(i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the
7 truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the
8 information.” 31 U.S.C. § 3729(b)(1)(A). However, the FCA itself provides that “no proof of
9 specific intent to defraud” is required to satisfy the scierter requirement. 31 U.S.C. §
10 3729(b)(1)(B). See, e.g., Castillo-Villagra v. INS, 972 F.2d 1017, 1026 (9th Cir. 1992). In short,
11 “[s]o long as the statement in question is knowingly false when made, it matters not whether it is a
12 certification, assertion, statement, or secret handshake; False Claims liability can attach.”
13 Hendow, 461 F.3d at 1172.

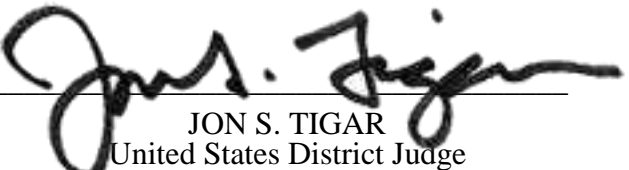
14 Plaintiff alleges that Natera knew its certifications of compliance were “known to be false
15 by [Natera] and the persons making them.” FAC ¶ 29. At the time the certifications were made,
16 Plaintiffs allege that Natera was “not in compliance with the mandatory financial monitoring
17 provisions for organizations receiving NIH grants.” Id. ¶ 31. By alleging that Natera certified its
18 compliance with requirements it was, at the time, failing to meet, is sufficient to allege scierter
19 under the FCA. Plaintiff is not required to allege anything more in order to survive a motion to
20 dismiss; the First Amended Complaint, as filed, sufficiently puts Natera on notice of the nature of
21 the claims against it.

22 **IV. CONCLUSION**

23 For the foregoing reasons, Defendants’ Motion to Dismiss Plaintiffs’ First Amended
24 Complaint is hereby DENIED.

25 **IT IS SO ORDERED.**

26 Dated: June 17, 2013

27 
28 JON S. TIGAR
United States District Judge