Zakharyan v. Aviir, Inc. Doc. 12

# IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLORADO

Civil Action No. 12-cv-02498-JLK

ARMEN ZAKHARYAN,

Plaintiff,

v.

AVIIR, INC., a Delaware corporation,

Defendant.

## ORDER DENYING MOTION TO DISMISS

Kane, J.

Defendant Aviir, Inc. ("Aviir") moves to dismiss per FRCP 12(b)6)<sup>1</sup>, arguing that Plaintiff has failed to state a claim for which relief can be granted. Doc. 7. Defendant's motion is predicated upon the theory that the at-will employment doctrine prevents recovery where an at-will employee alleges he was terminated because he exposed fraudulent employer conduct to his superiors and refused to stay idle while his superiors continued to perpetrate fraud in violation of public policy expressed in Federal Drug Administration ("FDA") guidance materials.

Defendants claim that because there is no specific *statutory* authority spelling out the public policy that Plaintiff maintains was flouted, because Plaintiff himself was not ordered to engage in active deceit, and because Plaintiff did not explicitly threaten to report the alleged malfeasance to some unknown entity never identified by Defendant, the public policy exception

<sup>1</sup> Under FRCP 12(b)(6), dismissal obtains where the complaint contains insufficient allegations of fact "to state a claim to relief that is plausible on its face," Bell Atlantic Corp. v. Twombly, 550

U.S. 544, 570 (2007). In considering whether dismissal is appropriate, all well-pleaded factual allegations in a complaint must be accepted as true and viewed in the light most favorable to the

plaintiff. Rosenfield v. HSBC Bank, USA, 681 F.3d 1172, 1178 (10th Cir. 2012).

to the at-will employment doctrine is inapplicable and Plaintiff's claims must therefore fail as a matter of law. Although Defendant is correct that the public policy exception to the at-will employment doctrine is narrow, it is not as insulating as Defendant contends and it is not intended to deflect only direct orders to actively participate in activity forbidden by statute. Similarly, it is unnecessary that Plaintiff needed to "whistle-blow" to a government entity to avail himself of the public policy exception. As explained below, Defendants are in error, and I DENY the Motion to Dismiss, Doc. 7.

### FACTUAL BACKGROUND

Aviir is a biotechnology company that discovers, develops, and commercializes products for the prevention and control of cardiovascular diseases and metabolic syndromes. *Doc.* 7 at 2. Aviir has developed a proprietary cardiac risk assessment tool called TruRisk. *Id.* TruRisk is designed to supplant the Framingham Risk Score and other similar tests currently used by physicians to determine the cardiovascular risk of their patients, Defendant claiming TruRisk is a superior product. The cost of testing with TruRisk is approximately \$1,500. *Doc.* 10 at 2. Because the Framingham Risk Score is a nonproprietary method within the public ken, it has little or no cost and is thus a significantly cheaper means of assessment than TruRisk. *Id.* 

Plaintiff Dr. Zakharyan is a mathematician with MS and PhD degrees in Applied mathematics with an emphasis on stochastic and probalistic models. *Doc. 10* at 1. Before his employment with Aviir, Dr. Zakharyan served as a director of biostatistics for the Colorado Prevention Center in Denver, Colorado. *Id.* As a director of biostatistics he was a subject matter expert in FDA guidelines pertaining to clinical trials and diagnostic tests. *Id.* More than a director, Dr. Zakharyan was also a member of the Colorado Prevention Center's executive committee and head of the biostatistics department. *Id.* at 2

Using the services of a "head hunting" company, Aviir recruited the services of Dr. Zakharyan in February of 2012 and Dr. Zakharyan accepted Aviir's offer of at-will employment shortly thereafter. *Id.* Dr. Zakharyan's first project was to review articles concerning TruRisk that Aviir had authored. *Id.* The end goal of the assignment was for Dr. Zakharyan to suggest changes to the literature that would facilitate it being accepted by scholarly journals that had hitherto rejected it for publication. *Id.* In order to review the documents, Dr. Zakharyan performed a mathematical analysis of the comparative success of TruRisk vis-à-vis the Framingham Risk Score in predicting which individuals would suffer from heart problems. *Id.* at 3.

Dr. Zakharyan's analysis indicated that there was not a statistically significant difference in the predictive ability of the two tests and that Aviir's studies proposing to the contrary were the results of false positives, specifically "Type 1" errors occasioned by structural flaws in the study and Aviir's computation of the analysis. *Id.* at 3. He immediately reported his findings to two superiors, one of whom likewise concluded that there was not a significant difference between the two tests. *Id.* 

Dr. Zakharyan posits the study was structurally flawed because the objectives/protocols of the TruRisk study were modified after the study was completed. *Id.* at 4. Dr. Zakharyan explains that objectives must be set forth before commencing a study to prevent the interruption of random events influencing the study. *Id.* Moreover, Dr. Zakharyan states the pre-definition of objectives is important to avoid defining objectives after the study is finished in order to achieve a desired result. *Id.* I accept this readily, as this is an elemental concept in any scientific experiment—even a fourth grader must tell his teacher his hypothesis before embarking on his science project. Not only was Dr. Zakharyan familiar with the fact that good clinical practice

requires that the objectives be defined before a study, but he was also aware that FDA guidelines require the same. *See Guidance for Industry Good Clinical Practice: Consolidated Guidance*<a href="http://www.fda.gov/downloads/drugs/.../Guidances/ucm071322.pdf">http://www.fda.gov/downloads/drugs/.../Guidances/ucm071322.pdf</a> and

<a href="http://www.fda.gov/downloads/drugs/GuidanceComplianceRegulatoryInformation/guidances/ucm073137.pdf">http://www.fda.gov/downloads/drugs/GuidanceComplianceRegulatoryInformation/guidances/ucm073137.pdf</a> .

Because Dr. Zakharyan believed the TruRisk study was conducted in violation of the FDA guidelines and because he knew a favorable endorsement would prime the product for mass consumption to be billed many times over to Medicaid and Medicare at an unnecessarily great cost (given the relative prices of two tests), Dr. Zakharyan felt he had an obligation to make Aviir aware that TruRisk was no better, if not worse, than the Framingham Risk Score. *Doc. 10* at 4. Dr. Zakharyan therefore suggested that further analysis of TruRisk was needed to determine its efficacy compared to the Framingham Risk Score. *Id.* at 5. Dr. Zakharyan reports his supervisors immediately rejected the idea that further analysis was needed. *Id.* When Aviir's President and Chief Operating Officer, Douglas S. Harrington, MD, was informed of Dr. Zakharyan's conclusions, the same ones corroborated by his colleague Dr. Biggs, Dr. Harrington pulled Dr. Zakharyan from the TruRisk project. *Id.* 

Dr. Zakhrayan was given a new assignment, which he timely completed, but he did not abandon his belief that the TruRisk study was flawed. *Id.* Although Dr. Harrington allegedly told Dr. Zakharyan to devote his efforts to a different project—apparently meaning *all* his efforts—Dr. Zakharyan sent out his review of TruRisk to his colleagues. *Id.* Within a week of sending out his TruRisk review, Dr. Zakharyan was terminated with no more explanation than that he "wasn't a good fit for Aviir." *Id.* After Dr. Zakharyan's separation, Aviir's website posted a "job opening" for a biostatistician. *Id.* at 6.

#### LEGAL CONSIDERATIONS

Employment contracts under Colorado law are generally at-will and either the employer or the employee may terminate the relationship at any time. *Rocky Mountain Hospital & Medical Service v. Mariani*, 916 P.2d 519, 524 (Colo.1996). Both the Colorado Supreme Court and the Tenth Circuit applying Colorado law have developed exceptions to the employment at-will doctrine, however, limiting the extent to which an employer may terminate without cause.

In the seminal case Martin Marietta Corp. v. Lorenz, 823 P.2d 100, 101 (Colo. 1992), the Colorado Supreme Court held that an employee will have a cognizable claim for wrongful discharge if "the discharge of the employee contravenes a clear mandate of public policy." (quoting Thompson v. St. Regis Paper Co., 685 P.2d 1081, 1089 (1984)). Under Lorenz, the elements of a wrongful discharge claim are: (1) the employer directed the employee to perform an illegal act or prohibited the employee from performing a public duty or exercising an important job-related right or privilege; (2) the action directed by the employer would violate a statute or a clearly expressed public policy; (3) the employee was terminated as a result of refusing to perform the illegal act; and (4) the employer was aware or should have been aware that the employee's refusal was based upon the employee's reasonable belief that the act was illegal. Lorenz, 823 P.2d at 109. While the public policy implicated in Lorenz was evidenced by a specific statute, the opinion's plain language supported the idea that non-legislative sources could provide sources of public policy for purposes of a wrongful termination claim. See id. *Marani* then reaffirmed that such sources would qualify, provided they served the public interest and were sufficiently concrete to notify employers and employees. 916 P.2d at 525. Colorado courts have interpreted a "public interest" to mean "matters affecting society as a whole, rather than the personal or proprietary interests of the parties; actions which strike at the heart of a

citizen's social rights, duties, and responsibilities; and actions by an employer which lead to an outrageous result clearly inconsistent with a stated public policy." *Hoyt v. Target Stores*, 981 P.2d 188, 191 (Colo.App.1998).

### DISCUSSION

Defendant mischaracterizes the nub of Plaintiff's allegations, stating that Plaintiff "simply alleges that he complained to his supervisors about the perceived value of TruRisk."

Doc. 11 at 1. This over-simplistic exaggeration misses the point by willfully ignoring the reason behind why Plaintiff believes TruRisk to be a poor value. Plaintiff objected to Defendant's failure to follow the FDA Guidelines requiring that the objectives of the TruRisk study be defined before the study was completed. Plaintiff was concerned that Aviir would mass-market at great cost to individuals and the Government a product that was clinically equal or inferior to the leading substitute product. At bottom, Plaintiff believed Aviir's study was perpetuating a fraud and was concerned that Aviir seemed unable to assure him otherwise.

Defendant's theory would have this Court believe that the at-will employment doctrine blocks recovery for all but the most egregious contraventions of public policy embedded in specific statutes, but that is not what *Lorenz* and its progeny stand for. The public policy exception line of cases underscores the long-standing rule that a contract violative of public policy is unenforceable. "An employee whether at will or otherwise, should not be put to the choice of either obeying an employer's order to violate the law or losing his or her job." *Lorenz*, 823 P.2d at 109. Courts have repeatedly recognized that though the at-will employment doctrine is important for preserving an employer's discretion in hiring and firing, the law must guard the likewise important interest of an employing maintaining his job. *Id.* at 105.

Defendant argues Dr. Zakharyan's Complaint implicates no clearly expressed public

policy. I disagree. The cost of medical care is a significant problem both nationally and to the

people of Colorado. Replacing a near free product with a \$1,500 one that might be no better and

is possibly worse irrefutably affects "society as a whole." Moreover, just as *Lorenz* devotes

nearly a whole paragraph to discussing the important public policy of truthfulness and accuracy,

albeit in the context of 18 U.S.C. §1001 (1988), id. at 111, a fortiori the same applies to

truthfulness and accuracy of healthcare goods.

Taking Dr. Zakharyan's allegations to be true, as I must for purposes of a motion to

dismiss under FRCP 12(b)(6), I find Dr. Zakharyan has made out the requisite prima facie

showing. The allegations suggest Aviir violated public policy by encouraging Dr. Zakharyan to

dress up a flawed study such that it would be suitable for publication and next by tacitly ordering

him to keep the fraud to himself by removing him from the project.

**CONCLUSION** 

Dr. Zakharyan has plead sufficient, plausible facts to find that Aviir may have terminated

him in violation of public policy. Accordingly, Defendant's Motion to Dismiss, Doc. 7, is

DENIED.

DATED:

February 13, 2013

BY THE COURT:

/s/John L. Kane

U.S. Senior District Judge