Glazing Employers and Glaziers' Union Local #27 Pension and Retirement Fund v. iRhythm Technologies, Inc.

COURT: United States District Court for the Northern District of California
CASE NUMBER: 24-cv-706
CLASS PERIOD: 11/05/2021 - 08/09/2024
CASE LEADERS: Hannah Ross, Avi Josefson, John Rizio-Hamilton, Katherine M. Sinderson
CASE TEAM: Thomas Sperber

On February 6, 2024, Bernstein Litowitz Berger & Grossmann LLP ("BLB&G") filed a class action lawsuit in the U.S. District Court for the Northern District of California alleging violations of the federal securities laws by iRhythm Technologies, Inc. ("iRhythm" or the "Company") and certain of the Company's current and former senior executives (collectively, "Defendants"). The action is brought on behalf of all persons or entities that purchased or otherwise acquired iRhythm common stock between November 5, 2021, and August 9, 2024, inclusive (the "Class Period").

BLB&G filed this action on behalf of its client, Glazing Employers and Glaziers' Union Local #27 Pension and Retirement Fund, and the case is captioned *Glazing Employers and Glaziers' Union Local #27 Pension and Retirement Fund v. iRhythm Technologies, Inc.*, No. 24-cv-706 (N.D. Cal.). The complaint is based on an extensive investigation and a careful evaluation of the merits of this case. To view the complaint, see the **Case Documents** section of this page.

iRhythm's Alleged Fraud

iRhythm develops and manufactures heart monitoring devices designed to diagnose arrythmias. The Company's principal product is a monitoring patch that provides electrocardiogram ("ECG") monitoring for up to 14 days, called Zio XT. The Zio XT is intended for non-critical patients, as it does not provide real-time reporting.

In 2017, iRhythm developed Zio AT, a device the Company described as "offer[ing] the full benefits of [its] Zio XT Service, with the addition of real-time data transmission and notification of actionable clinical events." Actionable arrhythmic events include atrial fibrillation, a condition that can cause troubling symptoms and serious medical complications, including blood clots that can lead to stroke and heart failure. The Zio AT comes with a cellular transmittal device that provides connectivity between the Zio AT and the proprietary algorithmic software that analyzes the ECG data and detects arrhythmic events for the 14-day wear period. Importantly, given its purported capabilities to provide "real-time" notifications of arrhythmic events, the Zio AT device is marketed to high-risk patients as a mobile cardiac telemetry device. These types of heart monitors that are approved for high-risk patients and provide near real-time alerts are also referred to as "real-time" monitors. Real-time monitors sell for a premium over monitors that do not provide real-time notifications of arrhythmic events.

The complaint alleges that, throughout the Class Period, Defendants falsely represented to investors that the Zio AT monitor was a real-time monitor intended for high-risk patients. Specifically, Defendants repeatedly touted the potential growth for the Zio AT as an innovative product that had only just begun to penetrate the market for real-

time monitoring, which investors looked upon favorably given the premium selling price associated with devices approved for high-risk patients. As a result of these misrepresentations, the price of iRhythm common stock traded at artificially inflated prices throughout the Class Period.

The truth emerged through a series of disclosures beginning on November 1, 2022, when the Company reported revised fourth quarter and full-year guidance, in part due to "Zio AT utilization." The Company explained during a conference call with investors that "coming into the fourth quarter, [iRhythm] voluntarily issued a Customer Advisory Notice to [its] Zio AT customers." Consequently, the Company lowered its Zio AT forecast for the quarter from the 40% growth target it had provided through the past three quarters to just 20%. Three days later, on November 4, 2022 the Company disclosed that it initiated the Customer Advisory Notice on September 28, 2022, following issues raised by the FDA during an inspection that culminated in an inspection observation report on Form 483, and that the Customer Advisory Notice warned patients of a "labeling correction" related to "the device's maximum transmission limits during wear," as well as other critical issues that prevent the device from working as advertised. However, Defendants tried to assuage investors' concerns and continued to tout the growth of the Zio AT.

Then, on May 4, 2023, the Company announced that "on April 4, 2023, [it] received a Subpoena Duces Tecum from the Consumer Protection Branch, Civil Division of the U.S. Department of Justice, requesting production of various documents regarding [its] products and services." Although the Company refrained from providing additional detail about the DOJ's request, in a May 5, 2023, report, J.P. Morgan analysts noted that one of iRhythm's competitors, Boston Scientific, had also disclosed that it received a subpoena from the DOJ relating to its real-time monitoring product, which indicated to the analysts that the DOJ investigation into iRhythm was related to the Zio AT.

Finally, on May 30, 2023, iRhythm disclosed that it had received a warning letter from the FDA, which addressed a series of deficiencies tied to the marketing and capabilities of the Zio AT device. In particular, the FDA noted that iRhythm had falsely marketed the Zio AT as approved for use in high-risk patients that require real-time cardiac monitoring. In truth, according to the FDA, Zio AT is only approved for "long-term monitoring of arrhythmia events for non-critical care patients where real-time monitoring is not needed." As a result of these disclosures, the price of iRhythm common stock declined precipitously.

If you wish to serve as Lead Plaintiff for the Class, you must file a motion with the Court no later than April 8, 2024, which is the first business day on which the U.S. District Court for the Northern District of California is open that is 60 days after the publication date of February 6, 2024. Any member of the proposed Class may seek to serve as Lead Plaintiff through counsel of their choice, or may choose to do nothing and remain a member of the proposed Class.

If you wish to discuss this action or have any questions concerning this notice or your rights or interests, please contact Scott R. Foglietta of BLB&G at 212-554-1903, or via e-mail at scott.foglietta@blbglaw.com.

Case Documents

- October 11, 2024 - Second Amended Class Action Complaint
- February 6, 2024 - Initial Complaint
- February 6, 2024 - PSLRA Notice