

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

SERGEY CHERNYSH, on behalf of
himself and all others similarly situated,

Plaintiff,

v.

CHEMBIO DIAGNOSTICS, INC.,
RICHARD L. EBERLY, and GAIL S.
PAGE,

Defendants.

Case No. 2:20-cv-02706-ARR-ARL

**MEMORANDUM OF LAW IN SUPPORT
OF MOTION OF JEFF KONE FOR
CONSOLIDATION, APPOINTMENT AS
LEAD PLAINTIFF, AND APPROVAL OF
LEAD COUNSEL**

ORAL ARGUMENT REQUESTED

JAMES GOWEN, Individually and on
Behalf of All Others Similarly Situated,

Plaintiff,

vs.

CHEMBIO DIAGNOSTICS, INC.,
RICHARD L. EBERLY, and GAIL S.
PAGE,

Defendants.

Case No. 2:20-cv-02758-ARR-ARL

ANTHONY BAILEY, Individually and
On Behalf of All Others Similarly
Situated,

Plaintiff,

v.

CHEMBIO DIAGNOSTICS, INC.,
RICHARD L. EBERLY, GAIL S. PAGE,
and NEIL A. GOLDMAN,

Defendants.

Case No. 2:20-cv-02961-ARR-ARL

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Movant Jeff Kone (“Kone”) respectfully submits this Memorandum of Law in support of his motion, pursuant to Section 21D(a)(3) of the Securities Exchange Act of 1934 (the “Exchange Act”), 15 U.S.C. § 78u-4(a)(3), as amended by the Private Securities Litigation Reform Act of 1995 (the “PSLRA”), and Federal Rule of Civil Procedure 42, for the entry of an Order: (1) consolidating the above-captioned related actions (the “Related Actions”); (2) appointing Kone as Lead Plaintiff on behalf of a class (the “Class”) consisting of all persons and entities other than the above-captioned defendants (“Defendants”) who purchased or otherwise acquired Chembio Diagnostics, Inc. (“Chembio” or the “Company”) securities between March 12, 2020 and June 16, 2020, both dates inclusive (the “Class Period”); and (3) approving proposed Lead Plaintiff’s selection of Pomerantz LLP (“Pomerantz”) as Lead Counsel for the Class.

PRELIMINARY STATEMENT

Pursuant to the PSLRA, the Court is to appoint as Lead Plaintiff the movant who possesses the largest financial interest in the outcome of the action and who satisfies the requirements of Rule 23 of the Federal Rules of Civil Procedure. 15 U.S.C. § 78u-4(a)(3)(B)(iii)(I). Kone, with losses of approximately \$285,485 in connection with his purchases of Chembio securities during the Class Period, believes that he has the largest financial interest in the relief sought in the Related Actions. Kone further satisfies the requirements of Rule 23 of the Federal Rules of Civil Procedure because he is an adequate representative with claims typical of the other Class members. Accordingly, Kone respectfully submits that he should be appointed Lead Plaintiff.

STATEMENT OF FACTS

As alleged in the Complaints in the Related Actions, Chembio purports to be a leading point-of-care (“POC”) diagnostics company focused on detecting and diagnosing infectious diseases. The Company claims its patented Dual Path Platform (“DPP”) technology platform, which uses a small drop of blood from the fingertip, provides high-quality, cost-effective results in approximately 15 minutes.

Furthermore, the Company asserts that its products “meet the highest standards for accuracy and superior performance to help prevent the spread of infectious diseases” and that its “innovative solutions, like the Chembio Dual Path Platform (DPP®), make POC testing faster, more accurate, and more cost effective.”

In light of the COVID-19 pandemic, the Company focused on the development and commercialization of a serological or antibody test. Chembio’s antibody test was one of the first antibody tests authorized by the United States (“U.S.”) Food and Drug Administration (“FDA”) during the COVID-19 public health emergency.

Throughout the Class Period, Defendants represented that Chembio’s DPP COVID-19 serological POC test for the detection of IgM and IgG antibodies aided in determining current or past exposure to the COVID-19 virus, that its test provides high sensitivity and specificity, and was 100% accurate. Test sensitivity is the ability of a test to correctly identify those with the disease (true positive rate), whereas test specificity is the ability of the test to correctly identify those without the disease (true negative rate).

Based on Defendants’ representations, during the Class Period the Company’s stock increased from a closing price on March 31, 2020, the day before the Class Period begins, of \$5.12 per share, to a Class Period high of \$15.54 per share on April 24, 2020.

Defendants took advantage of Chembio's inflated stock price. On May 11, 2020, the Company reported that it closed the public offering of approximately 2.6 million shares of Chembio stock at \$11.75 per share for gross proceeds of approximately \$30.8 million.

Then, on June 16, 2020, after the market closed, the FDA issued a press release disclosing that it had revoked the Company's Emergency Use Authorization ("EUA") for the Company's DPP COVID-19 Igm/IgG System:

Today, the U.S. Food and Drug Administration revoked the emergency use authorization (EUA) of the Chembio Diagnostic System, Inc. (Chembio) DPP COVID-19 Igm/IgG System, a SARS-CoV-2 antibody test, **due to performance concerns with the accuracy of the test**. Antibody tests, a type of serological test, can help provide information on a person's and population's exposure to COVID19.

"Since the beginning of the COVID-19 public health emergency, the FDA has balanced the urgent need for access to diagnostic and antibody tests with providing a level of oversight that helps to ensure accurate tests are being deployed," said Jeff Shuren, M.D., director of FDA's Center for Devices and Radiological Health. "By continuing to monitor authorized tests and emerging scientific evidence, we are able to make changes when appropriate – **including taking action when a test's benefits no longer outweigh its risks**. Through these efforts, we are able to help assure that FDA-authorized tests meet the needs of the American public."

The Chembio antibody test was one of the first antibody tests authorized by the FDA during the COVID-19 public health emergency. At the time of authorization, based on the information that Chembio submitted to the FDA at that time, the agency concluded that the test met the statute's "may be effective" standard for emergency use authorization, and that the test's known and potential benefits outweighed its known and potential risks.

As the FDA has learned more regarding the capability for performance of SARSCoV-2 serology tests during the pandemic, and what performance is necessary for users to make well-informed decisions—through both the continued review and authorization of serology tests as well as through a research partnership with the National Institutes of Health's National Cancer Institute (NCI)—the FDA was able to develop general performance expectations for these tests, which are listed in our serology templates.

Data submitted by Chembio as well as an independent evaluation of the Chembio test at NCI showed that this test generates a higher than expected

rate of false results and higher than that reflected in the authorized labeling for the device. Under the current circumstances of the public health emergency, it is not reasonable to believe that the test may be effective in detecting antibodies against SARS-CoV-2 or that the known and potential benefits of the test outweigh the known and potential risks of the test, including the high rate of false results. Moreover, the risk to public health from the false test results makes EUA revocation appropriate to protect the public health or safety. As such, the FDA decided to revoke the emergency use authorization of the Chembio test, and this test may not be distributed.

(Emphases added.)

On June 17, 2020, the Company filed a report with the U.S. Securities and Exchange Commission on Form 8-K that acknowledged receipt of the FDA's June 16, 2020 letter and stated, in part, the following:

On June 16, 2020, we received a letter from the U.S. Food and Drug Administration, or FDA, notifying us that the FDA was revoking the Emergency Use Authorization, or EUA, granted in April 2020 with respect to our DPP COVID-19 System, which consists of our serological test for COVID-19 and one of our Micro Reader analyzers. As a result of this decision by the FDA, we may no longer distribute the DPP COVID-19 System

In its letter of June 16, 2020, the FDA stated that it had decided to revoke the EUA for the DPP COVID-19 System due to performance concerns regarding the sensitivity and specificity of our test system

We intend to continue working with the FDA with respect to the modification of the DPP COVID-19 System and of the revocation of the EUA for our test system.

As a result of disclosure of the FDA letter, Chembio shares declined from a closing price on June 16, 2020 of \$9.93 per share to close at \$3.89 per share on June 17, 2020, a decline of \$6.04 per share, or over 60%, on heavier than usual volume of over 25 million shares.

Also on June 17, 2020, *Bloomberg* published a report titled "FDA Reversal on Chembio Antibody Test Sends Stock Down 63%" that noted that, in light of the FDA revocation of the Company's EUA, five analysts downgraded Chembio stock.

As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiffs and other Class members have suffered significant losses and damages.

ARGUMENT

A. THE RELATED ACTIONS SHOULD BE CONSOLIDATED FOR ALL PURPOSES

Consolidation of related cases is appropriate where, as here, the actions involve common questions of law and fact, and therefore consolidation would avoid unnecessary cost, delay, and overlap in adjudication: "If actions before the court involve a common question of law or fact, the court may: (1) join for hearing or trial any or all matters at issue in the actions; (2) consolidate the actions; or (3) issue any other orders to avoid unnecessary cost or delay." Fed. R. Civ. P. 42(a); *see also Manual for Complex Litigation (Third)* § 20.123 (1995).

Consolidation is appropriate when the actions before the court involve common questions of law *or* fact. *See* Fed. R. Civ. P. 42(a); *Malcolm v. Nat'l Gypsum Co.*, 995 F.2d 346, 350 (2d Cir. 1993) (citing *Johnson v. Celotex Corp.*, 899 F.2d 1281, 1284 (2d Cir. 1990)); *In re Tronox, Inc. Sec. Litig.*, 262 F.R.D. 338, 344 (S.D.N.Y. 2009) (consolidating securities class actions); *Blackmoss Invs., Inc. v. ACA Capital Holdings, Inc.*, 252 F.R.D. 188, 190 (S.D.N.Y. 2008) (same). Differences in causes of action, defendants, or the class period do not render consolidation inappropriate if the cases present sufficiently common questions of fact and law, and the differences do not outweigh the interest of judicial economy served by consolidation. *See In re GE Sec. Litig.*, No. 09 Civ. 1951 (DC), 2009 WL 2259502, at *1–3 (S.D.N.Y. July 29, 2009) (consolidating actions asserting different claims against different defendants over different class periods).

The Related Actions at issue here clearly involve common questions of law *and* fact. Each action was brought against the Company, as well as certain officers and directors of the Company, in connection with violations of the federal securities laws. Accordingly, the Related Actions allege substantially the same wrongdoing—namely, that Defendants issued materially false and misleading statements and omissions that artificially inflated the price of the Company’s securities and subsequently damaged the Class when the Company’s share price crashed as the truth emerged. Consolidation of the Related Actions is therefore appropriate. *See Bassin v. Decode Genetics, Inc.*, 230 F.R.D. 313, 315 (S.D.N.Y. 2005) (consolidation of securities class actions is particularly appropriate in the context of securities class actions where the complaints are based on the same statements and the defendants will not be prejudiced); *In re GE*, 2009 WL 2259502, at *2 (“Consolidation promotes judicial convenience and avoids unnecessary costs to the parties.”).

B. KONE SHOULD BE APPOINTED LEAD PLAINTIFF

Kone should be appointed Lead Plaintiff because he has the largest financial interest in the Related Actions and otherwise meets the requirements of Rule 23. Section 21D(a)(3)(B) of the PSLRA sets forth procedures for the selection of lead plaintiff in class actions brought under the Exchange Act. The PSLRA directs courts to consider any motion to serve as lead plaintiff filed by class members in response to a published notice of the class action by the later of (i) 90 days after the date of publication, or (ii) as soon as practicable after the Court decides any pending motion to consolidate. *See* 15 U.S.C. § 78u-4(a)(3)(B)(i) &(ii).

Further, under 15 U.S.C. § 78u-4(a)(3)(B)(iii)(I), the Court is directed to consider all motions by plaintiffs or purported class members to appoint lead plaintiff filed in response to any such notice. Under this section, the Court “shall” appoint “the presumptively most adequate

plaintiff” to serve as lead plaintiff and shall presume that plaintiff is the person or group of persons, that:

(aa) has either filed the complaint or made a motion in response to a notice . . .;

(bb) in the determination of the court, has the largest financial interest in the relief sought by the class; and

(cc) otherwise satisfies the requirements of Rule 23 of the Federal Rules of Civil Procedure.

15 U.S.C. § 78u-4(a)(3)(B)(iii)(I).

As set forth below, Kone satisfies all three of these criteria and thus is entitled to the presumption that he is the most adequate plaintiff of the Class and, therefore, should be appointed Lead Plaintiff for the Class.

1. Kone Is Willing to Serve as Class Representative

On June 18, 2020, counsel for plaintiff in the first-filed of the Related Actions caused a notice to be published over *Globe Newswire* pursuant to Section 21D(a)(3)(A)(i) of the PSLRA (the “Notice”), which announced that a securities class action had been filed against Defendants, and advised investors in Chembio securities that they had 60 days—*i.e.*, until August 17, 2020—to file a motion to be appointed as Lead Plaintiff. *See* Declaration of Jeremy A. Lieberman in Support of Motion (“Lieberman Decl.”), Ex. A.

Kone has filed the instant motion pursuant to the Notice, and has submitted a signed Certification attesting that he is willing to serve as a representative for the Class, and provide testimony at deposition and trial, if necessary. *See* Lieberman Decl., Ex. B. Accordingly, Kone satisfies the first requirement to serve as Lead Plaintiff of the Class.

2. Kone Has the “Largest Financial Interest”

The PSLRA requires a court to adopt a presumption that “the most adequate plaintiff . . . is the person or group of persons that . . . has the largest financial interest in the relief sought by the class.” 15 U.S.C. § 78u-4(a)(3)(B)(iii). To the best of his knowledge, Kone has the largest financial interest of any Chembio investor or investor group seeking to serve as Lead Plaintiff. For claims arising under federal securities laws, courts frequently assess financial interest based upon the four factors articulated in the seminal case *Lax v. First Merchants Acceptance Corp.*: (1) the number of shares purchased during the class period; (2) the number of net shares purchased during the class period; (3) the total net funds expended during the class period; and (4) the approximate losses suffered. No. 97 C 2715, 1997 WL 461036, at *5 (N.D. Ill. Aug. 6, 1997). In accord with other courts nationwide,¹ these *Lax* factors have been adopted and routinely applied by courts in this judicial district. See, e.g., *In re Olsten Corp. Sec. Litig.*, 3 F. Supp. 2d 286, 295 (E.D.N.Y. 1998); accord *In re Comverse Tech., Inc. Sec. Litig.*, No. 06-CV-1825 (NGG) (RER), 2007 WL 680779, at *6-8 (E.D.N.Y. Mar. 2, 2007).

During the Class Period, Kone: (1) purchased 85,102 shares of Chembio securities; (2) expended \$809,638 on his purchases of Chembio securities; (3) retained 61,000 shares of Chembio securities; and (4) as a result of the disclosures of the fraud, suffered a loss of \$285,485 in connection with his Class Period purchases of Chembio securities. See Lieberman Decl., Ex. C. Because Kone possesses the largest financial interest in the outcome of this litigation, he may be presumed to be the “most adequate” plaintiff. 15 U.S.C. § 78u-4(a)(3)(B)(iii)(I)(bb).

¹ See, e.g., *Chahal v. Credit Suisse Grp. AG*, No. 18-CV-2268 (AT) (SN), 2018 WL 3093965, at *4 (S.D.N.Y. June 21, 2018); *Nurlybaev v. ZTO Express (Cayman) Inc.*, No. 17-CV-06130 (LTS) (SN), 2017 WL 5256769, at *1 (S.D.N.Y. Nov. 13, 2017); *Pirelli Armstrong Tire Corp. Retiree Med. Benefits Tr. v. LaBranche & Co.*, 229 F.R.D. 395, 404-05 (S.D.N.Y. 2004); *In re Cendant Corp. Litig.*, 264 F.3d 201, 262 (3d Cir. 2001).

3. Kone Otherwise Satisfies the Requirements of Rule 23 of the Federal Rules of Civil Procedure

Section 21D(a)(3)(B)(iii)(I)(cc) of the PSLRA further provides that, in addition to possessing the largest financial interest in the outcome of the litigation, a Lead Plaintiff must “otherwise satisfy the requirements of Rule 23 of the Federal Rules of Civil Procedure.” Rule 23(a) generally provides that a class action may proceed if the following four requirements are satisfied:

(1) the class is so numerous that joinder of all members is impracticable; (2) there are questions of law or fact common to the class; (3) the claims or defenses of the representative parties are typical of the claims or defenses of the class; and (4) the representative parties will fairly and adequately protect the interests of the class.

Fed. R. Civ. P. 23 (a).

In making its determination that a Lead Plaintiff satisfies the requirements of Rule 23, the Court need not raise its inquiry to the level required in ruling on a motion for class certification; instead a *prima facie* showing that the movant satisfies the requirements of Rule 23 is sufficient. *Greebel v. FTP Software*, 939 F. Supp. 57, 60 (D. Mass. 1996). Moreover, “typicality and adequacy of representation are the only provisions relevant to a determination of lead plaintiff under the PSLRA.” *In re Oxford Health Plans, Inc. Sec. Litig.*, 182 F.R.D. 42, 49 (S.D.N.Y. 1998) (citing *Gluck v. CellStar Corp.*, 976 F. Supp. 542, 546 (N.D. Tex. 1997); *Fischler v. AMSouth Bancorporation*, No. 96-1567-Civ-T-17A, 1997 WL 118429, at *2 (M.D. Fla. Feb. 6, 1997)); *In re Olsten Corp. Sec. Litig.*, 3 F. Supp. 2d at 296.

The typicality requirement of Fed. R. Civ. P. 23(a)(3) “is satisfied if ‘each class member’s claim arises from the same course of events, and each class member makes similar legal arguments to prove the defendant’s liability.’” *In re Orion Sec. Litig.*, No. 08 Civ. 1328 (RJS), 2008 WL 2811358, at *5 (S.D.N.Y. July 7, 2008) (quoting *In re Drexel Burnham Lambert*

Grp., Inc., 960 F.2d 285, 291 (2d Cir. 1992)). “[T]he claims of the class representative need not be identical [to] those of all members of the class. ‘[T]he typicality requirement may be satisfied even if there are factual dissimilarities or variations between the claims of the named plaintiffs and those of other class members, including distinctions in the qualifications of the class members.’” *Janbay v. Canadian Solar, Inc.*, 272 F.R.D. 113, 120 (S.D.N.Y. 2010) (quoting *Bishop v. N.Y. City Dep’t of Hous. Pres. & Dev.*, 141 F.R.D. 229, 238 (S.D.N.Y. 1992)).

The claims of Kone are typical of those of the Class. Kone alleges, as do all class members, that Defendants violated federal securities laws by making what they knew or should have known were false or misleading statements of material facts concerning the Company, or omitted to state material facts necessary to make the statements they did make not misleading. Kone, as did all members of the Class, purchased Chembio securities during the Class Period at prices artificially inflated by Defendants’ misrepresentations or omissions and was damaged upon the disclosure of those misrepresentations and/or omissions. These shared claims, which are based on the same legal theory and arise from the same events and course of conduct as the Class claims, satisfy the typicality requirement of Rule 23(a)(3).

The adequacy of representation requirement of Rule 23(a)(4) is satisfied where “(1) class counsel is qualified, experienced, and generally able to conduct the litigation; (2) there is no conflict between the proposed lead plaintiff and the members of the class; and (3) the proposed lead plaintiff has a sufficient interest in the outcome of the case to ensure vigorous advocacy.” *Foley v. Transocean Ltd.*, 272 F.R.D. 126, 131 (S.D.N.Y. 2011); *see also Dookeran v. Xunlei Ltd.*, No. 18-cv-467 (RJS), 2018 WL 1779348, at *2 (S.D.N.Y. Apr. 12, 2018) (same).

Kone is an adequate representative for the Class. There is no antagonism between the interests of Kone and those of the Class, and his losses demonstrate that he has a sufficient

interest in the outcome of this litigation. Finally, Kone has retained counsel highly experienced in vigorously and efficiently prosecuting securities class actions such as this action, and submits his choice to the Court for approval pursuant to 15 U.S.C. § 78u-4(a)(3)(B)(v).

4. Kone Will Fairly and Adequately Represent the Interests of the Class and Is Not Subject to Unique Defenses

The presumption in favor of appointing Kone as Lead Plaintiff may be rebutted only upon proof “by a member of the purported plaintiff class” that the presumptively most adequate plaintiff:

(aa) will not fairly and adequately protect the interests of the class; or

(bb) is subject to unique defenses that render such plaintiff incapable of adequately representing the class.

15 U.S.C. § 78u-4(a)(3)(B)(iii)(II).

The ability and desire of Kone to fairly and adequately represent the Class has been discussed above. Kone is not aware of any unique defenses Defendants could raise that would render him inadequate to represent the Class. Accordingly, Kone should be appointed Lead Plaintiff for the Class.

C. LEAD PLAINTIFF’S SELECTION OF COUNSEL SHOULD BE APPROVED

The PSLRA vests authority in the Lead Plaintiff to select and retain lead counsel, subject to Court approval. *See* 15 U.S.C. § 78u-4(a)(3)(B)(v). The Court should only interfere with Lead Plaintiff’s choice if necessary to “protect the interests of the class.” 15 U.S.C. § 78u-4(a)(3)(B)(iii)(II)(aa); *see also Kaplan v. S.A.C. Capital Advisors, L.P.*, 311 F.R.D. 373, 383 (S.D.N.Y. 2015) (“The PSLRA ‘evidences a strong presumption in favor of approving a properly-selected lead plaintiff’s decisions as to counsel selection and counsel retention.’” (quoting *Varghese v. China Shenghuo Pharm. Holdings, Inc.*, 589 F. Supp. 2d 388, 398

(S.D.N.Y. 2008)); *In re Molson Coors Brewing Co. Sec. Litig.*, 233 F.R.D. 147, 151 (D. Del. 2005).

Here, Kone has selected Pomerantz as Lead Counsel for the Class. Pomerantz is highly experienced in the area of securities litigation and class actions and has successfully prosecuted numerous securities litigations and securities fraud class actions on behalf of investors, as detailed in the firm's resume. *See* Lieberman Decl., Ex. D. Pomerantz recently secured a recovery of \$3 billion on behalf of investors in the securities of *Petróleo Brasileiro S.A. — Petrobras*, the largest class action settlement in a decade and the largest settlement ever in a class action involving a foreign issuer. Petrobras is part of a long line of record-setting recoveries led by Pomerantz, including the \$225 million settlement in *In re Comverse Technology, Inc. Securities Litigation*, No. 06-CV-1825 (E.D.N.Y.), in June 2010. *See* Lieberman Decl., Ex. D. Most recently, Pomerantz announced as Lead Counsel on behalf of a class of Fiat investors that it has reached a \$110 million settlement with the company. *Id.* As a result of Pomerantz's extensive experience in securities litigation and class actions involving issues similar to those raised in the Related Actions, Pomerantz has the skill and knowledge necessary to enable the effective and expeditious prosecution of the Related Actions. Thus, the Court may be assured that by approving the selection of Lead Counsel by Kone, the members of the class will receive the best legal representation available.

CONCLUSION

For the foregoing reasons, Kone respectfully requests that the Court issue an Order: (1) consolidating the Related Actions; (2) appointing Kone as Lead Plaintiff for the Class; and (3) approving Pomerantz as Lead Counsel for the Class.

Dated: August 17, 2020

Respectfully submitted,

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