UNITED STATES DISTRICT COURT DISTRICT OF MARYLAND

KAREN KERSCHEN and WALLACE
LOVEJOY on behalf of themselves and all
others similarly situated,

Case No.

CLASS ACTION COMPLAINT

JURY TRIAL DEMANDED

Plaintiffs,

v.

ELLUME USA LLC.

Defendant.

CLASS ACTION COMPLAINT AND JURY DEMAND

Plaintiffs Karen Kerschen and Wallace Lovejoy ("Plaintiffs") bring this action against Ellume USA LLC ("Ellume" or "Defendant"), by and through their attorneys, individually and on behalf of all others similarly situated, and allege as follows:

INTRODUCTION

- 1. Plaintiffs and the putative Class are purchasers of Ellume's Rapid Antigen At-Home COVID-19 Test Kits ("Ellume COVID Tests") that Ellume voluntarily recalled in two separate lots due to the potential for providing false positive test results, on October 1, 2021 and November 10, 2021, respectively.¹
- 2. This class action lawsuit arises from Ellume's failure and refusal to refund purchasers of recalled Ellume COVID Tests, despite Ellume recalling certain production lots because they were inaccurate, unsafe, and ineffective.

¹ The Class COVID Tests include, but are not limited to, Ellume's At-Home Rapid Antigen COVID-19 Test Kits manufactured between February 24, 2021 and August 11, 2021 and distributed from April 13, 2021 to August 26, 2021.

- 3. Throughout the COVID-19 pandemic, consumers sought reliable methods to test for COVID-19 in the convenience and safety of their own homes, rather than scheduling an appointment at a clinic or medical facility. To meet this demand, Ellume, a biotech company and manufacturer of diagnostic tests, developed an at-home rapid COVID-19 test it claimed would produce quick and accurate results from the convenience of the purchaser's home or while travelling.
- 4. The Ellume COVID Tests were designed to produce a test result within fifteen minutes by detecting proteins from the SARS-CoV-2 virus collected from a nasal sample. Ellume COVID Tests are available over the counter to any individual above two years of age.
- 5. Ellume touts the reliability of its tests. "The Ellume COVID-19 Home Test demonstrated 96% accuracy in clinical studies. Our test is the only OTC antigen home test to: Give you accurate results in a single test, in 15 minutes (all other OTC antigen tests require a second test 24 36 hours later)."²
- 6. False positive COVID-19 test results can lead to an individual receiving unnecessary treatment from health care providers, such as antiviral treatment, convalescent plasma, or monoclonal antibody treatment, which can result in side effects. False positive test results also threaten individuals with unnecessary isolation, including monitoring households or close contacts for symptoms, limiting contact with family or friends, and missing school or work, or may lead to an individual being sequestered with individuals who are actually COVID-19 positive, leading to exposure and further spread of the disease. Additionally, false positives may lead to a delayed diagnosis or treatment for the actual cause of an individual's illness, which could be a serious life-threatening disease that is not COVID-19, or lead individuals to avoid

² https://www.ellumecovidtest.com/home-test#accuracy (last visited March 11, 2022).

vaccination because they believe they already contracted the virus, even if they have not.

Further, false positive test results can result in unnecessary self-isolation and quarantine which imposes significant financial costs on consumers such as cancelled travel, cancelation and rescheduling fees, and the inability to attend and enjoy prior scheduled and paid for events and occasions.

- 7. Ellume COVID Tests, however, provided false positive test results to Plaintiffs and Class members, or became unusable because certain production lots reportedly produced higher than acceptable false positive results due to a manufacturing issue.
- 8. On or about October 1, 2021, Ellume issued a voluntary recall of approximately 427,994 Ellume COVID Tests and explained that it had done so because certain lots were found to produce higher than acceptable false positive results due to a manufacturing issue.³
- 9. The recall did not end there: on or about November 10, 2021, Ellume identified additional defective lots of its Ellume COVID tests and issued a second voluntary recall of additional production lots, placing the total number of recalled Ellume COVID Tests at approximately 2,212,335 units.
- 10. The Food and Drug Administration ("FDA") identified the Ellume recall as a "Class I recall," the most severe type of recall, because use of the Ellume COVID Tests risked "serious adverse health consequences or death."
- 11. Plaintiffs and members of the Class did not know, and had no reason to know at the time they purchased their Ellume COVID Tests, that the tests produced higher than

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³ <u>https://www.ellumecovidtest.com/return</u> (last visited March 17, 2022); <u>https://www.usnews.com/news/health-news/articles/2021-10-05/the-latest-j-j-seeks-fda-ok-for-vaccine-booster-doses</u> (last visited March 15, 2022).

⁴ *See* <u>https://www.fda.gov/medical-devices/medical-device-recalls/ellume-recalls-covid-19-home-test-potential-false-positive-sars-cov-2-test-results</u> (last visited March 3, 2022).

acceptable false positive results that would result in a Class I recall of over two-million Ellume COVID Tests.

- 12. Despite voluntarily recalling these defective Ellume COVID Tests—including test kits that Plaintiffs and the Class already had purchased—and implicitly agreeing to refund Plaintiffs and the Class in connection therewith, Ellume has failed and refused to provide refunds to Class members.
- 13. Ellume's actions and inactions injured consumers by causing them to pay for inaccurate, unsafe, ineffective, and worthless Ellume COVID Tests, and allowing it to retain the profits it derived from the sale of recalled products would unjustly enrich Ellume at the expense of the Class. Accordingly, Plaintiffs seek injunctive, declaratory, and monetary relief, including restitution, on behalf of themselves and all others similarly situated.

JURISDICTION AND VENUE

- 14. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332(d)(2)(A), as modified by the Class Action Fairness Act of 2005, because at least one member of the Class, as defined below, is a citizen of a different state than Defendant, there are more than 100 members of the Class, and the aggregate amount in controversy exceeds \$5,000,000 exclusive of interest and costs. This Court has supplemental jurisdiction over the state law claims pursuant to 28 U.S.C. § 1367.
- 15. This Court has personal jurisdiction over Defendant because it maintains and operates its flagship U.S. manufacturing facility and North American base of operations in this district, and has purposefully availed itself of the benefits and protections of Maryland by conducting continuous, systematic, and substantial business in this judicial district, directs advertising and marketing materials to districts within Maryland, and intentionally and purposefully places Ellume COVID Tests into the stream of commerce within this district and

throughout the United States with the expectation and intent that they would be purchased by consumers.

PARTIES

A. Plaintiff Karen Kerschen

- 16. Plaintiff Karen Kerschen ("Ms. Kerschen") is a resident of the State of Indiana, and currently resides in Nineveh, Indiana.
- 17. In or about 2021, Ms. Kerschen purchased an Ellume COVID test kit online for \$65 (including kit cost of \$50 and postage of \$15), from Azova.com.
- 18. Shortly after Ms. Kerschen placed her on-line order for an Ellume COVID test kit, she received two such kits in the mail.
- 19. Ms. Kerschen purchased her Ellume COVID test kit in anticipation of a vacation to Ireland with her sister with the 50 Plus Travel Program offered through Johnson County Park & Recreation District via Collette, departing on October 4, 2021.
- 20. On or about October 11, 2021 which was approximately 72 hours before she was scheduled to return to the United States, Ms. Kerschen used her Ellume COVID Test. She was required to have a negative COVID-19 test result within 72 hours of returning to the United States.
- 21. Before taking one of her Ellume COVID-19 tests, Ms. Kerschen opened the box in which the Ellume COVID test kit was delivered to her. She understood that, upon opening the box, she could not return the test kit.
- 22. To use her Ellume COVID test kit, Ms. Kerschen downloaded the Azova application to her cell phone, provided her test kit's lot number to Azova as requested and was advised that she could proceed to take the test. During the test, Ms. Kerschen was visually monitored by Azova.

- 23. Approximately 20 minutes after Ms. Kerschen took her COVID-19 test, she learned that she had a positive result.
- 24. Upon learning of her positive COVID-19 test result, Ms. Kerschen notified her tour group leader of her positive result and was advised that the entire tour group would have to quarantine beginning immediately and thus miss a scheduled excursion and related meal (for which she spent \$380).
- 25. Upon learning of her positive COVID-19 test result, Ms. Kerschen tried to use her second test kit but was unable to schedule a test though her phone application, which indicated she had already taken the test.
- 26. Ms. Kerschen then attempted to use her sister's extra Ellume COVID test kit, but when she attempted to do so, she was advised through the Ellume phone application that the lot number had been recalled (although her sister never received notice of the purported recall).
- 27. When Ms. Kerschen was unable to schedule her second test through her phone application to use her sister's extra Ellume COVID test kit, she attempted to call Ellume's Customer Service phone number, but Ellume was closed due to the time difference.
- 28. After several hours of trying to reach Ellume, Plaintiff Kerschen eventually succeeded in doing so at approximately 9:00 a.m. EST, and was advised to "go out and buy another test kit." She responded that she was unable to leave her hotel as she was required to quarantine.
- 29. Despite Ellume's representation to Ms. Kerschen that she could ignore her test results, Plaintiff's tour group company required a negative test and was able to arrange for Ms. Kerschen to take a taxi to a testing facility at her own expense of €40.

- 30. Upon testing at the testing facility at an out-of-pocket cost of €99, Ms. Kerschen learned that she was in fact negative for COVID-19.
- 31. Approximately five hours after Ms. Kerschen took the Ellume COVID test, she received an email from Ellume indicating that the test lot number she used had been recalled, due in part to frequent false positive results. She subsequently spoke with another Ellume representative who advised her that her Ellume COVID test kit had been recalled and that she should ignore her test results.
- 32. When Ms. Kerschen arrived home, she contacted Ellume in writing and asked for a refund of the cost of her test kit. She was asked for the kit's lot number, which she supplied.
- 33. As of the date of this Complaint, Ellume has not refunded Ms. Kerschen the cost of her Ellume test kit or any of the incidental costs related thereto.

B. <u>Plaintiff Wallace Lovejoy</u>

- 34. Plaintiff Wallace Lovejoy ("Mr. Lovejoy") is a resident of the State of Ohio, and currently resides in Cincinnati, Ohio.
- 35. On or about July 1, 2021, Mr. Lovejoy purchased two packages of four Ellume COVID Test kits online for \$538 from Azova.com, one package for himself and one for his wife, Angela Lovejoy.
- 36. Mr. Lovejoy placed an on-line order for two packages of four Ellume COVID test kits and received the test kits in the mail.
- 37. Mr. Lovejoy purchased his Ellume COVID Tests in anticipation of a vacation to the U.K. scheduled to depart on or about July 22, 2021.
- 38. On or about July 20, 2021, Mr. Lovejoy and his wife took their first Ellume COVID Tests prior to departing for their trip to the U.K.

- 39. Before taking their Ellume COVID tests, Mr. Lovejoy and his wife opened the boxes in which the Ellume COVID were delivered to them. They understood that, upon opening the boxes, they could not return the test kits.
- 40. Approximately 30 45 minutes after Mr. Lovejoy and his wife took their first Ellume COVID tests, they learned that he had a negative result, and that she had a positive result.
- 41. Upon receiving her positive COVID test result, Mr. Lovejoy's wife attempted to confirm her results by testing elsewhere, including paying \$215 out-of-pocket for two PCRs tests at walk-in clinics and at a Velocity clinic connected with her status as a Moderna trial participant. The first two clinics advised her that she was COVID-negative; the Velocity clinic did not report her result to her due to the study's confidentiality requirements, but strongly implied that if she had been positive they would have notified her.
- 42. Despite the negative COVID-19 test results, the Lovejoys cancelled their trip to the U.K. as the false-positive test from the Ellume COVID Test kit would have required Angela Lovejoy to remain in quarantine during the entire trip.
- 43. The Lovejoys were unable to cancel their flights. The Lovejoys rebooked their flights several months later, paying approximately \$1,000 due to a fare increase, and were unable to cancel a planned excursion for which they had prepaid.
- 44. Following Angela Lovejoy's false positive test result, Mr. Lovejoy attempted to exchange the remaining unused tests he had purchased for a refund, but was denied by Ellume.
- 45. On or about October 1, 2021, the Lovejoys received emails indicating that their test kits had been voluntarily recalled because of a potential false positive result. The email offered them a "free replacement test." The Lovejoys did not need the replacement test and instead contacted Ellume for a full refund.

- 46. On or about October 26, 2021, Plaintiff Lovejoy received a letter from Ellume indicating that it was "processing a refund for your home test(s) you purchased and the Azova proctoring fees incurred related to our home tests."
- 47. On or about November 19, 2021, Mr. Lovejoy received a check from Ellume for \$215 with no cover note or explanation as to the basis for the amount of the check.
- 48. As of the date of this Complaint, Plaintiff Lovejoy has not been refunded the full amount of his and his wife's Ellume COVID Tests.

C. Defendant

- 49. Defendant Ellume USA LLC is a Delaware corporation with its principal place of business located at 25350 Magic Mountain Parkway, Suite 300 Valencia, California 91355.
- 50. Defendant Ellume USA LLC conducts business in Maryland and throughout the United States.
- 51. In 2021, Defendant opened a "state-of-the-art" diagnostic manufacturing facility in Frederick, Maryland, at which it employs the bulk of its North American workforce.
- 52. Defendant's key officers and directors also operate from its Maryland facilities.

 For example, both Dr. Jeff Boyle, the company's first U.S. President responsible for overseeing all domestic business operations, and Dan Mallon the company's Vice President of Business Development and Alliance Management, carry out their responsibilities from Ellume's Maryland headquarters.⁵

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⁵ See https://www.ellumehealth.com/about/jeff-boyle/ (last visited March 21, 2022);
https://www.biospace.com/article/releases/ellume-establishes-flagship-u-s-manufacturing-facility-in-marylandindustry-veterans-jeff-boyle-phd-and-dan-mallon-will-lead-ellume-s-u-s-team-to-support-the-company-s-rapid-growth/">https://www.biospace.com/article/releases/ellume-establishes-flagship-u-s-manufacturing-facility-in-marylandindustry-veterans-jeff-boyle-phd-and-dan-mallon-will-lead-ellume-s-u-s-team-to-support-the-company-s-rapid-growth/ (last visited March 21, 2022).

COMMON FACTUAL ALLEGATIONS

53. The Ellume COVID Home Test Kits are an over-the-counter antigen test that detect proteins from the SARS-CoV-2 virus taken from a nasal sample in individuals two years or older. The Ellume COVID Tests are available without prescription and for use by individuals with or without COVID-19 symptoms. The Ellume COVID Tests use an analyzer that connects with a smartphone app to demonstrate to consumers how to perform the test and understand the results.



(Screenshot of Ellume COVID Test available on Ellume's website)⁶

54. Not until they open Ellume COVID Test kits are consumers able to access applicable instructions, including those that direct consumers to download essential smartphone applications. The Ellume COVID-19 Home Test kit's packaging makes no mention of any

⁶ See https://www.ellumecovidtest.com/buy (last visited March 3, 2022).

applicable terms or conditions and, in fact, explicitly states that "To get started, refer to the Quick Start Guide inside the box[,]" as visible in the right most portion of the image below.⁷



- 55. The in-the-box Ellume COVID Test guide then goes on to provide step-by-step instructions, the first of which is "Unbox components." *See* Ex. A at 2, 4. Only then are purchasers or other potential test subjects instructed to "Download and open" the Ellume COVID-19 Home Test app, at which point the now unboxed components, including the test kits, cannot be returned.
- 56. The Ellume COVID-19 Home Test guide likewise makes no mention of any applicable terms and conditions. *See generally* Ex. A.
- 57. On October 1, 2021, Ellume recalled certain lots of its Ellume COVID Tests because of higher than acceptable false-positive test results due to a reported manufacturing

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⁷ This guide is included in every Ellume COVID-19 Home Test kit, a copy of which is made available via the FDA's website and attached hereto as Exhibit A. *See* https://www.fda.gov/media/144593/download (last visited March 21, 2022).

issue. Ellume voluntarily recalled approximately 40 lots of affected test kits, or approximately 427,994 individual Ellume COVID Tests.

- 58. On or about November 10, 2021, Ellume identified additional defective Ellume COVID Tests that suffered from the higher than acceptable false positive rate that that served as the catalyst for the October 1, 2021 recall. In total, Ellume recalled 2,212,225 Ellume COVID Tests. The recall included all Ellume COVID-19 Home Tests manufactured between February 24, 2021 to August 11, 2021 with distribution dates of April 13, 2021 to August 11, 2021.
- 59. The FDA identified the recall as a "Class I recall", the most severe type of recall, and warned that use of the Ellume COVID Tests may cause serious adverse health consequences or death.⁸
- 60. False positive test results may lead to a delay in both the correct diagnosis and appropriate treatment for the actual cause of a person's illness, which could be another lifethreatening disease that is not COVID-19. False positive results may also lead to the further spread of the SARS-CoV-2 virus when presumed positive individuals are housed together.
- 61. False positive COVID-19 test results may also lead to an individual receiving unnecessary treatment from health care providers, such as antiviral treatment, convalescent plasma, or monoclonal antibody treatment, which can result in side effects. False positive test results also threaten individuals with unnecessary isolation, including monitoring households or close contacts for symptoms, and disruption of personal and business-related plans and events. A false positive may also result in the disregard for the recommended precautions against COVID-19, including vaccination.

⁸ See FDA Recall Notice "Ellume Recalls COVID-19 Home Test for Potential False Positive SARS-CoV-2 Test Results" available at https://www.fda.gov/medical-devices/medical-device-recalls/ellume-recalls-covid-19-home-test-potential-false-positive-sars-cov-2-test-results (las visited March 7, 2022).

- 62. Plaintiffs and Class members did not know and had no reason to know at the time they purchased Ellume COVID Tests that the tests produced high than acceptable false positive results that would result in a voluntary "Class I" recall of over two million Ellume COVID Tests. Plaintiffs did not know and had no reason to know at the time of purchases that Ellume would fail to provide consumers with a refund for the recalled Ellume COVID Tests.
- 63. Plaintiffs would not have purchased the Ellume COVID Tests had they known that they were defective, produced false positive test results, and would be recalled because of their ineffectiveness and the danger they pose to the health and safety of the purchaser.
- 64. Plaintiffs and Class members were injured when they paid full price for the Ellume COVID Tests that are inaccurate and unreliable in that they produce higher than acceptable false positive results, were recalled, and now are worthless because of their defect.
- 65. Plaintiffs and Class members bargained for Ellume COVID-19 tests that were accurate and usable. Ellume's actions deprived Plaintiffs the basis of their bargain when Ellume sold Plaintiffs COVID Tests that produced false positive results and that were twice recalled because of a manufacturing defect while failing to provide Plaintiffs and the Class a refund for the purchase price of the COVID Tests.
- 66. Most importantly, however, Ellume has refused to provide the relief it implicitly agreed to provide when it engaged in a self-imposed undertaking: its voluntary recall of Ellume COVID-19 Home Tests.
- 67. Per the FDA, a "[r]ecall is a voluntary action that takes place because manufacturers and distributors carry out their responsibility to protect the public health and well-being from products that present a risk of injury or gross deception or are otherwise defective."

- 68. When issuing a recall, whether voluntary or involuntary, manufacturers have only three options: repair or replace the recalled product or refund the product's purchase price.
- 69. In the case of Ellume's recall of its COVID-19 Home Tests, a refund is the only viable remedy. Consumers purchase COVID-19 Home Tests for specific purposes—typically travel or to secure clearance to visit specific places or attend particular events—and, like Plaintiffs, have no use for a "replacement" test they no longer need to take.
- 70. Accordingly, upon voluntarily recalling COVID-19 Home Tests, Ellume imposed upon itself an obligation to refund its customers the purchase price they paid for recalled test kits, whether used or unused.
- 71. Rather than refund the purchase price of the Ellume COVID Tests, Ellume has unjustly retained the monies that customers spent on the recalled test kits. Accordingly, Ellume unjustly enriched itself at the expense of Plaintiffs and Class members, as they have failed to disgorge the benefit that Class members conferred upon Ellume when they purchased the now useless and recalled Ellume COVID Tests.
- 72. Allowing Ellume to retain ill-gotten gains it derived from its sale of defective COVID-19 Home Tests thus not only deprives Plaintiffs and the Class of the benefit of their bargain, but also would unjustly enrich Ellume. To date, however, Ellume has failed to refund the money that Plaintiffs and the Class spent when they purchased the recalled Ellume COVID Tests.
- 73. Plaintiffs and Class members are entitled to damages for the monies paid to purchase the Ellume COVID Tests, statutory and punitive damages, attorneys' fees and costs, declaratory, and injunctive relief.

CLASS ALLEGATIONS

74. Plaintiffs bring this action on behalf of themselves and a Nationwide Class pursuant to Federal Rule of Civil Procedure Rule 23(a), 23(b)(2), and/or 23(b)(3). This action satisfies the numerosity, commonality, typicality, adequacy, predominance, and superiority requirements of those provisions.

Nationwide Class:

All persons in the United States who purchased Ellume COVID Tests that were subject to Ellume's October 1, 2021 and November 10, 2021 recalls. In the alternative to the Nationwide Class, and pursuant to the Federal Rule of Civil Procedure 23(c)(5), Plaintiffs seek to represent the following State Classes in the event the Court declines to certify the Nationwide Class:

Indiana Class:

All persons in Indiana who purchased Ellume COVID Tests that were subject to the October 1, 2021 and November 10, 2021 recalls.

Ohio Class:

All persons in Ohio who purchased Ellume COVID Tests that were subject to the October 1, 2021 and November 10, 2021 recalls.

- 75. The Nationwide Class and State Classes shall be collectively referred to as the "Class."
- 76. Specifically excluded from the Classes are Defendant, Defendant's officers, directors, agents, trustees, parents, children, corporations, trusts, representatives, employees, principals, servants, partners, joint ventures, or entities controlled by Defendant, and its heirs, successors, assigns, or other persons or entities related to or affiliated with Defendant and/or Defendant's officers and/or directors, the judge assigned to this action, and any member of the judge's immediate family.

- 77. **Numerosity.** The members of the proposed Class are geographically dispersed throughout the United States and are so numerous that individual joinder is impracticable. Upon information and belief, Plaintiffs reasonably estimate that there are millions of individuals who are members of the proposed Class. Although the precise number of proposed members is unknown to Plaintiffs, the true number is known by Defendant. Members of the Class may be notified of the pendency of this action by mail and/or publication through the distribution records of Defendant and third-party retailers and vendors.
- 78. **Typicality.** The claims of the representative Plaintiffs are typical of the claims of the Class in that the representative Plaintiffs, like all members of the Class, purchased the Ellume COVID Tests that were voluntarily recalled by Defendant due to their higher than acceptable false positive test results for SAR-CoV-2. The representative Plaintiffs, like all members of the Class, have been damaged by Defendant's misconduct in the very same way as the members of the Class. Further, the factual bases of Defendant's misconduct are common to all members of the Class and represent a common thread of misconduct resulting in injury to all members of the Class.
- 79. **Existence and predominance of common questions of law and fact.** Common questions of law and fact exist as to all members of the Class and predominate over any questions affecting only individual members of the Class. These common legal and factual questions include, but are not limited to, the following:
- (a) whether Defendant is liable to Plaintiffs and the Class for unjust enrichment;
- (b) whether Plaintiffs and the Class have sustained monetary loss and the proper measure of that loss;

- (c) whether Plaintiffs and the Class are entitled to declaratory and injunctive relief;
- (d) whether Plaintiffs and the Class are entitled to restitution and disgorgement from Defendant; and
 - (e) whether Defendant breached its implied warranties.
- 80. **Adequacy of Representation.** Plaintiffs will fairly and adequately protect the interests of the Class. Plaintiffs have retained counsel who are highly experienced in complex consumer class action litigation, and Plaintiffs intend to vigorously prosecute this action on behalf of the Class. Plaintiffs have no interests that are antagonistic to those of the Class.
- 81. **Superiority.** A class action is superior to all other available means for the fair and efficient adjudication of this controversy. The damages or other financial detriment suffered by members of the Class are relatively small compared to the burden and expense of individual litigation of their claims against Defendant. It would, thus, be virtually impossible for members of the Class, on an individual basis, to obtain effective redress for the wrongs committed against them. Furthermore, even if members of the Class could afford such individualized litigation, the court system could not. Individualized litigation would create the danger of inconsistent or contradictory judgments arising from the same set of facts. Individualized litigation would also increase the delay and expense to all parties and the court system from the issues raised by this action. By contrast, the class action device provides the benefits of adjudication of these issues in a single proceeding, economies of scale, and comprehensive supervision by a single court, and presents no unusual management difficulties under the circumstances.
 - 82. In the alternative, the Class may be certified because:

- (a) the prosecution of separate actions by individual members of the Class would create a risk of inconsistent or varying adjudication with respect to individual members of the Class that would establish incompatible standards of conduct for the Defendant;
- (b) the prosecution of separate actions by individual members of the Class would create a risk of adjudications with respect to them that would, as a practical matter, be dispositive of the interests of other members of the Class not parties to the adjudications, or substantially impair or impede their ability to protect their interests; and/or
- (c) Defendant has acted or refused to act on grounds generally applicable to the Class as a whole, thereby making appropriate final declaratory and/or injunctive relief with respect to the members of the Class as a whole.

CAUSES OF ACTION

COUNT I

(Unjust Enrichment)

On Behalf of Plaintiffs, the Nationwide, Indiana, and Ohio Classes

- 83. Plaintiffs incorporate by reference and re-allege each and every allegation set forth above as though fully set forth herein.
- 84. Plaintiffs and the Class conferred a benefit on Defendant in the form of monies paid to purchase Ellume COVID Tests.
 - 85. Defendant voluntarily accepted, retained, and had knowledge of this benefit.
- 86. Because this benefit was obtained unlawfully by Defendant, namely selling and accepting compensation for the Ellume COVID Tests that were inaccurate and produced false positive results, it would be unjust and inequitable for Defendant to retain the benefit without paying the value thereof.

87. The Defendant's unjust enrichment damaged the Plaintiffs and Class members.

Defendant will be unjustly enriched if it is allowed to retain the revenues derived from the sale of the Ellume COVID Tests, Defendant must pay restitution to Plaintiffs and the members of the Class in the amount which Defendant was unjustly enriched by each of their purchases of Ellume's COVID Tests.

COUNT II (Declaratory Judgment)

- On Behalf of Plaintiffs, the Nationwide, Indiana, and Ohio Classes
- 88. Plaintiffs incorporate by reference and re-allege each and every allegation set forth above as though fully set forth herein.
- 89. When Ellume implemented a recall of defective Ellume COVID-19 Tests, it implicitly agreed to refund Plaintiffs and the Class for costs incurred in purchasing the kits, since replacement tests are of no value to Class members.
- 90. Ellume has declined to do so, either voluntarily or upon demand when contacted by Class members.
- 91. Accordingly, there is an actual controversy between Plaintiffs and Defendant regarding the sufficiency of Ellume's October 1, 2021 and November 10, 2021 recalls of the Ellume COVID Tests regarding whether Plaintiffs and the Class are entitled to a refund of the purchase price of their Ellume COVID Tests.
- 92. Plaintiffs, on behalf of themselves and all others similarly situated, therefore seek an order from the Court (1) declaring that Ellume is obligated to provide notice of the recall to all Class members who purchased the recalled Ellume COVID Tests, and (2) ordering Ellume to refund all Class members who have not received a refund for the purchase price of the recalled Ellume COVID Tests.

PRAYER FOR RELIEF

Wherefore, Plaintiffs, on behalf of themselves and all Class members they seek to represent, respectfully request that the Court enter a judgment on their behalf and against Ellume, and further grant the following relief:

- An order certifying the proposed Nationwide Class or state classes pursuant to Rule 23 of the Federal Rules of Civil Procedure and naming Plaintiffs as Class Representatives and their attorneys as Class Counsel to represent the Class members;
- b. An order declaring that Ellume was unjustly enriched;
- c. An order entering judgment in favor of Plaintiffs and the Class members against Ellume:
- d. An order awarding damages against Ellume in favor of Plaintiffs and Class members in an amount to be determined by the Court as fair and just for Ellume's wrongful conduct;
- e. An order awarding Plaintiffs and Class members prejudgment interest on any damages awarded by the Court;
- f. An order of restitution and all other forms of equitable monetary relief;
- g. Injunctive and declaratory relief as pleaded or as the Court may deem proper;
- h. An order awarding Plaintiffs and Class members reasonable attorneys' fees and expenses, and costs of suit; and
- i. Grant such further relief as this Court deems appropriate.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Plaintiffs hereby demand a trial by jury on all issues so triable in this action.

Dated: March 22, 2022 By: /s/ James P. Ulwick

James P. Ulwick (Federal Bar No. (00536)

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ClassAction.org

This complaint is part of ClassAction.org's searchable class action lawsuit database and can be found in this post: <u>Ellume Has Refused to Refund Buyers After Recalling Certain At-Home COVID-19 Tests, Class Action Says</u>