# UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

JORDAN JUDT, on behalf of himself and a class of all others similarly situated,

Case No. 7:24-cv-2718

Plaintiff,

**CLASS ACTION COMPLAINT** 

v.

ALCHEMEE, LLC and TARO PHARMACEUTICALS U.S.A., INC.,

**DEMAND FOR JURY TRIAL** 

Defendants.

Plaintiff Jordan Judt ("Plaintiff") individually and on behalf of himself and all others similarly situated, brings this class action lawsuit against Defendants Alchemee, LLC ("Alchemee") and Taro Pharmaceuticals U.S.A., Inc. ("Taro USA") (collectively, "Defendants") based upon personal knowledge as to himself, the investigation of his counsel, and on information and belief as to all other matters.

### **INTRODUCTION**

- 1. This is a class action lawsuit against Defendants regarding the manufacturing, distribution, advertising, marketing, and sale of Proactiv branded benzoyl peroxide ("BPO") acne treatment products (the "BPO Products")<sup>1</sup> that contain and/or degrade into dangerously unsafe levels of benzene, a known human carcinogen.
- 2. The BPO Products are used to treat acne vulgaris ("acne") and are formulated with BPO and other inactive ingredients to make treatments for acne in various forms such as creams, scrubs, washes, and bars.

<sup>&</sup>lt;sup>1</sup> The BPO Products include, but are not limited to, Proactiv+® 3-Step Routine, Proactiv+® Skin Smoothing Exfoliator, Proactiv® Solution Repairing Treatment, Proactiv® Solution Renewing Cleanser, Proactiv® Solution 3-Step Routine, and Proactiv+® Pore Targeting Treatment. Plaintiff reserves the right to amend this list if further investigation and/or discovery reveals that the list should be amended.

- 3. Benzene is a known human carcinogen. The World Health Organization ("WHO") and the International Agency for Research on Cancer ("IARC") have classified benzene as a Group 1 compound thereby defining it as "carcinogenic to humans." Similarly, the Department of Health and Human Services ("DHHS") has determined that benzene causes cancer in humans. Benzene exposure has been linked with acute lymphocytic leukemia, chronic lymphocytic leukemia, multiple myeloma, and non-Hodgkin lymphoma.
- 4. On March 5, 2024, Valisure LLC ("Valisure"), an independent laboratory that analyzes the safety of consumer products, filed a citizen petition (the "Valisure Petition") with the FDA detailing its findings that it detected high levels of benzene in BPO products, including Defendants' BPO Products. Valisure called for the FDA to recall and suspend the sale of all products containing BPO, including Defendants' BPO Products. Valisure argued that the products containing BPO are adulterated under Section 301 of the Federal Drug and Cosmetics Act ("FDCA") in violation of 21 U.S.C. § 331 and misbranded under Section 502 of the FDCA in violation of 21 U.S.C. § 352, among various other FDCA violations.
- 5. Valisure's Petition detailed that products containing BPO, including the BPO Products marketed and sold by the Defendants, decomposed into benzene under normal and expected use, handling, and storage, rendering them materially different than advertised, *i.e.*, by

<sup>&</sup>lt;sup>2</sup> IARC Monographs on the Identification of Carcinogenic Hazards to Humans: List of Classifications, INTERNATIONAL AGENCY FOR RESEARCH ON CANCER, WORLD HEALTH ORGANIZATION, <a href="https://monographs.iarc.who.int/list-of-classifications">https://monographs.iarc.who.int/list-of-classifications</a> (last visited April 10, 2024).

<sup>&</sup>lt;sup>3</sup> Facts About Benzene, CENTERS FOR DISEASE CONTROL AND PREVENTION (April 4, 2018) <a href="https://emergency.cdc.gov/agent/benzene/basics/facts.asp">https://emergency.cdc.gov/agent/benzene/basics/facts.asp</a> (last visited April 10, 2024).

<sup>&</sup>lt;sup>4</sup> Benzene and Cancer Risk, AMERICAN CANCER SOCIETY <a href="https://www.cancer.org/cancer/cancer-causes/benzene.html">https://www.cancer.org/cancer/cancer-causes/benzene.html</a> (last visited April 10, 2024).

<sup>&</sup>lt;sup>5</sup> David Light, Wolfgang Hinz, PhD, and Kaury Kucera, PhD, *Valisure Citizen Petition on Benzene in Benzoyl Peroxide Drug Products*, VALISURE (March 5, 2024), *available at:* <a href="https://www.valisure.com/valisure-newsroom/valisure-detects-benzene-in-benzoyl-peroxide">https://www.valisure.com/valisure-newsroom/valisure-detects-benzene-in-benzoyl-peroxide</a> (last visited April 10, 2024).

containing unsafe levels of benzene. Many of the BPO products that Valisure tested were found to contain benzene in many multiple times higher than allowed in any regulated drug.<sup>6</sup>

- 6. This led Valisure to conduct a stability study on a diverse market sweep of BPO products and formulations. Valisure's results show that on-market BPO products can form over **800 times** the conditionally restricted FDA concentration limit of 2 parts per million ("ppm") for benzene, suggesting this problem applies broadly to BPO Products currently on the market.<sup>7</sup>
- 7. Incubation of one of Defendants' BPO Products at the temperature of a hot car (70°C), a temperature the BPO Products are expected to be exposed to through normal consumer and distributor handling, resulted in the detection of benzene at ~1,270 times the Environmental Protection Agency's ("EPA") calculated threshold for increased cancer risk by long-term inhalation exposure to benzene.<sup>8</sup> Overall, the testing led Valisure to conclude that on-market BPO Products appear to be fundamentally unstable and form unacceptably high levels of benzene.<sup>9</sup>
- 8. The presence of benzene, or the risk of benzene contamination via degradation of BPO, is not disclosed on the BPO Products' labels. Therefore, Plaintiff, by use of reasonable care, could not have discovered that the BPO Products were contaminated with benzene and/or were at risk of benzene contamination via the degrading of BPO.
- 9. Although BPO is known within the scientific community to degrade into benzene, this fact is not known among consumers. Defendants knew or should have known the BPO Products contain benzene and/or degraded to form benzene when exposed to normal and expected consumer use, handling, and storage.

<sup>&</sup>lt;sup>6</sup> *Id*.

<sup>&</sup>lt;sup>7</sup> Valisure Discovers Benzoyl Acne Treatment Products are Unstable and Form Benzene, VALISURE (March 6, 2024), <a href="https://www.valisure.com/valisure-newsroom/valisure-detects-benzene-in-benzoyl-peroxide">https://www.valisure.com/valisure-newsroom/valisure-detects-benzene-in-benzoyl-peroxide</a> (last visited April 10, 2024).

<sup>&</sup>lt;sup>8</sup> *Id*.

<sup>&</sup>lt;sup>9</sup> *Id*.

- 10. Plaintiff and Class Members purchased the BPO Products with the expectation that the products were safe, including free of carcinogens that are not listed on the label. Because Defendants sold products to consumers that contain dangerous levels of benzene and/or degrade into benzene, Plaintiff and the Class Members were deprived of the benefit of their bargain.
- 11. Defendants are therefore liable to Plaintiff and Class members for misrepresenting and/or failing to disclose or warn that the BPO Products contain benzene and/or that the BPO Products degrade into benzene.
- 12. As a result of Defendants' misconduct and consumer deception, Plaintiff, the Class, and the public, have been economically harmed. Plaintiff would not have purchased the BPO Products or would have paid less for them, had he known the truth.
- 13. Plaintiff seeks damages, reasonable attorneys' fees and costs, interest, restitution, other equitable relief, including an injunction and disgorgement of all benefits and profits Defendants received from misconduct.

#### **PARTIES**

14. Plaintiff Jordan Judt is a resident of Madison County, Nebraska. In November 2023, Plaintiff purchased one of Defendants' BPO Products, the Proactiv<sup>®</sup> Solution 3-Step Routine, from a Target retail store located in Norfolk, Nebraska. When purchasing the BPO Products, Plaintiff reviewed the accompanying labels and disclosures and understood them as representations and warranties by Defendants that the product was properly manufactured, free from defects, and safe for its intended use. Plaintiff relied on these representations and warranties in deciding to purchase the BPO Product and these representations and warranties were part of the basis of the bargain in that he would not have purchased, or would have paid less for, the BPO Product, if he had known that the BPO Product was not, in fact, properly manufactured, free from defects, or safe for their intended use.

- 15. Defendant Alchemee is a Delaware limited liability company with its principal place of business at 3 Skyline Drive, Hawthorne, New York. Alchemee is a subsidiary of Taro Pharmaceuticals Industries Ltd. Alchemee owns and operates the website proactiv.com and markets and distributes dermatology products, including the BPO Products, in the U.S. market.
- 16. Defendant Taro USA is a New York corporation with its principal place of business at 3 Skyline Drive, Hawthorne, New York. Taro USA markets and distributes dermatology products, including the BPO Products, in the U.S. market.

#### **JURISIDICITION AND VENUE**

- 17. 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 at least one 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.
- 18. This Court has personal jurisdiction over Defendants because Defendants are headquartered in this District, which subjects them to general personal jurisdiction.
- 19. Venue is proper in this Court pursuant to 28 U.S.C. § 1391, because many of the acts and transactions giving rise to this action occurred in this District, Defendants conduct substantial business in this District, and Defendants reside in this District.

#### **FACTUAL ALLEGATIONS**

#### A. The Dangers of Benzene

20. According to the U.S. Centers for Disease Control and Prevention ("CDC"), the U.S. Department of Health and Human Services has determined that benzene causes cancer in

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humans. Similarly, the WHO and the IARC have classified benzene as a Group 1 compound thereby defining it as "carcinogenic to humans." <sup>10</sup>

- 21. The National Institute for Occupational Safety and Health ("NIOSH") and CDC identify "exposure routes" for benzene to include: "inhalation, skin absorption, ingestion, skin and/or eye contact." <sup>11</sup>
- 22. The NIOSH and CDC identify "target organs" associated with human exposure to benzene to include: "eyes, skin, respiratory system, blood, central nervous system, bone marrow.<sup>12</sup>
- 23. The CDC warns that "[b]enzene works by causing cells not to work correctly. For example, it can cause bone marrow not to produce enough red blood cells, which can lead to anemia. Also, it can damage the immune system by changing blood levels of antibodies and causing the loss of white blood cells." <sup>13</sup>
- 24. As for "where benzene is found and how it is used," the CDC states that "[s]ome industries use benzene to make other chemicals that are used to make plastics, resins, and nylon and synthetic fibers. Benzene is also used to make some types of lubricants, rubbers, dyes, detergents, drugs, and pesticides."<sup>14</sup>
- 25. The CDC has stated that ways in which people "could be exposed to benzene" include:
  - Outdoor air contains low levels of benzene from tobacco smoke, gas stations, motor vehicle exhaust, and industrial emissions.
  - Indoor air generally contains levels of benzene higher than those in outdoor air.

<sup>&</sup>lt;sup>10</sup> David Light, Wolfgang Hinz, PhD, and Kaury Kucera, PhD, *Valisure Citizen Petition on Benzene in Benzoyl Peroxide Drug Products*, VALISURE (March 5, 2024), *available at:* <a href="https://www.valisure.com/valisure-newsroom/valisure-detects-benzene-in-benzoyl-peroxide">https://www.valisure.com/valisure-newsroom/valisure-detects-benzene-in-benzoyl-peroxide</a> (last visited April 10, 2024).

<sup>&</sup>lt;sup>11</sup> NIOSH Pocket Guide to Chemical Hazards: Benzene, CENTERS FOR DISEASE CONTROL AND PREVENTION, https://www.cdc.gov/niosh/npg/npgd0049.html (last visited April 10, 2024).

<sup>&</sup>lt;sup>13</sup> Facts About Benzene, CENTERS FOR DISEASE CONTROL AND PREVENTION (April 4, 2018) https://emergency.cdc.gov/agent/benzene/basics/facts.asp (last visited April 10, 2024).

<sup>&</sup>lt;sup>14</sup> *Id*.

The benzene in indoor air comes from products that contain benzene such as glues, paints, furniture wax, and detergents.

- The air around hazardous waste sites or gas stations can contain higher levels of benzene than in other areas.
- Benzene leaks from underground storage tanks or from hazardous waste sites containing benzene can contaminate well water.
- People working in industries that make or use benzene may be exposed to the highest levels of it.
- A major source of benzene exposure is tobacco smoke. 15
- 26. A 2010 study titled "Advances in Understanding Benzene Health Effects and Susceptibility" summarized the epidemiological studies of the carcinogenic effects of benzene exposure and an overview of the hematotoxic effects of benzene. <sup>16</sup> The 2010 study concluded:
  - a. There is probably no safe level of exposure to benzene, and all exposures constitute some risk in a linear, if not supralinear, and additive fashion.
  - b. Exposure to benzene can lead to multiple alterations that contribute to the leukemogenic process, indicating a multimodal mechanism of action.
  - c. Benzene is a ubiquitous chemical in our environment that causes acute leukemia and probably other hematological cancers.
- 27. The FDA currently recognizes the danger of benzene and, as a result, has claimed it should not be used in the manufacture of any component of a drug product due to its unacceptable toxicity effect.<sup>17</sup>

<sup>15</sup> I.A

<sup>&</sup>lt;sup>16</sup> Martyn T. Smith, *Advances in Understanding Benzene Health Effects and Susceptibility*, ANNUAL REVIEWS, Vol. 31:133-148 (April 21, 2010) <a href="https://www.annualreviews.org/doi/full/10.1146/annurev.publhealth.012809.103646">https://www.annualreviews.org/doi/full/10.1146/annurev.publhealth.012809.103646</a> (last visited April 10, 2024).

<sup>&</sup>lt;sup>17</sup> David Light, Wolfgang Hinz, PhD, and Kaury Kucera, PhD, *Valisure Citizen Petition on Benzene in Benzoyl Peroxide Drug Products*, VALISURE (March 5, 2024), *available at:* <a href="https://www.valisure.com/valisure-newsroom/valisure-detects-benzene-in-benzoyl-peroxide">https://www.valisure.com/valisure-newsroom/valisure-detects-benzene-in-benzoyl-peroxide</a> (last visited April 10, 2024).

- 28. Where the use of benzene or other Class 1 solvents is unavoidable to produce a drug product with a significant therapeutic advance, the FDA has stated that the levels should be restricted, and benzene is restricted under such guidance to 2 ppm.<sup>18</sup>
- 29. Recognizing the risks of benzene, in December 2022, the FDA issued a statement alerting manufacturers to the risk of benzene contamination and warned that any drug product containing more than 2 ppm benzene was adulterated and should be recalled. This statement was updated on December 27, 2023, and still provides that drug manufacturers "should not release any drug product batch that contains benzene above 2 ppm" and "[i]f any drug product batches with benzene above 2 ppm are already in distribution, the manufacturer should contact FDA to discuss the voluntary initiation of a recall[.]" <sup>19</sup>
- 30. Over the past three years alone, the FDA has announced over a dozen recalls of various drug and cosmetic products identified as containing "low levels" or even "trace levels" of benzene, including certain hand sanitizers and aerosol drug products like sunscreens and antiperspirants.<sup>20</sup>

<sup>&</sup>lt;sup>18</sup> *Id*.

<sup>&</sup>lt;sup>19</sup> FDA alerts drug manufacturers to the risk of benzene contamination in certain drugs, U.S. FOOD & DRUG ADMINISTRATION, <a href="https://www.fda.gov/drugs/pharmaceutical-quality-resources/fda-alerts-drug-manufacturers-risk-benzene-contamination-certain-drugs">https://www.fda.gov/drugs/pharmaceutical-quality-resources/fda-alerts-drug-manufacturers-risk-benzene-contamination-certain-drugs</a> (last visited April 10, 2024) (The FDA cannot force a drug manufacturer to recall a contaminated or adulterated drug); Facts About the Current Good Manufacturing Practice (CGMP), U.S. FOOD & DRUG ADMINISTRATION, <a href="https://www.fda.gov/drugs/pharmaceutical-quality-resources/facts-about-current-good-manufacturing-practice-cgmp">https://www.fda.gov/drugs/pharmaceutical-quality-resources/facts-about-current-good-manufacturing-practice-cgmp</a> (last visited April 10, 2024) ("While FDA cannot force a company to recall a drug, companies usually will recall voluntarily or at FDA's request").

<sup>&</sup>lt;sup>20</sup> Johnson & Johnson Consumer Inc. Issues Voluntary Recall of Specific NEUTROGENA® and AVEENO® Aerosol Sunscreen Products Due to the Presence of Benzene, U.S. FOOD & DRUG ADMINISTRATION, <a href="https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/johnson-johnson-consumer-inc-issues-voluntary-recall-specific-neutrogenar-and-aveenor-aerosol">https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/johnson-johnson-consumer-inc-issues-voluntary-recall-specific-neutrogenar-and-aveenor-aerosol</a> (last visited April 10, 2024); Edgewell Personal Care Issues Voluntary Nationwide Recall of Banana Boat Hair & Scalp Sunscreen Due to the Presence of Benzene, U.S. FOOD & DRUG ADMINISTRATION, <a href="https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/edgewell-personal-care-issues-voluntary-nationwide-recall-banana-boat-hair-scalp-sunscreen-due">https://www.fda.gov/safety/recall-banana-boat-hair-scalp-sunscreen-due</a> (last visited April 10, 2024); P&G Issues Voluntary Recall of Specific Old Spice and Secret Aerosol Spray Antiperspirants and Old Spice Below Deck Aerosol Spray Products Due to Detection of Benzene, U.S. FOOD & DRUG ADMINISTRATION, <a href="https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/pg-issues-voluntary-recall-specific-old-spice-and-secret-aerosol-spray-antiperspirants-and-old-spice">https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/pg-issues-voluntary-recall-specific-old-spice-and-secret-aerosol-spray-antiperspirants-and-old-spice</a> (last visited April 10, 2024).

### B. <u>Defendants' History in the Industry</u>

- 31. Defendants manufacturer, market, distribute, and sell various skin care products containing BPO, including Proactiv+® Skin Smoothing Exfoliator, Proactiv® Solution Repairing Treatment, Proactiv® Solution Renewing Cleanser, Proactiv+® Pore Targeting Treatment, Proactiv+® 3-Step Routine, and Proactiv® Solution 3-Step Routine. Proactiv is a registered trademark of Taro and is distributed in the U.S. through Taro's subsidiary, Alchemee. Taro was started in the 1950s and entered the U.S. market in the 1980s. Taro makes hundreds of prescriptions, over the counter, and generic topical dermatological products used by millions of Americans every year, including well known products such as hydrocortisone and antibiotic creams. Taro employs hundreds of scientists globally with 16% of its employees working in research and development. 22
  - 32. BPO is an active ingredient in all of Defendants BPO Products.
  - 33. All of Defendants' BPO Products are manufactured in the same manner.
- 34. All lots of Defendants' BPO Products systematically degrade to form benzene. As noted below, this is supported by testing of acne treatment products containing benzoyl peroxide, all of which tested positive for benzene at various levels ranging from 2,000 ppm to 1.8 ppm.
- 35. Defendants' BPO Products are widely marketed, available, sold, and used by children, teenagers, and adults throughout the United States and the world. The acne treatment industry is a highly competitive billion-dollar market. To that end, Defendants spend millions of dollars every year promoting the BPO Products directly to consumers, focusing heavily on young consumers such as teenagers.

<sup>&</sup>lt;sup>21</sup> TARO PHARMACEUTICALS INDUSTRIES, LTD., USA, https://www.taro.com/usa (last visited April 10, 2024).

<sup>&</sup>lt;sup>22</sup> Form 20-F, TARO PHARMACEUTICALS INDUSTRIES, LTD., USA (March 31, 2023), <a href="https://www.sec.gov/edgar/search/#taro-20230331.htm">https://www.sec.gov/edgar/search/#taro-20230331.htm</a> (last visited April 10, 2024)..(last visited April 10, 2024).

36. Defendants make promises to consumers such as affirming the BPO Products are tested, backed by science, and approved by dermatologists. Defendants further describe themselves to consumers as market leaders and acne experts that care about the consumers.

# C. The Valisure Petition Identified High Levels of Benzene in Defendants' BPO Products

- 37. Valisure is an accredited independent laboratory who has developed validated analytical methods<sup>23</sup> to test drugs and consumer products to address rising concerns about public safety. Valisure has tested a wide variety of drugs and products for benzene including hand sanitizers, sunscreens, antiperspirants, and dry shampoos. Their work has led to widely publicized product recalls protecting the public from dangerous and carcinogenic consumer products.
- 38. On March 5, 2024, Valisure submitted a public citizens petition to the FDA requesting a recall and suspension of sales of products containing benzoyl peroxide from the U.S. market. The petition was based on testing conducted by Valisure in 2023 that found common acne treatment products formulated with BPO are not only contaminated with benzene but have levels dangerous to public health.
- 39. Valisure tested 175 finished acne treatment products to determine whether any had benzene. Of the 175 products tested, 99 were formulated with BPO.<sup>24</sup> 83 of the BPO Products were purchased over the counter from major retailers and 16 were prescription products purchased from licensed wholesalers.<sup>25</sup> The BPO Products tested by Valisure included various popular products such as Proactiv 2.5% BPO Cream, Target Up & Up 2.5% BPO Cream, Equate Beauty 10% BPO Cream, Equate BPO Cleanser, Neutrogena 10% BPO Cleanser, Clearasil 10% BPO

<sup>&</sup>lt;sup>23</sup> Valisure's test methods largely mirror those utilized by FDA's own "Drug Quality Sampling and Testing" ("DQST") Program. See Valisure FDA Citizen's Petition on Benzoyl Peroxide at 4.

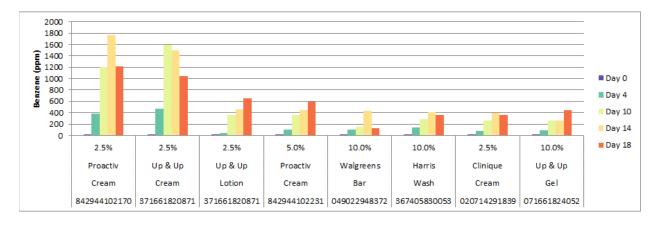
<sup>&</sup>lt;sup>24</sup> See Valisure FDA Citizen's Petition on Benzoyl Peroxide (March 5, 2024).

<sup>&</sup>lt;sup>25</sup> *Id*.

Cream, CVS Health 10% BPO Face Wash, Walgreens 10% BPO Cream, La Roche Posay BPO Cream, and Clean & Clear 10% BPO Lotion.

- 40. To evaluate the effects of common distributor and consumer use, handling, and storage conditions on benzene formation, Valisure used three incubation temperatures: (1) 37°C/98.6°F was used for human body temperature, (2) 50°C/122°F was used to evaluate shelf-life performance as an accelerated stability testing temperature used by the pharmaceutical industry, <sup>26</sup> and (3) 70°C/158°F to model storage in a hot vehicle.
- 41. The BPO products that Valisure tested were incubated at 50°C for 18 days and benzene concentration was measured at day 0, 4, 10, 14, and 18 using industry standard gas chromatography and detection by mass spectrometry ("GC-MS") instrumentation. These BPO containing products included creams, lotions, gels, washes, liquids, and bars, and included analysis of some of Defendants' BPO Products.<sup>27</sup> The results below were submitted to the FDA in Valisure's Petition on Benzoyl Peroxide:

Figure 4A



<sup>&</sup>lt;sup>26</sup> Ghimire, Prakash, et al., Guidelines on Stability Studies of Pharmaceutical Products and Shelf-Life Estimation. INTERNATIONAL JOURNAL OF ADVANCES IN PHARMACY AND BIOTECHNOLOGY (Mar. 2020), available at: <a href="https://www.researchgate.net/publication/342998982">https://www.researchgate.net/publication/342998982</a> Guidelines on Stability Studies of Pharmaceutical Product s and Shelf Life Estimation (last visited April 10, 2024).

<sup>&</sup>lt;sup>27</sup> Valisure Petition at 15-16

Figure 4B

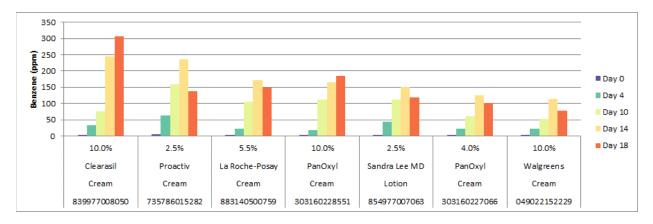


Figure 4C

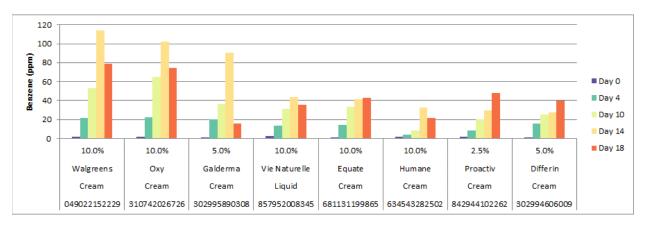


Figure 4D

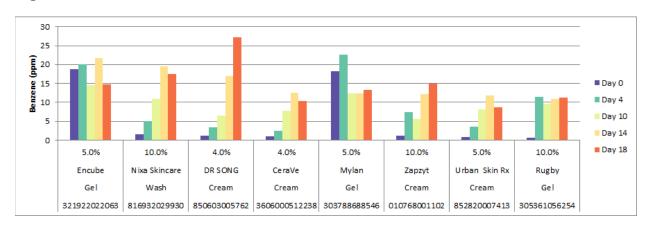


Figure 4E

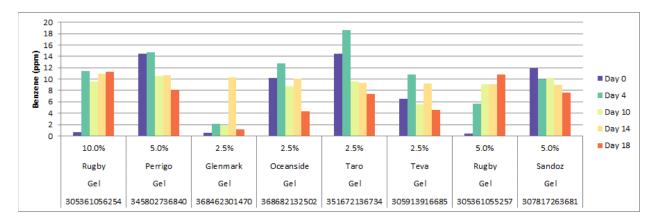


Figure 4F

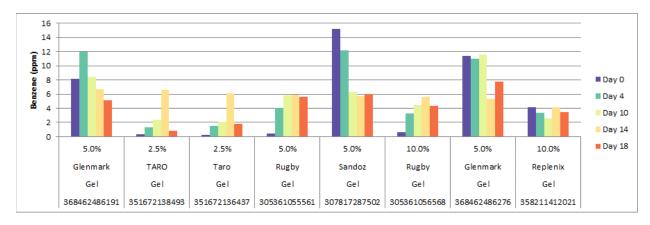


Figure 4G

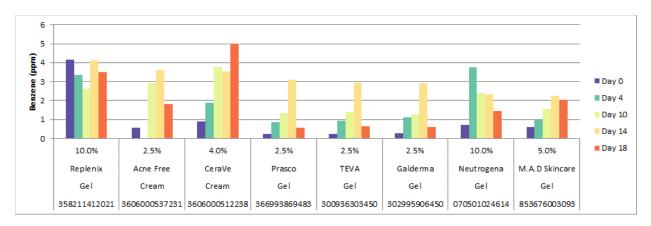


Figure 4H

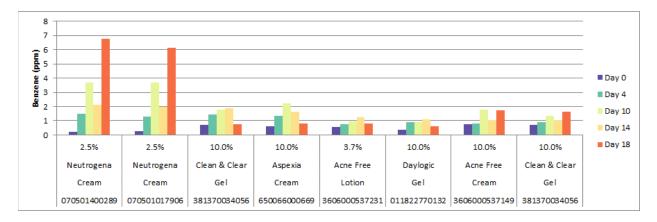
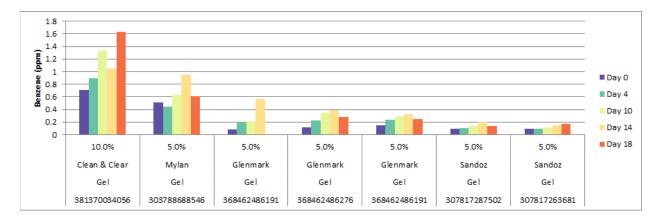


Figure 4I



- 42. As demonstrated in the above charts, results from the 50°C stability testing showed that every one of the tested BPO products, including Defendants' BPO Products contained and/or degraded into, dangerous levels of benzene well over 2ppm, the maximum amount allowed in any U.S. regulated drug. <sup>28</sup> In fact, Defendants' Proactiv labeled BPO Products consistently topped the charts for benzene levels over 2 ppm, including Proactiv's 2.5% BPO Cream which reached as high as *1700 ppm*.
- 43. Valisure's Petition concluded that all on-market BPO acne formulations seem to be fundamentally unstable and form unacceptably high levels of benzene under normal use, handling,

<sup>&</sup>lt;sup>28</sup> Valisure FDA Citizen's Petition at 16-18.

and storage temperatures. Importantly, no such evidence was observed for acne treatment products not formulated with BPO.

# D. <u>Defendants' Failure to Warn Consumers About BPO Degradation</u>

- 44. It is well known among the scientific community that BPO degrades to benzene when exposed to heat over time and was first reported as early as 1936. <sup>29</sup>
  - 45. The BPO Products are not designed to contain benzene.
- 46. Defendants hold themselves out to be experts in acne drug research and development, and employed high-level scientists, chemists, and researchers to formulate their drug products for public use.
- 47. Defendants with these resources and expertise knew, or should have known, of the well-known chemical processes that degrades the BPO in products into benzene when exposed to common use temperatures and conditions.
- 48. Each of Defendants' BPO Products lists the ingredients of the BPO Products on their labels, including benzoyl peroxide. What Defendants fail to disclose on the BPO Products' labeling or anywhere in its marketing is that the BPO Products contain benzene and/or that the BPO in the BPO Products degrade to form benzene even under normal and expected use, handling, and storage.
- 49. Defendants should have known through their own research, development, formulation, manufacturing, and testing that the BPO Products were not chemically and physically stable. Defendants were required to make sure they adequately tested its BPO Products for safety and stability before selling them to the public, as well as monitor their internal practices, processes,

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<sup>&</sup>lt;sup>29</sup> H. Erlenmeyer and W. Schoenauer, *Über die thermische Zersetzung von Di-acyl-peroxyden*, HELVETICA, Vol. 19, Issue 1, 338 (1936), *available at:* <a href="https://onlinelibrary.wiley.com/doi/10.1002/hlca.19360190153">https://onlinelibrary.wiley.com/doi/10.1002/hlca.19360190153</a> (last visited April. 10, 2024).

and specifications to make sure their processes and procedures met current and emerging scientific methodologies. This means that during expiration and stability studies examining the "shelf life" of the BPO Products, Defendants knew or should have known that the chemical changes in BPO to benzene took place during normal and expected use and storage conditions.

- 50. Moreover, Defendants knew or should have known the BPO Products would be handled, used, and stored by distributors, sellers, and consumers under various temperatures that affect chemical stability. For example, Defendants knew or should have known the BPO Products would travel by commercial carriers and distributors in varying storage conditions. Defendants knew or should have known that the BPO Products would be stored by consumers in bathrooms, showers, and in vehicles during warm months where the BPO Products would be exposed to heat.
- 51. The use, handling, and storage conditions were known or should have been known to Defendants prior to the BPO Products being marketed and sold to Plaintiff and the Class. Defendants knew, or should have known, that under these normal use, handling, and storage conditions by consumers, that the BPO in the BPO Products would degrade to benzene, exposing consumers to the dangerous carcinogen. Regardless of this fact, Defendants still sold them to Plaintiff, the Class, and the public anyway, without warning of the risk of exposure.

#### **CLASS ACTION ALLEGATIONS**

52. Plaintiff brings this action pursuant to Rule 23(a), (b)(2), and (b)(3) of the Federal Rules of Civil Procedure, individually and on behalf of the following Classes:

All persons who purchased one or more of Defendants' BPO Products in the United States for personal/household use within any applicable limitations period (the "Nationwide Class").

53. Plaintiff brings this action individually and on behalf of the following Nebraska subclass:

All persons who purchased one or more of Defendants' BPO Products in the state of Nebraska for personal/household use within any applicable limitations (the "Nebraska Subclass").

- 54. Excluded from the Class and Subclass are: (1) any Judge or Magistrate presiding over this action and any members of their families; (2) Defendants, Defendants' subsidiaries, parents, successors, predecessors, and any entities in which Defendants or their parents and any entities in which Defendants have a controlling interest and its current or former employees, officers, and directors; and (3) individuals who allege personal bodily injury resulting from the use of BPO Products.
- Numerosity (Rule 23(a)(1)): The exact number of Class Members is unknown and currently unavailable to Plaintiff, but joinder of individual members herein is impractical. The Class is likely comprised of thousands of consumers. The precise number of Class Members, and their addresses, is unknown to Plaintiff at this time, but can be ascertained from Defendants' records and/or retailer records. The Class Members may be notified of the pendency of this action by mail or email, Internet postings and/or publications, and supplemented (if deemed necessary or appropriate by the Court) by published notice.
- 56. <u>Predominant Common Questions (Rule 23(a)(2) and (b)(3)):</u> The Class's claims present common questions of law and fact, and those questions predominate over any questions

that may affect individual Class Members. The common and legal questions include, but are not limited to, the following:

- a. Whether the BPO Products contain and/or degrade into benzene;
- b. Whether Defendants knew or should have known that the BPO Products contain and/or degrade into benzene;
- c. Whether Defendants' representations and omissions, in its marketing, advertising, labeling, and packaging of the BPO Products, are misleading;
- d. Whether Defendants' representations and omissions, in its marketing, advertising, labeling, and packaging of the BPO Products are reasonably likely to deceive;
- e. Whether Defendants engaged in false and misleading advertising;
- f. Whether Defendants' internal testing showed that its products contained and/or degraded to form benzene;
- g. Whether Defendants violated the state consumer protection statutes alleged herein;
- h. Whether Defendants breached their implied warranties;
- i. Whether Defendants were unjustly enriched;
- j. The nature of relief, including damages and equitable relief, to which Plaintiff and Class Members are entitled.
- 57. <u>Typicality of Claims (Rule 23(a)(3)):</u> Plaintiff's claims are typical of the claims of the Class because Plaintiff, like all other Class Members, purchased the BPO Products, suffered damages as a result of that purchase, and seeks the same relief as the proposed Class Members.
- Adequacy of Representation (Rule 23(a)(4)): Plaintiff adequately represents the Class because his interests do not conflict with the interests of the Class Members, and he has retained counsel competent and experienced in complex class action and consumer litigation. Plaintiff and his counsel will fairly and adequately protect the interest of the Class Members.
- 59. <u>Superiority (Rule 23(b)(3)):</u> A class action is superior to other available means of adjudication for this controversy. It would be impracticable for Class Members to individually

litigate their own claims against Defendants because the damages suffered by Plaintiff and the Class Members are relatively small compared to the cost of individually litigating their claims. Individual litigation would create the potential for inconsistent judgments and delay and expenses to the court system. A class action provides an efficient means for adjudication with fewer management difficulties and comprehensive supervision by a single court.

60. <u>Declaratory Relief (Fed. R. Civ. P. 23(b)(1) and (2)):</u> In the alternative, this action may properly be maintained as a class action because the prosecution of separate actions by individual Class Members would create a risk of inconsistent or varying adjudication with respect to individual Class Members, which would establish incompatible standards of conduct for the Defendants; or the prosecution of separate actions by individual Class Members would create a risk of adjudications with respect to individual Class Members which would, as a practical matter, be dispositive of the interests of other Class Members not parties to the adjudications, or substantially impair or impede their ability to protect their interests; or Defendants have acted or refused to act on grounds generally applicable to the Class, thereby making appropriate final injunctive or corresponding declaratory relief with respect to the Class as a whole.

#### **CAUSES OF ACTION**

#### **COUNT I**

# NEBRASKA UNIFORM DECEPTIVE TRADE PRACTICES ACT Neb. Rev. Stat. §§ 87-301, et seq. (On behalf of Plaintiff and the Nebraska Subclass against Defendants)

- 61. Plaintiff, on behalf of himself and the Nebraska Subclass, hereby incorporates all other paragraphs of this Complaint and restates them as if fully set forth herein.
- 62. Defendants and Nebraska Subclass Members are "persons" as defined by Neb. Rev. Stat. § 87-301(19).
- 63. Defendants advertised, offered, or sold goods or services in Nebraska and engaged in trade or commerce directly or indirectly affecting the people of Nebraska.
- 64. Defendants engaged in deceptive trade practices in the course of its business, in violation of Neb. Rev. Stat. § 87-302(a).
- 65. Defendants failed to disclose material facts to consumers in advertising and on the BPO Product labels, including but not limited to, that the BPO Products contain and/or degrade into benzene, a known human carcinogen, with normal and expected usage, handling, and storage, and are unsafe for use. The labels for the BPO Products did not warn consumers that benzene was and/or would become present, and that as a result, the BPO Products were of a particular standard, quality, or grade when they were of another.
- 66. Additionally, because Defendants failed to disclose that the BPO Products contained and/or degraded to form benzene, and therefore advertised the products with intent not to sell them as advertised, this conduct created a likelihood of confusion or of misunderstanding.
- 67. Defendants knew or should have known that its conduct violated Nebraska's Uniform Deceptive Trade Practices Act.

- 68. Defendants had a duty to disclose material facts to consumers, including but not limited to, that the BPO Products contain and/or degrade into benzene through normal ad expected usage, handling, and storage, and are unsafe for use. These material facts should have been disclosed because they were contrary to Defendants' representations about the BPO Products.
- 69. Defendants acted intentionally, knowingly, and maliciously to violate Nebraska's Uniform Deceptive Trade Practices Act, and recklessly disregarded Plaintiff's and Nebraska Subclass members' rights.
- 70. Consumers could not have reasonably avoided injury because Defendants' business acts and practices unreasonably created or took advantage of an obstacle to the free exercise of consumer decision-making. By withholding important information from consumers, Defendants created an asymmetry of information between it and consumers that precluded consumers from taking action to avoid or mitigate injury.
- 71. As a direct and proximate cause of Defendants' deceptive acts and practices, Plaintiff Judt and the Nebraska Subclass members have been injured and harmed because they would not have purchased the BPO Products on the same terms if they knew the true facts regarding the benzene content in the BPO Products.

### **COUNT II**

# BREACH OF IMPLIED WARRANTY (On behalf of Plaintiff and the Class against Defendants)

- 72. Plaintiff hereby incorporates all other paragraphs of this Complaint and restates them as if fully set forth herein.
- 73. Defendants, as manufacturers and sellers of the BPO Products, made implied warranties including warranting the Products were of the same quality and purity represented on the labels, in advertising, and on Defendants' websites and in advertising. Defendants represented

the Products were fit for the ordinary purpose and conformed to the promises made on the containers, labels, advertising, and websites that all ingredients were listed, and all warnings given.

- 74. Defendants advertised their BPO Products as safe, when they knew, or should have known, that the BPO in the PBO Products degraded to benzene. Defendants did not list benzene as an ingredient or contaminant anywhere on the Products or advertising. Defendants did not list proper storage procedures anywhere on the BPO Products or advertising to limit the risk of BPO degradation into benzene. The Products are not of the quality and purity represented by Defendants because the BPO in the BPO Products degrade to benzene under normal use, handling, and storage conditions.
- 75. Defendants did not tell Plaintiff, the Class, or Subclass members the BPO Products were not fit for their ordinary use because the BPO Products, as advertised and sold by Defendants, degraded to benzene under normal and expected handling, use, and storage.
- 76. Plaintiff, the Class, and Subclass members purchased the BPO Products in reasonable reliance on Defendants' statements, affirmations, and omissions of material health and safety information.
  - 77. Defendants' acts and omissions are ongoing and continuing to cause harm.
- 78. Because of Defendants' misconduct, Plaintiff, on behalf of himself, the Class, and Subclass members, seeks recovery of his actual damages, injunctive relief, attorneys' fees, punitive damages, and all other relief allowable under the law. The damages sought are uniform to the Class and Subclasses and the actual damages can be measured and returned to consumers who bought Defendants' BPO Products.

#### **COUNT III**

# UNJUST ENRICHMENT (On behalf of the Plaintiff and the Class against Defendants)

- 79. Plaintiff hereby incorporates all other paragraphs of this Complaint and restates them as if fully set forth herein.
- 80. Plaintiff and Class Members conferred benefits upon Defendants. Plaintiff and Class Members paid money for Defendants' worthless and defective BPO Products.
- 81. Defendants have unjustly retained the benefits conferred upon them by Plaintiff and Class Members.
- Defendants retained those benefits under circumstances that make it inequitable for Defendants to retain such benefits. Specifically, Defendants retained those benefits even though Defendants' BPO Products contain and/or degrade into benzene through normal and expected handling, use, and storage and are unfit and unsafe for human use. If Plaintiff and Class Members had known the true nature of Defendants' BPO Products, they would not have purchased the products or would have paid less for them. Plaintiff and Class Members are therefore entitled to disgorgement and/or restitution as prayed for hereunder.
- 83. Because Defendants' retention of the non-gratuitous benefits conferred on them by Plaintiff and Class Members is unjust and inequitable, Defendants must pay restitution to Plaintiff and Class Members for their unjust enrichment, as ordered by the Court.

#### **PRAYER FOR RELIEF**

**WHEREFORE**, Plaintiff, on behalf of himself and the proposed Classes, prays for relief and judgment against Defendant as follows:

a. Certifying the Classes pursuant to Rule 23 of the Federal Rules of Civil Procedure, appointing Plaintiff as representative of the Class, and designating Plaintiff's counsel as Class Counsel;

- b. Awarding Plaintiff and the Classes compensatory damages, in an amount exceeding \$5,000,000, to be determined by proof;
- c. Awarding Plaintiff and the Classes appropriate relief, including but not limited to actual damages;
- d. For declaratory and equitable relief, including restitution and disgorgement;
- e. For an order enjoining Defendants from continuing to engage in the wrongful acts and practices alleged herein;
- f. Awarding Plaintiff and the Classes the costs of prosecuting this action, including expert witness fees;
- g. Awarding Plaintiff and the Classes reasonable attorneys' fees and costs as allowable by law;
- h. Awarding pre-judgment and post-judgment interest; and
- i. Granting any other relief as this Court may deem just and proper.

# **JURY TRIAL DEMANDED**

Plaintiff hereby demands a trial by jury of all claims so triable.

Dated: April 10, 2024 Respectfully submitted,

#### LEVI & KORSINSKY, LLP

/s/ Mark S. Reich

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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>Acne Treatment Lawsuit Says Certain Proactiv Benzoyl Peroxide Products Contain Carcinogen Benzene</u>