UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK
WHITE PLAINS COURTHOUSE

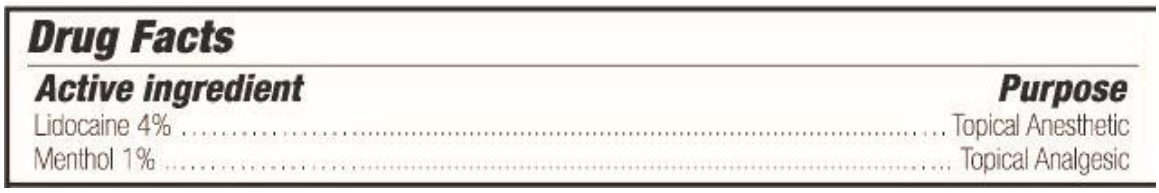
Katherine Barnes, individually and on behalf of all others similarly situated, Plaintiff, - against - Big Lots, Inc., Defendant	7:22-cv-09782 Class Action Complaint Jury Trial Demanded

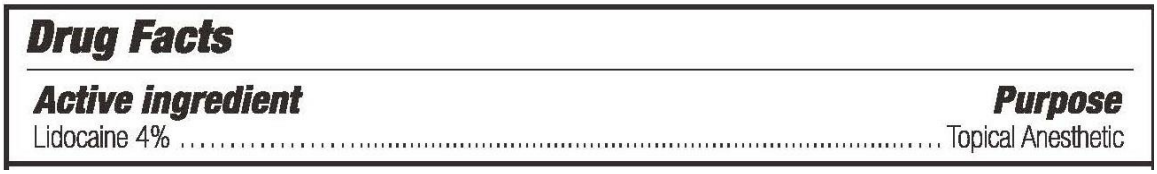
Plaintiff alleges on information and belief, except for allegations about Plaintiff, which are based on personal knowledge:

1. Big Lots, Inc. ("Defendant") markets, labels and sells regular and menthol adhesive lidocaine patches under the SoundBody brand ("Products").

2. The relevant common front label representations include "Fast Acting," "Lidocaine," "pain relieving ointment on a breathable adhesive pad," "For back, neck, leg & arm," formulated for "Maximum Strength," and a picture of a body with a patch applied to the upper back,

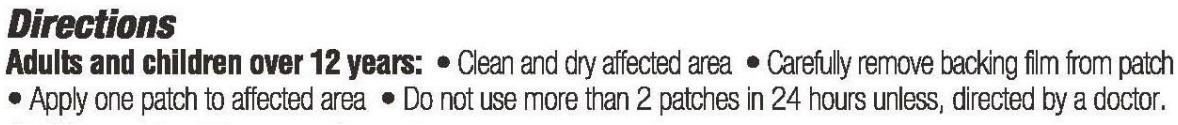
3. Each version contains "Lidocaine 4%," shown on the front label of the regular and back label Drug Facts for both regular and menthol.





4. While the front label of the regular describes it as a "Pain Relief Patch," the menthol version promises "Targeted Immediate Pain Relief" through "Desensitiz[ing] Aggravated Nerves" to provide "Long Lasting First Aid for Pain."

5. Both versions purport to be "long lasting," as indicated in their identical directions stating, "Do not use more than 2 patches in 24 hours unless, directed by a doctor."



I. PRODUCTS FAIL TO DELIVER LIDOCAINE IN PROMISED WAY

6. Lidocaine is a topical anesthetic used to treat pain by blocking the transmission of pain signals from nerve endings in the skin to the spinal cord and brain.

7. Although lidocaine patches can be prescribed by doctors, they are available to consumers as an over-the-counter ("OTC") product.

8. In 2003, the Food and Drug Administration ("FDA") initiated rulemaking to classify

products which delivered lidocaine through the skin in a patch form.

9. This was because there was no data on "[t]he safe and effective concentration" of lidocaine in this format, and uncertainties regarding the frequency of application that is considered safe and effective.

10. However, the FDA concluded that transdermal drug delivery systems, such as the patches used in the Products, systematically fail to adhere to the body.

11. The FDA Adverse Events Reporting System reports that approximately 70% of concerns stemming from lidocaine patches involve their poor adhesion.

12. A 2021 peer-reviewed study in the Journal of Pain Research found that approximately half of lidocaine patches promising adhesion for eight hours failed to completely adhere to the participant's skin for the entire time.

13. The study required that users be sedentary while the patches were applied, as they are prone to much greater detachment when engaging in regular activities such as walking, stretching, and sleeping.

14. However, lidocaine patch technology exists which can maintain adhesion for at least eight hours under regular conditions.

15. Although the study published by the Journal of Pain Research only tested generic prescription lidocaine patches, upon information and belief, the Products have not undergone the rigorous approval process required by the FDA and use the same outdated and defective adhesion technology as the lidocaine patches studied.

16. The claim that the Products provide "Pain relieving ointment on a breathable adhesive pad" is misleading because they regularly peel off skin within three to four hours, and sometimes in minutes, after being applied.

17. Consumers expect that when they are told the Products are "long lasting" (menthol) and directed to "not use more than 2 patches in 24 hours," the patches will adhere to their bodies for no less than twelve hours or even longer.

18. However, the Products cannot adhere to the skin for twelve hours, which renders the instructions to "not use more than 2 patches in 24 hours" misleading, because it assumes the patches will not have fallen off by then.

19. The result of the failure to adhere for twelve hours means that the Products cannot deliver the "Maximum Strength" amount of lidocaine.

20. The front label representation that the Products can provide "pain relief," coupled with the instructions implying the patches will adhere for twelve hours, is false and misleading given that the patches systematically fails to fully adhere to the bodies of users.

21. Moreover, the implication the Products will adhere for twelve hours is inconsistent with the "Uses" disclosed on the Drug Facts which indicates they can only "Temporarily relieve[s] minor pain," which consumers will understand as for a short time, not twelve hours.

II. MAXIMUM STRENGTH CLAIMS

22. The representations of "Maximum Strength" tells consumers the Products contain and deliver the maximum amount of lidocaine available in patch form and is superior or equivalent in efficacy and results to other OTC and prescription-strength lidocaine patches.

23. The representation of "Maximum Strength" is misleading because the actual strength of a lidocaine patch is measured by the "mass of drug relative to the mass of the adhesive per patch" delivered to the target area.

24. According to the FDA, when a patch delivering lidocaine becomes "partially

detached," its efficacy of delivery and absorption of the active ingredient is greatly reduced.

25. Since "[a]dequate adhesion is a critical quality attribute for topical delivery systems," if the patches lift or detach during wear such as walking, sleeping or exercising, dosing will be compromised.

26. Numerous studies and reports revealed that users of adhesive lidocaine patches seldom experience anything close to the promised hours of pain relief, because the patches fail to remain adhered for an extended period of time.

27. In contrast, newly developed 1.8% lidocaine patch technology, bioequivalent to 5% lidocaine patches, maintained a mean adhesion >90% across all time points (0, 3, 6, 9, and 12 h).

III. DESENSITIZING CLAIMS

28. The menthol product's promise to deliver "Targeted Immediate Pain Relief" by "Desensitiz[ing] Aggravated Nerves" is misleading because it implies application of the patch will completely block and numbs nerves and pain receptors, eliminate responses to painful stimuli, and can treat neuropathic and musculoskeletal pain, including back and spinal pain.

29. The FDA determined that statements about "desensitizing" in the context of pain and nerves are misleading to consumers in the context of transdermal patch delivery systems.

30. Consumers associate statements about "Desensitiz[ing] Aggravated Nerves" with medical treatments requiring a prescription and FDA approval, even though the menthol variety has neither.

31. The menthol's front label claim that it "Desensitizes Aggravated Nerves" is inconsistent with its limited approval, disclosed in the Drug Facts to "temporarily relieve[s] minor pain."

IV. CONCLUSION

32. Defendant makes other representations and omissions with respect to the Products which are false and misleading.

33. Had Plaintiff known the truth, she would not have bought the Products or would have paid less for it.

34. As a result of the false and misleading representations, the Products are sold at a premium price, approximately no less than no less than $1.29 per patch, excluding tax and sales, higher than similar products, represented in a non-misleading way, and higher than it would be sold for absent the misleading representations and omissions.

Jurisdiction and Venue

35. Jurisdiction is pursuant to Class Action Fairness Act of 2005 ("CAFA"). 28 U.S.C. § 1332(d)(2).

36. The aggregate amount in controversy exceeds $5 million, including any statutory damages, exclusive of interest and costs.

37. Plaintiff is a citizen of New York.

38. Defendant is an Ohio corporation with a principal place of business in Ohio.

39. The class of persons Plaintiff seeks to represent includes persons who are citizens of different states from which Defendant is a citizen.

40. The members of the class Plaintiff seeks to represent are more than 100, because the Products have been sold for several years, with the representations described here, in the hundreds of Defendant's stores and online, across the States covered by Plaintiff's proposed classes.

41. Venue is in this District with assignment to the White Plains Courthouse because a substantial part of the events or omissions giving rise to these claims occurred in Westchester

County and Rockland County, including Plaintiff's purchase, consumption, transactions and/or use of the Products and awareness and/or experiences of and with the issues described here.

Parties

42. Plaintiff Katherine Barnes is a citizen of Mount Vernon, Westchester County, New York.

43. Defendant Big Lots, Inc. is an Ohio corporation with a principal place of business in Columbus, Franklin County, Ohio.

44. Founded as Consolidated International, Inc. in 1967, Big Lots operates over 1,400 stores across 47 states.

45. While Big Lots sells leading national brands, they also sell a large number of products under one of their private label brands, SoundBody.

46. Private label products are made by third-party manufacturers and sold under the name of the retailer, or its sub-brands.

47. Previously referred to as "generic" or "store brand," private label products have increased in quality, and often are superior to their national brand counterparts.

48. Products under the SoundBody brand have an industry-wide reputation for quality and value.

49. In releasing products under the SoundBody brand, Defendant's foremost criteria was to have high-quality products that were equal to or better than the national brands.

50. Defendant is able to get national brands to produce its private label items due its loyal customer base and tough negotiating.

51. That SoundBody branded products met this high bar was proven by focus groups, which rated them above the name brand equivalents.

52. Private label products generate higher profits for retailers because national brands spend significantly more on marketing, contributing to their higher prices.

53. A survey by The Nielsen Co. "found nearly three out of four American consumers believe store brands are good alternatives to national brands, and more than 60 percent consider them to be just as good."

54. Private label products under the SoundBody brand benefit by their association with consumers' appreciation for the Big Lots brand as a whole.

55. The development of private label items is a growth area for Big Lots, as it selects only top suppliers to develop and produce SoundBody products.

56. Plaintiff purchased the Products at locations including Big Lots, 125 NY-59, Nanuet, NY 10954, between May 2020 and November 2022, among other times.

57. Plaintiff believed and expected the Products would reliably adhere to her body to deliver 4% lidocaine for not less than twelve hours, that they were the maximum strength available, would relieve pain, deliver immediate pain relief through desensitizing aggravated nerves (menthol), because that is what the representations and omissions said and implied, on the front label and the absence of any reference or statement elsewhere on the Products.

58. Plaintiff relied on the words, terms coloring, descriptions, layout, placement, packaging, and/or images on the Products, on the labeling, statements, omissions, claims, statements, and instructions, made by Defendant or at its directions, in digital, print and/or social media, which accompanied the Products and separately, through in-store, digital, audio, and print marketing.

59. Plaintiff bought the Products at or exceeding the above-referenced price.

60. Plaintiff paid more for the Products than she would have had she known the

representations and omissions were false and misleading, or would not have purchased it.

61. The value of the Products that Plaintiff purchased was materially less than its value as represented by Defendant.

62. Plaintiff chose between Defendant's Products and products represented similarly, but which did not misrepresent their attributes, features, and/or components.

Class Allegations

63. Plaintiff seeks certification under Fed. R. Civ. P. 23 of the following classes:

> **New York Class:** All persons in the State of New York who purchased the Products during the statutes of limitations for each cause of action alleged; and
>
> **Consumer Fraud Multi-State Class**: All persons in the States of Idaho, North Carolina, Nebraska, Kansas, Mississippi, Utah, Oklahoma, Wyoming, Tennessee, South Dakota, Virginia, Louisiana and West Virginia who purchased the Products during the statutes of limitations for each cause of action alleged.

64. Common questions of issues, law, and fact predominate and include whether Defendant's representations were and are misleading and if Plaintiff and class members are entitled to damages.

65. Plaintiff's claims and basis for relief are typical to other members because all were subjected to the same unfair, misleading, and deceptive representations, omissions, and actions.

66. Plaintiff is an adequate representative because her interests do not conflict with other members.

67. No individual inquiry is necessary since the focus is only on Defendant's practices and the class is definable and ascertainable.

68. Individual actions would risk inconsistent results, be repetitive and are impractical

to justify, as the claims are modest relative to the scope of the harm.

69. Plaintiff's counsel is competent and experienced in complex class action litigation and intends to protect class members' interests adequately and fairly.

New York General Business Law ("GBL") §§ 349 and 350

70. Plaintiff incorporates by reference all preceding paragraphs.

71. Plaintiff believed the Products would reliably adhere to her body and provide a continuous dose of maximum strength lidocaine to desensitize nerves.

72. Defendant's false, misleading and deceptive representations and omissions are material in that they are likely to influence consumer purchasing decisions.

73. Plaintiff would not have purchased the Products or paid as much if the true facts had been known, suffering damages.

Violation of State Consumer Fraud Acts
(Consumer Fraud Multi-State Class)

74. The Consumer Fraud Acts of the States in the Consumer Fraud Multi-State Class are similar to the consumer protection statute invoked by Plaintiff and prohibit the use of unfair or deceptive business practices in the conduct of commerce.

75. The members of the Consumer Fraud Multi-State Class reserve their rights to assert their consumer protection claims under the Consumer Fraud Acts of the States they represent and/or the consumer protection statute invoked by Plaintiff.

76. Defendant intended that members of the Consumer Fraud Multi-State Class would rely upon its deceptive conduct, which they did, suffering damages.

Breaches of Express Warranty,
Implied Warranty of Merchantability/Fitness for a Particular Purpose
and Magnuson Moss Warranty Act, 15 U.S.C. §§ 2301, *et seq*.

77. The Products were manufactured, identified, marketed and sold by Defendant and

expressly and impliedly warranted to Plaintiff that they would reliably adhere to her body and provide a continuous dose of maximum strength lidocaine to desensitize nerves.

78. Defendant directly marketed the Products to Plaintiff through its advertisements and marketing, through various forms of media, on the packaging, in print circulars, direct mail, product descriptions distributed to resellers, and targeted digital advertising.

79. Defendant knew the product attributes that potential customers like Plaintiff were seeking and developed its marketing and labeling to directly meet those needs and desires.

80. Defendant's representations about the Products were conveyed in writing and promised it would be defect-free, and Plaintiff understood this meant that they would reliably adhere to her body and provide a continuous dose of maximum strength lidocaine to desensitize nerves.

81. Defendant's representations affirmed and promised that the Products would reliably adhere to her body and provide a continuous dose of maximum strength lidocaine to desensitize nerves.

82. Defendant described the Products so Plaintiff believed that they would reliably adhere to her body and provide a continuous dose of maximum strength lidocaine to desensitize nerves, which became part of the basis of the bargain that it would conform to its affirmations and promises.

83. Defendant had a duty to disclose and/or provide non-deceptive descriptions and marketing of the Products.

84. This duty is based on Defendant's outsized role in the market for this type of Products, a trusted company known for its high-quality SoundBody products.

85. Plaintiff recently became aware of Defendant's breach of the Products' warranties.

86. Plaintiff provided or provides notice to Defendant, its agents, representatives, retailers, and their employees that it breached the Products' warranties.

87. Defendant received notice and should have been aware of these issues due to complaints by third-parties, including regulators, competitors, and consumers, to its main offices, and by consumers through online forums.

88. The Products did not conform to its affirmations of fact and promises due to Defendant's actions.

89. The Products were not merchantable because they were not fit to pass in the trade as advertised, not fit for the ordinary purpose for which it was intended and did not conform to the promises or affirmations of fact made on the packaging, container or label, because they were marketed as if they would reliably adhere and provide a continuous dose of maximum strength lidocaine to desensitize nerves.

90. The Products were not merchantable because Defendant had reason to know the particular purpose for which the Products were bought by Plaintiff, because she expected they would reliably adhere to her body and provide a continuous dose of maximum strength lidocaine to desensitize nerves, and she relied on Defendant's skill and judgment to select or furnish such a suitable product.

Unjust Enrichment

91. Defendant obtained benefits and monies because the Products were not as represented and expected, to the detriment and impoverishment of Plaintiff and class members, who seek restitution and disgorgement of inequitably obtained profits.

Jury Demand and Prayer for Relief

Plaintiff demands a jury trial on all issues.

WHEREFORE, Plaintiff prays for judgment:

1. Declaring this a proper class action, certifying Plaintiff as representative and the undersigned as counsel for the class;
2. Awarding monetary, statutory and/or punitive damages and interest;
3. Awarding costs and expenses, including reasonable fees for Plaintiff's attorneys and experts; and
4. Other and further relief as the Court deems just and proper.

Dated: November 16, 2022

Respectfully submitted,

/s/ Spencer Sheehan

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ClassAction.org