IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

Edward Fuller, individually and on behalf of all others similarly situated, Plaintiff, - against - Chattem, Inc., Defendant	Case No. 7:21-cv-03386 Class Action Complaint Jury Trial Demanded

Plaintiff alleges upon information and belief, except for allegations pertaining to plaintiff, which are based on personal knowledge:

1. Chattem, Inc. ("defendant") manufactures, distributes, markets, labels and sells over-the-counter ("OTC") external analgesic patches with an active ingredient of lidocaine, under the IcyHot brand ("Product").

2. The representations of the Product are false, misleading and deceptive to consumers.

I. FDA Regulations

3. Lidocaine is a topical anesthetic used to treat pain by depressing sensory receptors in the nerve endings in the skin, which prevents pain signals from reaching the brain.

4. Lidocaine has been approved for use by the FDA since the early 1950s.

5. FDA regulates products containing lidocaine through "OTC Monographs."

6. The 1983 Tentative Final Monography for External Analgesic Drug Products for Over-the-Counter Human Use, ("TFM"), provides guidelines for labeling OTC products containing between 0.5% to 4% lidocaine.[1]

[1] 48 Fed. Reg. 5852-01 (Feb. 8, 1983).

7. Lidocaine is permitted for use as an active ingredient for only the temporary relief of pain and itching associated with minor burns, sunburn, minor cuts, scrapes, insect bites or minor skin irritations. *Id*. at 5863.

8. In its 2003 proposed rule, the FDA proposed adding the following language to the TFM for external analgesic products until the FDA could determine whether patches containing analgesic ingredients, such as lidocaine, were "generally recognized as safe and effective" ("GRASE").[2] (emphasis added).

9. Around 2003, the FDA initiated rulemaking to classify products which delivered lidocaine in a patch form.[3]

10. 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.

11. The FDA proposed categorizing external analgesic patches as Category III products, that require agency review and approval of the product and its labeling through a New Drug Application ("NDA") or Abbreviated New Drug Application ("ANDA").[4]

II. Defendant's Misleading representations

12. Defendant's Icy Hot Patches contain 4% lidocaine by weight and are marketed as compliant with FDA regulations for Category I products, based on the numerous claims with respect to the Product's functions.

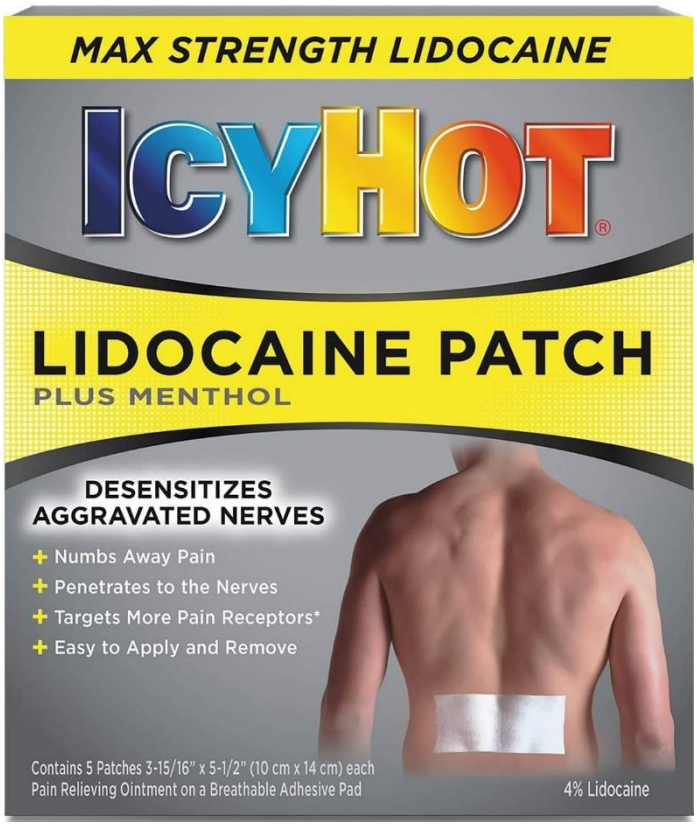
[2] 68 Fed. Reg. 42324-01, 42325-26 (July 17, 2003).
[3] *See* External Analgesic Drug Products for Over-the-Counter Human Use; Reopening of the Administrative Record and Amendment of Tentative Final Monograph, 68 Fed. Reg. 42324-01, 42326 (July 17, 2003).
[4] Category I products are considered "GRASE" and can be marketed without approvals required for Category III.

13. However, the Product does not comply with the TFM requirements for Category I ingredients and has not undergone any review process for products containing Category III ingredients.

14. No independent, credible studies support the claims made in support of the Product.

15. Moreover, the FDA has recognized that several of the claims of the type made by defendant are misleading to consumers.

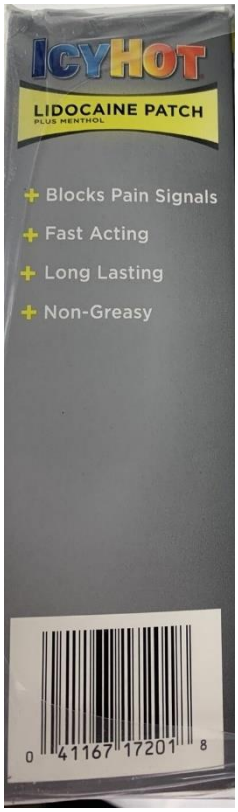
16. These include the front label statements, "MAX STRENGTH LIDOCAINE" and "DESENSITIZES AGGRAVATED NERVES."



17. The front label also states: "Numbs Away Pain," "Penetrates to the Nerves," "Targets More Pain Receptors*" and "Easy to Apply and Remove."

18. The lower right corner of the label indicates the Product contains "4% Lidocaine."

19. The side panel states, "Blocks Pain Signals," "Fast Acting" and "Long Lasting."



20. Defendant has run non-stop commercials featuring ex-NBA star Shaquille O'Neal touting all the above claims about the Product since the Product's release in 2016.

21. Defendant has even used Mr. O'Neal to promote the Product as an alternative to dangerous and addictive opioids – "1 out of 12 High School Athletes Have Abused Painkillers."

A. Max Strength and Fast Acting Claims

22. The Product's "*MAX STRENGTH LIDOCAINE*" claim is misleading because it implies it contains and delivers the maximum amount of lidocaine in patch form to the affected area.

23. However, this is false because other patch products deliver more lidocaine to affected areas, are more effective, are approved by the FDA for more purposes than defendant's Product and are supported by clinical studies.

24. The "fast acting" claim is misleading because it implies the Product provides immediate pain relief when it does not.

25. The Product uses a thicker patch than similar products, resulting in a less effective and slower delivery of lidocaine to the affected area.

B. "Continuously Relieve Pain" Claims

26. The Product claims to be "Long Lasting" (side panel) and indicates to only "use 1 patch for up to 12 hours" (Drug Facts).


Directions
adults and children over 12 years: ■ clean and dry affected area
■ remove backing from patch by firmly grasping both ends and gently pulling until backing separates in middle
■ carefully remove smaller portion of backing from patch and apply exposed portion of patch to affected area
■ once exposed portion of patch is positioned, carefully remove remaining backing to completely apply patch to affected area
■ use 1 patch for up to 12 hours

27. These statements and the representations, such as "COMFORTABLE FABRIC STAYS IN PLACE," tells consumers the Product will adhere to their body and continuously relieve pain for the specified amount of time – 12 hours.

28. However, numerous studies and reports revealed that users of the Product seldom experience anything close to 12 hours of relief, because the patch fails to adhere for even six hours.

29. 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.

C. "Numb" or "Completely Block Pain" Claims

30. The claims that the Product "Blocks Pain Signals" and "Numbs Away Pain" falsely imply the Product completely blocks pain receptors, eliminates responses to painful stimuli and provides a numbing sensation.

31. These statements are misleading to consumers because whether a product such as IcyHot is capable of these effects depends on the how they are used.[5]

[5] FDA concluded that "[c]laims regarding numbness or similar claims, such as completely blocking pain receptors or abolishing responses to painful stimuli, may be misleading to consumers because the manner in which external analgesic drug products are used determines whether they cause numbness or not." Id.

32. Additionally, the FDA determined that statements such as "numb[] away pain" on external analgesic products like Icy Hot are misleading because these products lack the ability to perform this function.

D. "Desensitizes Nerves" and "Targets More Pain Receptors"

33. The label and commercials claim the Product "Targets More Pain Receptors, ""DESENSITIZES AGGRAVATED NERVES" and "DESENSITIZES NERVES." *See image of patch adhering to person's back.*

34. These representations imply that the Product provides pain relief by desensitizing nerves and/or pain receptors.

35. Consumers understand these representations to mean the Product contains ingredients that target nerves and pain receptors when it does not.

36. Since "nerves" and "pain receptors" are associated by consumers with medical treatments typically requiring a prescription and approval by the FDA, seeing these claims tells them the Icy Hot patch can achieve these results.

37. However, the FDA prohibits external analgesic products containing lidocaine from claiming they "completely block pain receptors" because this is misleading to consumers.[6]

E. Misleading as to Product's Indications

38. The representations indicate the Product provides "Targeted Relief" for "Back," "Neck," "Leg" and "Arm" pain.

39. The Product's website states that it "Temporarily relieves pain caused by back" and "neck" [issues"] and is "designed to work on muscle aches, strains, sprains, simple backache, and bruises."

40. These representations give consumers the impression that the Product can treat neuropathic and musculoskeletal pain, including back and spinal pain.

[6] 48 Fed. Reg. 5852-01, 5860-61 (Feb. 8, 1983).

41. However, products such as Icy Hot Patches, which contain 4% or less of lidocaine, are only authorized for "temporary relief" of "pain," "itching," or "pain and itching" "associated with" "minor burns," "sunburn," "minor cuts," "scrapes," "insect bites," or "minor skin irritations."[7]

42. However, the front and back of the Product fail to indicate it should only be used for "minor burns," "sunburn," "minor cuts," "scrapes," "insect bites," or "minor skin irritations," which is what it is approved by the FDA for.

Warnings

For external use only

Do not use

- more than 1 patch on your body at a time or on cut, irritated or swollen skin
- on puncture wounds
- for more than one week without consulting a doctor

When using this product

- use only as directed. Read and follow all directions and warnings on this carton.
- rare cases of serious burns have been reported with products of this type
- do not apply to wounds or damaged, broken or irritated skin
- do not allow contact with the eyes and mucous membranes
- do not bandage tightly or apply local heat (such as heating pads) to the area of use
- do not use at the same time as other topical analgesics
- dispose of used patch in manner that always keeps product away from children and pets. Used patches still contain the drug product that can produce serious adverse effects if a child or pet chews or ingests this patch.

Stop use and ask a doctor if

- condition worsens
- redness is present
- irritation develops
- symptoms persist for more than 7 days or clear up and occur again within a few days
- you experience signs of skin injury, such as pain, swelling, or blistering where the product was applied

43. The only mention of "burns" and "irritations" is with respect to the Product's warnings.

III. Conclusion

44. Reasonable consumers must and do rely on defendant to honestly describe the components and features of the Product, relative to itself and other comparable products.

45. Plaintiff did not scrutinize the drug facts nor was he required to do so.

46. Even if Plaintiff did scrutinize the drug facts, it would not cure the

[7] 48 Fed. Reg. 5852-01, 5868 (Feb. 8, 1983).

misrepresentations.

47. Defendant misrepresented the Products through affirmative statements, half-truths, and omissions.

48. Defendant sold more of the Product and at a higher price than it would have in absence of this misconduct, resulting in additional profits at the expense of consumers.

49. Had plaintiff and the proposed class members known the truth, they would not have bought the Product or would have paid less for it.

50. Plaintiff paid more for the Product based on the representations it contained appreciable amounts of real lemons and real raspberries.

51. As a result of the false and misleading representations, the Product is sold at a premium price, approximately no less than no less than $1.79 for 33.8 OZ, excluding tax, compared to other 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

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

53. Plaintiff Edward Fuller is a citizen of New York.

54. Defendant Chattem, Inc. is a Tennessee corporation with a principal place of business in Chattanooga, Hamilton County, Tennessee.

55. Diversity exists because plaintiff Edward Fuller and defendant are citizens of different states.

56. Upon information and belief, sales of the Product and any available statutory and other monetary damages, exceed $5 million during the applicable statutes of limitations, exclusive

of interest and costs.

57. Venue is proper because a substantial part of the events or omissions giving rise to the claim occurred here – plaintiff's purchase of the Product.

58. Venue is further supported because many class members reside in this District.

Parties

59. Plaintiff Edward Fuller is a citizen of Tomkins Cove, Rockland County, New York.

60. Defendant Chattem, Inc. is a Tennessee corporation with a principal place of business in Chattanooga, Tennessee, Hamilton County.

61. Defendant markets, distributes, and sells the IcyHot Lidocaine Patch through drug stores, mass retailers, and online retailers.

62. Plaintiff bought the Product on one or more occasions within the statute of limitations for each cause of action alleged, from one or more locations, including ShopRite of Stony Point at 22 Holt Dr, Stony Point, NY 10980, between March and April 2021.

63. Plaintiff bought the Product at or exceeding the above-referenced price because he wanted to buy a product with the qualities and attributes represented herein and relied upon what the label and other representations indicated and/or omitted.

64. Plaintiff would not have purchased the Product in the absence of Defendant's misrepresentations and omissions.

65. The Product was worth less than what Plaintiff paid and he would not have paid as much absent Defendant's false and misleading statements and omissions.

66. Plaintiff intends to, seeks to, and will purchase the Product again when he can do so with the assurance that Product's labeling is consistent with its composition.

Class Allegations

67. The class will consist of all purchasers of the Product who reside in New York, during the applicable statutes of limitations.

68. Plaintiff seeks class-wide injunctive relief based on Rule 23(b) in addition to a monetary relief class.

69. Common questions of law or fact predominate and include whether defendant's representations were and are misleading and if plaintiff and class members are entitled to damages.

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

71. Plaintiff is an adequate representative because his interests do not conflict with other members.

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

73. 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.

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

75. Plaintiff seeks class-wide injunctive relief because the practices continue.

New York General Business Law ("GBL") §§ 349 & 350
(Consumer Protection Statutes)

76. Plaintiff incorporates by reference all preceding paragraphs.

77. Plaintiff and class members desired to purchase products with the attributes highlighted by the labeling and marketing – representing to current and potential consumers that the products are approved by the FDA for treatment of nerve and neuropathic pain, including back

and spinal pain.

78. The representations are material because they influence purchasing decisions.

79. Defendants' false and deceptive advertising statements and claims are material in that they are likely to influence consumer purchasing decisions.

80. Defendant's acts and omissions are not unique to the parties and have a broader impact on the public.

81. Defendant misrepresented the Product through its statements, omissions, ambiguities, half-truths and/or actions.

82. Defendant intended that Plaintiff rely upon Defendant's deceptive conduct.

83. Defendant knew or should have known that its representations about the Product's components and qualities were material and likely to mislead consumers.

84. Plaintiff and class members would not have purchased the Product or paid as much if the true facts had been known, suffering damages.

Breaches of Express Warranty, Implied Warranty of Merchantability and Magnuson Moss Warranty Act, 15 U.S.C. §§ 2301, *et seq.*

85. Plaintiff incorporates by reference all preceding paragraphs.

86. The Product was manufactured, labeled and sold by defendant and warranted to plaintiff and class members that it possessed functional, neuropathic, medical and other qualities which it did not.

87. The presence or absence of the relevant abilities of the Product was expressly and impliedly warranted to Plaintiff and others.

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

89. This duty is based on Defendant's outsized role in the market for this type of Product – custodian of one of the most respected brands in the external analgesic industry and the most well-known, based primarily on its spokesperson, all-time great NBA player Shaquille O'Neal.

90. Plaintiff provided or will provide notice to defendant, its agents, representatives, retailers and their employees.

91. Defendant received notice and should have been aware of these misrepresentations due to complaints by regulators, competitors and consumers to its main office over the past several years.

92. The Product did not conform to its affirmations of fact and promises due to defendant's actions and were not merchantable because they were not fit to pass in the trade as advertised.

93. Plaintiff and class members would not have purchased the Product or paid as much if the true facts had been known, suffering damages.

Negligent Misrepresentation

94. Plaintiff incorporates by reference all preceding paragraphs.

95. Defendant had a duty to truthfully represent the Product, which it breached.

96. This duty is based on defendant's position, holding itself out as having special knowledge and experience in the sale of the product type.

97. The representations took advantage of consumers' cognitive shortcuts made at the point-of-sale and their trust in defendant, a well-known and respected brand or entity in this sector.

98. Plaintiff and class members reasonably and justifiably relied on these negligent misrepresentations and omissions, which served to induce and did induce, their purchase of the Product.

99. Plaintiff and class members would not have purchased the Product or paid as much if the true facts had been known, suffering damages.

Fraud

100. Defendant misrepresented and/or omitted the attributes and qualities of the Product.

101. Defendant's fraudulent intent is evinced by its failure to accurately disclose the issues described herein, when it knew not doing so would mislead consumers.

102. Plaintiff and class members would not have purchased the Product or paid as much if the true facts had been known, suffering damages.

Unjust Enrichment

103. Plaintiff incorporates by reference all preceding paragraphs.

104. Defendant obtained benefits and monies because the Product was 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. Entering preliminary and permanent injunctive relief by directing defendant to correct the challenged practices to comply with the law;
3. Injunctive relief to remove, correct and/or refrain from the challenged practices and representations, and restitution and disgorgement for members of the class pursuant to the applicable laws;
4. Awarding monetary damages, statutory damages pursuant to any statutory claims and

interest pursuant to the common law and other statutory claims;

5. Awarding costs and expenses, including reasonable fees for plaintiff's attorneys and experts; and

6. Other and further relief as the Court deems just and proper.

Dated: April 16, 2021

Respectfully submitted,

Sheehan & Associates, P.C.
/s/Spencer Sheehan
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- against -

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Defendant

Class Action Complaint

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Pursuant to 22 NYCRR 130-1.1, the undersigned, an attorney admitted to practice in the courts of New York State, certifies that, upon information, and belief, formed after an inquiry reasonable under the circumstances, the contentions contained in the annexed documents are not frivolous.

Dated: April 16, 2021

/s/ Spencer Sheehan
Spencer Sheehan