IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

Sherry Cruz, individually and on behalf of all others similarly situated, Plaintiff, - against - Sanofi US Corporation, Defendant	1:21-cv-02351 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. Sanofi US Corporation ("defendant") manufactures, markets and sells over-the-counter ("OTC") external analgesic patches with an active ingredient of lidocaine (4%), under the Aspercreme brand ("Product").

I. Lidocaine in OTC Products

2. 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.

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

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

5. 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).

6. 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.[2]

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

8. 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.

9. 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

10. Defendant's Product contains 4% lidocaine and is marketed as compliant with FDA regulations for Category I products, based on the numerous claims with respect to the Product's functions.

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

[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.

12. The Product's front label focuses on its ability to "numb" and affect "nerves."

- MAX STRENGTH
- NUMBS AWAY PAIN
- FAST ACTING
- TARGETS NERVES
- Flexible Fabric

- MAX STRENGTH LIDOCAINE
- NUMBS AWAY PAIN
- Desensitizes Aggravated Nerves
- FAST ACTING
- Targets More Pain Receptors*
- Non Irritating

13. The lidocaine percentage is indicated in the fine print, next to "LIDOCAINE" or in the lower right corner of the label.

14. The side panels indicate "Targeted Relief" for the main joint areas.

- Targeted No Mess Relief
- Easy to Apply & Remove
- Flexible Fabric

- TARGETED RELIEF
- BACK, NECK & SHOULDER
- KNEE & ELBOW
- HAND & WRIST
- FOOT, ANKLE & LEG

A. Max Strength and Fast Acting Claims

15. The "Max Strength" claims are misleading because it implies the Product contains and delivers the maximum amount of lidocaine in patch form to the affected area.

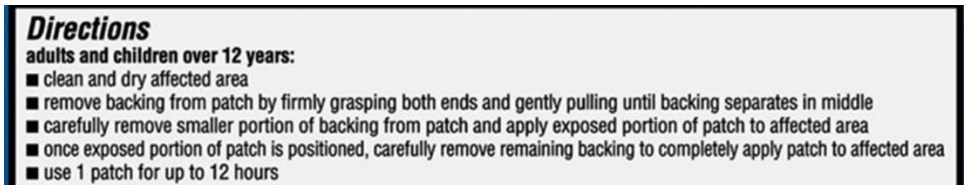
16. However, this is false because other patch products deliver more lidocaine to affected areas, are more effective, are approved by the FDA for more purposes than defendant's Product and are supported by clinical studies.

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

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

B. "12 hours" Claim

19. The Directions on the Drug Facts state to "use 1 patch for up to 12 hours."


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

20. The other representations, such as "FLEXIBLE FABRIC," "Easy to Apply & Remove," and "Non Irritating," further the impression that the Product will adhere to the body and continuously relieve pain for the promised amount of time – 12 hours.

21. 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.

22. 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

23. The claim that the Product "NUMBS AWAY PAIN" falsely imply the Product completely blocks pain receptors, eliminates responses to painful stimuli and provides a numbing sensation.

24. These statements are misleading to consumers because whether a lidocaine patch like the Product is capable of these effects depends on the how it is 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.

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