Lanham Act and Other Private Actions

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FDLI Advertising & Promotion
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The Problem: Unlevel Playing Fields

- FDA has a daunting task
  - FDA-regulated products account for 25¢ of every dollar spent by consumers annually
- FDA has inadequate resources to police all FDCA violators
- When a competitor violates the law, it can
  - Jeopardize law-abiding companies' ability to recoup investment
  - Put the public at risk

Traditional Strategies Often Inadequate

- CPs cannot be used to request enforcement actions
  - CPs can ask FDA to issue, amend, or revoke, a regulation or order, or to take or refrain from taking any other "administrative action"
  - "Administrative actions" do not include "enforcement actions" – 21 C.F.R. §§ 10.30(k), 10.25(a), 10.3
- Trade complaints often do not work
  - FDA has competing priorities and often focuses on violations that present the largest risks to public health
  - FDA "*is treading lightly in its enforcement of advertising regulations because of First Amendment concerns*." Pink Sheet, 9/23/18 (citing Dr. Woodcock)

POM Wonderful v. Coca-Cola Co.

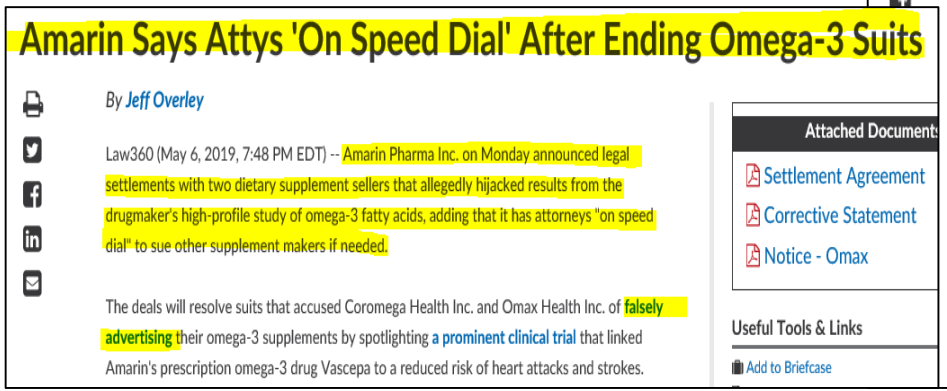
- Holding:
  - FDCA does not preclude a private party from bringing a Lanham Act claim in district court challenging a misleading food label regulated under the FDCA. *POM Wonderful LLC v. Coca-Cola Co.*, 134 S.Ct. 2228, 2241 (2014)
- Impact:
  - Lanham Act challenges are now being brought for more than just false/ misleading statements about competitor's products

Competitors Are Taking Matters Into Their Own Hands

Amarin Seeks ITC Action Against Products 'Cloaked' As Dietary Supplements

Going After Those Whose Don't 'Play By The Rules'

30 Aug 2017 | NEWS



Amarin Says Attys 'On Speed Dial' After Ending Omega-3 Suits

By *Jeff Overley*

Law360 (May 6, 2019, 7:48 PM EDT) -- Amarin Pharma Inc. on Monday announced legal settlements with two dietary supplement sellers that allegedly hijacked results from the drugmaker's high-profile study of omega-3 fatty acids, adding that it has attorneys "on speed dial" to sue other supplement makers if needed.

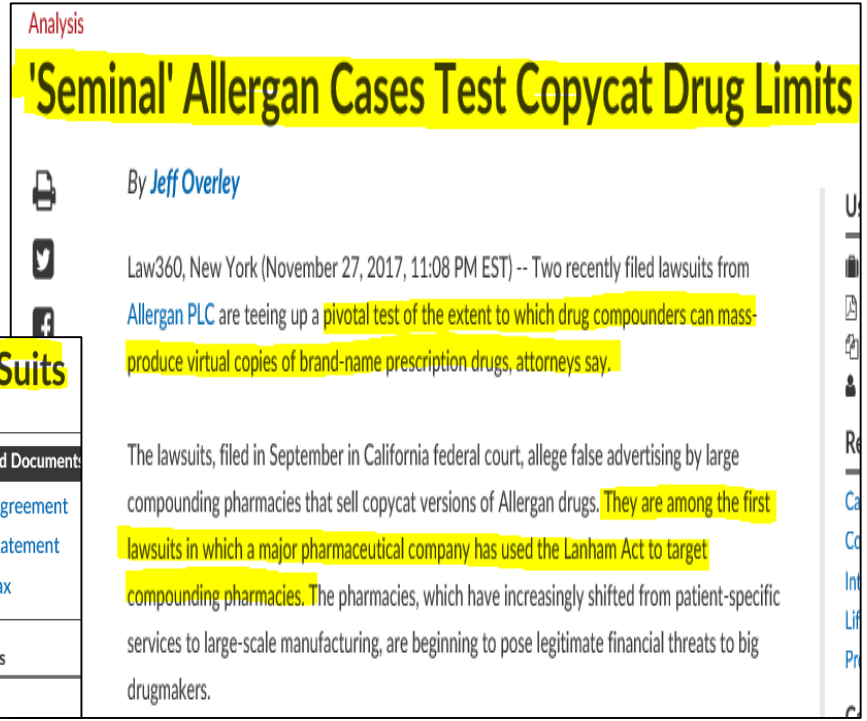
The deals will resolve suits that accused Coromega Health Inc. and Omax Health Inc. of falsely advertising their omega-3 supplements by spotlighting a prominent clinical trial that linked Amarin's prescription omega-3 drug Vascepa to a reduced risk of heart attacks and strokes.

Attached Documents

- Settlement Agreement
- Corrective Statement
- Notice - Omax

Useful Tools & Links

Add to Briefcase



Analysis

'Seminal' Allergan Cases Test Copycat Drug Limits

By *Jeff Overley*

Law360, New York (November 27, 2017, 11:08 PM EST) -- Two recently filed lawsuits from Allergan PLC are teeing up a pivotal test of the extent to which drug compounders can mass-produce virtual copies of brand-name prescription drugs, attorneys say.

The lawsuits, filed in September in California federal court, allege false advertising by large compounding pharmacies that sell copycat versions of Allergan drugs. They are among the first lawsuits in which a major pharmaceutical company has used the Lanham Act to target compounding pharmacies. The pharmacies, which have increasingly shifted from patient-specific services to large-scale manufacturing, are beginning to pose legitimate financial threats to big drugmakers.

FDA/HHS (Sometimes) Have Encouraged Lawsuits

FDA

Advertising Enforcement: US FDA Content To Let Competitors 'Duke It Out,' Woodcock Says

23 Sep 2018 | ANALYSIS

by Derrick Gingery

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Executive Summary

Office of Prescription Drug Promotion is focused on most egregious issues where human safety is at stake; CDER's Woodcock also says that First Amendment issues are affecting enforcement.

HHS

Trump Administration's Rx Drug Price Disclosure Reg Seen As Unworkable

21 Oct 2018 | ANALYSIS

by Brenda Sandburg

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A striking feature of the proposed rule is the virtual absence of any penalty for non-compliance,

CMS says no other HHS-specific enforcement mechanism is proposed in the rule. "However, we anticipate that the primary enforcement mechanism will be the threat of private actions under the Lanham Act" for unfair competition in the form of false or misleading advertising, the rule says.

Pros/Cons of Private Actions

- Pros
  - Tool to stop unfair practices
  - Injunction can minimize impact of defendant's unfair practice on business
  - Can send a strong message to other competitors
  - Can send a message to payors

- Cons
  - Litigation can be resource-intensive and protracted
  - May not be cost-effective to seek more than nominal damages
  - Not a silver bullet
  - May trigger counter-claims

Lanham Act v. FDA Standards

Lanham Act v. FDA Standards: The Basics

Lanham Act

- False or Misleading
- Commercial advertisement
- Actual deception or capacity to deceive
- Material
- Written and oral statements

FDA Promotional Standards

- False and Misleading
- Promotion
- Substantial evidence
- On Label v. Off-label
  - FDA Approval
  - Consistent with FDA Labeling (CFL) Guidance
- Written and oral statements

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Lanham Act v. FDA Standards: Key Questions

- Which standard is the “floor”?
  - Can you comply with FDA standards and still be subject to a Lanham Act claim?
  - Is every violation of FDA standards actionable as a Lanham Act claim?
- Can you have claims based on “omissions” rather than “affirmative statements”?
- If it’s wrong, is that enough?

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Lanham Act v. FDA: Key Considerations

- Compliance with FDA standards
- Type of Claim at issue
- Evidence of Injury
- Approaches to Resolve
  - Cease and Desist Letter
  - Competitor Complaint
  - FDA Complaint
  - Counter-Statements
  - Litigation

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Lanham Act Defenses

- No private right of action
- Preclusion
- Primary jurisdiction
- First Amendment (is it even advertising?)
- Who is the audience? Who is deceived?
- Puffery

Lanham Act Remedies

- Injunctive relief
- Monetary damages (profits/ damages/ exemplary award)
- Defendant issues corrective advertising
- Costs of Plaintiff's corrective advertising
- Costs of the action
- Reasonable attorneys' fees (exceptional cases)

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Lanham Act Trends

Key Types of Claims

- Unapproved drugs and devices
- “Generic” drugs
- Therapeutic equivalence
- Linking in pricing databases
- Claims relating to scientific studies (“tests show”)

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National Advertising Division

What is NAD?

- Voluntary industry self-regulation for over 40 years.
- Mission: To protect the **integrity** and **credibility** of advertising by ensuring that claims are **truthful** and **accurate**, and to preserve "**fair play**" between competitors.

BBB National Programs, Inc.

What is NAD?

- Cost effective, (relatively) quick, confidential alternative to litigation.
- Initial burden on the advertiser. No discovery.
- NAD makes recommendations about advertising, it does not make findings of wrongdoing or provide compensation or restitution.
- Because no compensation, materiality is less of an issue than in Lanham Act litigation.
- Decisions are published at: http://case-report.bbb.org/Search/LatestCases (subscription required).

BBB National Programs, Inc.

NAD and Disputes Over Regulated Products

- NAD regularly handles disputes over the advertising of FDA-regulated products, including food labeling and advertising, OTC drugs, medical devices and dietary supplements.
- Often deal with nutrition content claims, comparative and monadic efficacy claims, health benefit claims, and other advertising issues.
- CRN/NAD Initiative: Launched in 2006 to promote self-regulation of dietary supplement industry and increase consumer confidence in industry advertising. Result has been hundreds of cases initiated by NAD, CRN and competitors.
- Do not generally apply "structure/function claim" analysis—if it is a health-related claim, we seek competent and reliable scientific evidence as support.

BBB National Programs, Inc.

The Procter & Gamble Company (Pepto Bismol Ultra), Report #6307, *NAD/CARU Case Reports* (September 2019)

- Challenge Claims: “Ultra Coat” and “2x Strength per ounce.”
- Product had increased concentration for smaller dose, but not more efficacy per dose.
- NAD found that to consumers may reasonably understand the “2x” claim to mean superior efficacy per dose and were unlikely to reference back to the Pepto Original label for reference.
- “Ultra Coat” in this context was not puffery. Viscosity data was not necessarily indicative of superior coating action.
- NAD recommended that both claims be discontinued.

NAD and Disputes Over Regulated Products

- How NAD treats FDA regulatory guidance:

> "Generally NAD seeks to harmonize its efforts with the relevant regulatory guidance. NAD accords great weight to FDA regulations to ensure that advertisers are held to consistent standards ... NAD's role is not to enforce regulations blindly but rather to consider them when evaluating the messages reasonably conveyed by adverting claims."

The Kraft Heinz Company (Kraft Salad Dressings), Report #6035, *NAD/CARU Case Reports* (December 2016)

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NAD and Disputes Over Regulated Products

Some limitations on NAD jurisdiction over regulated products:

- NAD does not review language "mandated or expressly approved by federal law or regulation." See, NAD Policy & Procedures § 2.2(B)(6). The rule was designed to avoid a situation where a claim required or expressly approved by a law or regulation could be rejected by NAD as unsupported.

- NAD only has jurisdiction over "national advertising," defined as a having "the purpose of inducing a sale or other commercial transaction or persuading the audience of the value or usefulness of [a product]." See NAD Policy & Procedure § 1.1(A).

- This balancing act can be tricky, a case example . . .

BBB National Programs, Inc.

Oatly, Inc. (Oatmilk Products), Report #6287, *NAD/CARU Case Reports* (June 2019)

- Competitor challenged various “No added sugar” claims. Oatmilk sugars were created *in situ*.
- NAD declined jurisdiction over the “0g Added Sugar” statement on the Nutrition Facts Panel. Not advertising.
- NAD retained jurisdiction over the front of label claim. In that context, NAD found the no added sugar claim unsupported. NAD did not determine whether the advertiser was in compliance with FDA rules.

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