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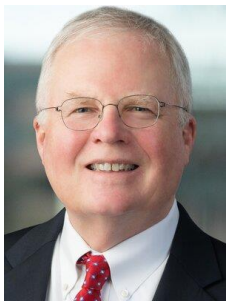
What's At Play In Rising Lanham Act Cases At The ITC

By **Brian Busey and Maryrose McLaughlin** (March 11, 2024, 6:12 PM EDT)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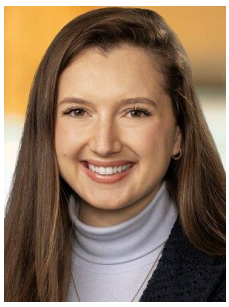

Maryrose McLaughlin

Intellectual property practitioners recognize that most claims in Section 337 investigations at the U.S. International Trade Commission involve patent infringement or other statutory IP claims.

Recently, however, there has been a noticeable increase in Lanham Act claims involving false advertising or false designation of origin. The focus of these recent claims relates to drug and medical devices.

Although Section 337 singles out protection of statutory IP such as patents, registered trademarks and registered copyrights, a separate, often overlooked part of the statute — Title 19 of the U.S. Code, Section 1337(a)(1)(A) — is extremely broad and applies to any "unfair methods of competition and unfair acts in the importation of articles."

This portion of the statute authorizes claims of trade secret misappropriation, antitrust violations and gray market, as well as false advertising under the Lanham Act.

This article discusses the requirements for Lanham Act claims at the ITC, reviews recent false advertising cases involving medical-related products, explores possible limits on such claims under the Federal Food, Drug, and Cosmetic Act, and outlines practical issues practitioners face in bringing and defending such cases at the ITC.

Requirements for a Lanham Act False Advertising Claim at the ITC

Complainants asserting a false advertising claim must satisfy the elements of the Lanham Act and Section 337.[1] The commission's investigative staff in the matter of Certain Clidinium Bromide and Products Containing Same — Investigation No. 337-TA-1109 — discussed these requirements in a 2018 written submission on domestic industry in false advertising investigations.[2]

The staff noted that the Lanham Act requires a complainant to show:

(1) that the defendant made a false or misleading statement of fact about a product;

(2) that the deception was material, in that it was likely to influence the consumers' purchasing decisions;

(3) that the statement either deceived or had the capacity to deceive a substantial number of potential customers;

(4) that the product was in interstate commerce; and

(5) that the plaintiff has been or is likely to be injured as a result of a false or misleading statement of fact.[3]

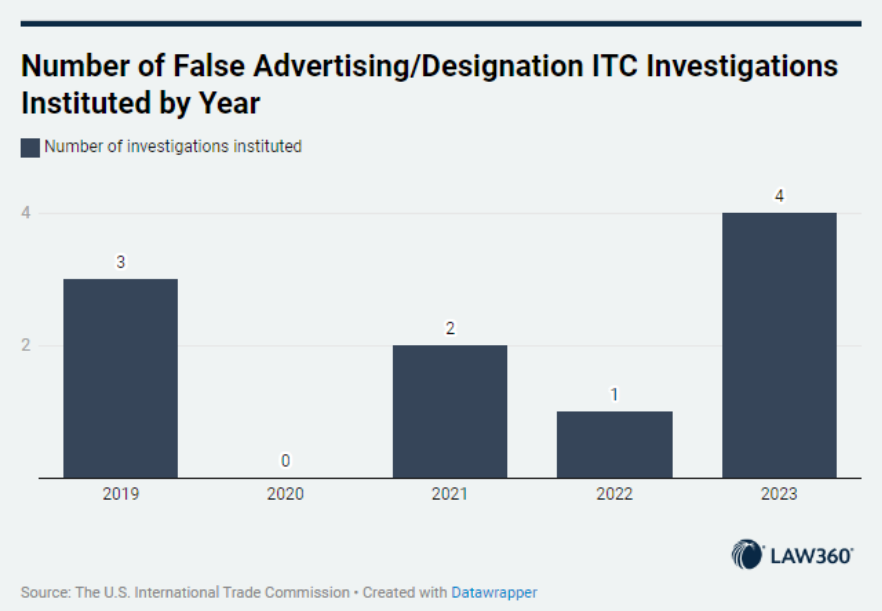
For these so-called nonstatutory claims, according to Section 1337(a)(1)(A), complainants must show that the accused unfair acts have "the threat or effect of which is — (i) to destroy or substantially injure an industry in the United States; (ii) to prevent the establishment of an industry; or (iii) to restrain or monopolize trade or commerce in the United States."[4]

Section 337 also requires a complainant to satisfy the importation requirement — the accused unfairly traded products must be imported into the U.S., sold for importation into the U.S., or sold after importation.[5]

At the time of the submission, "[o]nly about 50 investigations ha[d] involved false advertising — most occurring before 1988."[6] The purpose of the submission was to address the Section 337 domestic industry requirement in false advertising investigations because "[m]ost of the recent false advertising investigations were terminated without much insight on the scope of" a U.S. domestic industry.[7]

The submission is notable because the administrative law judge in the investigation requested briefing on the issue.[8] False advertising claims were so infrequent that briefing on "the current state of the law" was appropriate.[9]

Recent Uptick in Lanham Act False Advertising Claims at the ITC



2023 saw the most Lanham Act claims asserted since 2019. Figure 1 shows the uptick in these

investigations from zero in 2020 to four in 2023. Two of the four investigations instituted in 2023 that included Lanham Act claims dealt with drugs or medical devices that implicated the FDCA.[10]

False Advertising Investigations Involving Drugs and Medical Devices at the ITC

Recently major companies have brought false advertising and false designation of origin claims under the Lanham Act at the ITC against medical-related products.

For example, Eli Lilly and Co. and R.J. Reynolds Tobacco Co. are currently seeking relief under Section 337 alleging false advertising relating to drug and medical device-related products.[11]

These complainants have had to navigate carefully around possible assertions that the claims under the Lanham Act are precluded by the FDCA and binding precedent that there is no private right of action to enforce the FDCA.[12] In each of these cases it is instructive to examine the U.S. Food and Drug Administration's guidance to the ITC, which had a strong impact on institution of the investigations.

Eli Lilly's and R.J. Reynolds' complaints seek to steer clear of the U.S. Court of Appeals for the Federal Circuit's 2019 decision in Amarin Pharma Inc. v. ITC, where the court upheld the ITC's determination not to institute an investigation based on preclusion under the FDCA.[13]

In Amarin, a pharmaceutical company alleged certain companies were falsely labeling and advertising imported synthetically produced Omega-3 products as dietary supplements.

The court noted that Amarin claimed respondents' products did not meet the FDCA's definition of "dietary supplement" and were instead unapproved new drugs under the FDCA.[14]

The decision noted that the FDA had not issued guidance on whether the accused products should be considered new drugs and without such guidance there was no cognizable claim under Section 337.[15]

In conclusion, the Federal Circuit held that Amarin's Lanham Act claims under Section 337 were actually "an attempt to enforce requirements of the FDCA."[16]

In a clear effort to avoid Amarin and potential FDCA preemption issues, Eli Lilly's complaint in the matter of Certain Products Containing Tirzepatide and Products Purporting To Contain Tirzepatide argues that its false advertising claims do not require any interpretation of the FDCA.

Eli Lilly's complaint concerns its blockbuster drug, marketed under the trademark "Mounjaro," that is approved by the FDA for treatment of Type II diabetes.[17]

Eli Lilly's complaint alleges, among other things, that all respondents are falsely and misleadingly claiming their competing unapproved products are generic or FDA-approved.[18]

Interestingly, Eli Lilly's complaint proactively includes a section arguing that preclusion and primary jurisdiction do not bar its complaint under Section 337 and the Lanham Act.[19]

That effort appears to thus far have been successful. Prior to institution, the FDA submitted a letter indicating that Eli Lilly's false advertising claims did not implicate the FDCA.

Specifically, the FDA states that Eli Lilly's claims that respondents falsely represent their products as FDA

approved and misleadingly refer to Mounjaro's clinical trials are not barred by the FDCA.[20]

In late 2023, R.J. Reynolds filed a Section 337 complaint in the matter of Certain Disposable Vaporizer Devices and Components and Packaging Thereof alleging false and misleading advertising claims under the Lanham Act relating to the import and sale of certain disposable vaping products.[21]

R.J. Reynolds alleges that a large number of mostly Chinese respondents falsely advertised their disposable vaping products as FDA-approved and misled consumers that their products are "clear" or not flavored.[22]

In extended preinstitution proceedings, the FDA submitted a letter objecting to institution on R.J. Reynolds' false advertising claims that the accused vaping products were not FDA authorized.

The FDA argued that R.J. Reynolds' so-called false authorization claims would usurp the FDA's exclusive authority to enforce the FDCA because they related to FDA policy regarding electronic nicotine delivery systems.

In a letter to R.J. Reynolds' counsel dated Dec. 15, 2023, the ITC concluded that it could not institute an investigation on the portion of R.J. Reynolds' complaint alleging false advertising based on FDA authorization.[23]

By contrast, the ITC determined to institute an investigation based on false advertising relating to alleged misleading labeling and advertising of the accused vaping products as not flavored.[24]

The commission's notice of institution therefore limited R.J. Reynolds' false advertising claims to those based on allegations of misleading consumers regarding whether the vaping products were flavored or not.

Thus, the commission carefully considered and apparently gave deference to the FDA's views as to which Lanham Act false advertising claims were precluded by the FDCA and which were cognizable under Section 337.[25]

Practical Tips for Bringing and Defending Lanham Act Claims in the ITC

The recent rise in false advertising and false designation claims under the Lanham Act at the ITC appears to reflect strong interest in the broad relief available under Section 337.

It is also noteworthy that the Lanham Act claims are concentrated on medical products such as drugs and devices. There are clearly opportunities and pitfalls involved in such medical-related cases.

As the Amarin and R.J. Reynolds cases reflect, there is a risk in asserting false advertising claims relating to medical products regulated by the FDA due to potential preclusion under the FDCA.

A key lesson from Amarin and recent complaints is that in bringing medical-related false advertising claims, complainants should avoid claims that involve any interpretation of the FDCA or FDA policy.

In such cases, there are opportunities for respondents and the FDA to object and successfully block institution of claims. Complainants contemplating similar ITC cases are well advised to confer in advance with the FDA and ITC staff as to whether their claims will be deemed cognizable under Section 337.

Another aspect of false advertising claims that practitioners must be prepared for is whether consumer surveys may be necessary to prove actual consumer confusion or materiality in cases where advertising may only be impliedly false.

It is interesting that Eli Lilly states in its complaint that it will demonstrate that consumers believe accused drug products are FDA approved "through consumer surveys."[26] Thus far, there appear to be relatively few ITC false advertising cases where consumer surveys have been used.

Another challenge that complainants in statutory IP cases at the ITC do not face is proving injury or the threat of injury to a domestic industry.

Complainants in false advertising cases at the ITC should carefully collect and prepare evidence of their injuries including evidence of underselling, price erosion, lost profits and harm to reputation. This will likely entail retention of economic and/or industry experts to demonstrate injuries.

Because most of the recent Lanham Act complaints at the ITC involve drugs and other medical-related products, practitioners should also carefully plan for possible public interest delegation and discovery issues.

In both the Eli Lilly and R.J. Reynolds investigations, public interest issues were delegated to the ALJs for fact-finding, discovery and a recommendation.

There is a high likelihood where an ITC complaint involves medical-related products that the statutory "public health and welfare" factor in Section 337(d)(1) will compel the commission to delegate public interest. Public interest delegations often increase the complexity and cost of ITC investigations.

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[1] 15 U.S.C. § 1125; 19 U.S.C. § 1337.

[2] Certain Clidinium Bromide and Products Containing the Same, Inv. No. 337-TA-1109, Commission Investigative Staff's Written Submission on Domestic Industry in False Advertising Investigations (May 9, 2018) ("Staff's Written Submission").

[3] Id. at 2, n.2 (citing Verisign Inc. v. XYZ.com LLC, 848 F.3d 292, 298-99 (4th Cir. 2017) and 15 U.S.C. § 1125).

[4] 19 U.S.C. § 1337(a)(1)(A).

[5] 19 U.S.C. §§ 1337(a)(1)(A)-(E).

[6] Staff's Written Submission at 2.

[7] Id.

[8] Id. at 1-2.

[9] Id.

[10] List of ITC investigations instituted involving false advertising and/or designation between 2019 and 2023. Data examined through Feb. 2024, captured from IDS at https://ids.ustic.gov/ where Investigation Type is "Unfair Imports" and Unfair Acts are "False Advertising" or "False Designation of Origin." (Last accessed Feb. 21, 2024).

INV. NO.	INVESTIGATION	DATE INSTITUTED	CLAIMS ASSERTED	OUTCOME
337-1381	Certain Disposable Vaporizer Devices and Components and Packaging Thereof	12/14/2023	false advertising false designation of origin unfair competition	Active
337-1377	Products Containing Tirzepatide and Products Purporting to Contain Tirzepatide	11/20/2023	false designation of source false and misleading advertising trademark infringement	Active
337-1360	Certain Portable Battery Jump Starters and Components Thereof (III)	4/12/2023	common law trade dress infringement false designation of origin false advertising unfair competition patent infringement	Active
337-1359	Certain Portable Battery Jump Starters and Components Thereof (II)	4/12/2023	common law trade dress infringement false designation of origin false advertising unfair competition patent infringement	Active
337-1337	Certain Hazelnuts and Products Containing the Same	10/17/2022	false advertising	Terminated based on withdrawal of the complaint

337-976	Certain Woven Textile Fabrics and Products Containing the Same	3/4/2021	false advertising patent infringement	Fourteen of fifteen respondents settled. Section 337 violation found against one respondent. General Exclusion Order issued and subsequently rescinded
337-1238	Certain Plant-Derived Recombinant Human Serum Albumins ("rHSA") and Products Containing Same	1/14/2021	false designation of origin patent infringement	Section 337 violation for Lanham Act claim against defaulting respondent. Limited Exclusion Order and Cease and Desist Order issued.
337-1175	Certain Bone Cements and Bone Cement Accessories	9/16/2019	misappropriation of trade secrets false advertising tortious interference	No Section 337 violation
337-1163	Certain Light-Emitting Diode Products, Systems, and Components Thereof (I)	6/19/2019	false advertising patent infringement	Terminated based on withdrawal of the complaint
337-1164	Certain Light-Emitting Diode Products, Systems, and Components Thereof (II)	6/19/2019	false advertising patent infringement	Terminated based on withdrawal of the complaint

Source: The U.S. International Trade Commission

[11] Certain Products Containing Tirzepatide and Products Purporting to Contain Tirzepatide, Inv. No. 337-TA-1377 (instituted Nov. 21, 2023); Certain Disposable Vaporizer Devices and Components and Packaging Thereof, Inv.No. 337-TA-1381 (instituted Dec. 15, 2023).

[12] See 21 U.S.C. § 337 (a); see also Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 121 S. Ct. 1012, 349, n. 4 (2001) (federal government, rather than private litigants, is authorized to enforce the FDCA).

[13] American Pharma, Inc. v. Int'l Trade Comm'n, 923 F.3d 959, 969 (Fed. Cir. 2019).

[14] Id. at 967.

[15] Id. at 968; the FDA also filed a letter with the ITC urging it not to institute an investigation. Id. at 962.

[16] Id. at 969.

[17] Certain Products Containing Tirzepatide, 337-TA-1377, Complaint ¶ 106.

[18] Id. ¶¶ 83-84.

[19] Id. ¶¶ 100-108.

[20] Letter from Mark Raza, Chief Counsel, FDA, to Lisa Barton, Secretary of ITC, dated Oct. 27, 2023.

[21] Certain Disposable Vaporizer Devices, 337-TA-1381, Complaint (Oct. 13, 2023).

[22] Id. ¶¶ 137-42.

[23] Letter from Lisa Barton, Secretary of the ITC to Harold H. Davis, counsel for Reynolds, at 1-3, dated Dec. 15, 2023.

[24] Id. at 3-4.

[25] Certain Disposable Vaporizer Devices, 337-TA-1381, 88 Fed. Reg. 8811 (Dec. 20, 2023) (limiting investigation to Lanham Act false advertising claims in paragraphs 137-142 of the complaint and allowing Lanham Act false designation of origin claim in paragraphs 143-147 of the complaint). The ITC also declined to institute Reynolds' separate claims of unfair competition and unfair acts in violation of Customs laws and regulations. Letter to Harold Davis, supra, at 3.

[26] Certain Products Containing Tirzepatide, 337-TA-1377, Complaint ¶ 108.