

No. 26-1518

---

**United States Court of Appeals  
for the Federal Circuit**

---

RAI STRATEGIC HOLDINGS, INC., R.J. REYNOLDS VAPOR COMPANY,  
R.J. REYNOLDS TOBACCO COMPANY, RAI SERVICES CO.,

*Appellants*

v.

INTERNATIONAL TRADE COMMISSION,

*Appellee.*

---

**Appeal from the United States International Trade Commission  
Investigation in No. 337-TA-1410**

---

**BRIEF OF ENERGY MARKETERS OF AMERICA  
AS AMICUS CURIAE IN SUPPORT OF APPELLANTS' MOTION FOR  
SUMMARY REVERSAL**

---

ALPHONSE M. ALFANO  
JEFFREY L. LEITER  
BASSMAN, MITCHELL, ALFANO & LEITER,  
CHARTERED  
1707 L Street, N.W., Suite 560  
Washington, DC 20036  
(202) 466-6502

## CERTIFICATE OF INTEREST

Pursuant to Federal Circuit Rules 27(a)(3) and 47.4, counsel for the Energy Marketers of America (“EMA”) certifies as follows:

1. The full name of the party that I represent is Energy Marketers of America.
2. There are no real parties in interest of the party that I represent.
3. There are no parent corporations or publicly held companies that own ten percent or more of the stock of the party that I represent.
4. No other law firms, partners, or associates who have not entered an appearance in this appeal either appeared for the party that I represent in the originating court or are expected to so appear in this Court.
5. I do not know of any case in this or any other court or agency that will directly affect or be directly affected by this Court’s decision in this case.
6. No disclosure regarding organizational victims in criminal cases or debtors or trustees in bankruptcy cases is required under Fed. R. App. P. 26.1(b) or (c).

March 23, 2026

/s/ Alphonse M. Alfano

**TABLE OF CONTENTS**

	<b><u>Page</u></b>
Certificate of Interest .....	i
Table of Contents .....	ii
Table of Authorities.....	iv
I. INTEREST OF AMICUS CURIAE.....	1
II. ARGUMENT.....	3
A. STRICT ENFORCEMENT OF LAWS AND REGULATIONS PROHIBITING THE SALE OF ILLEGAL TOBACCO AND VAPING PRODUCTS IS ESSENTIAL TO PROTECT LAW-ABIDING RETAILERS WHO COMPLY WITH EVERY REQUIREMENT THE LAW IMPOSES.....	3
B. ILLICIT DISPOSABLE VAPING PRODUCTS ARE DELIBERATELY DESIGNED AND MARKETED TO APPEAL TO CHILDREN; STRICT ENFORCEMENT OF THE LAWS BANNING THESE PRODUCTS IS ESSENTIAL TO PROTECT AMERICAN YOUTH.....	7
1. The Products Are Designed to Appeal to Minors .....	8
2. Illicit Products Pose Demonstrated Health Risks .....	9
C. RIGOROUS ENFORCEMENT OF THE LAWS BANNING ILLEGAL TOBACCO AND VAPING PRODUCTS SERVES THE BROAD PUBLIC INTEREST IN A FAIR, LAWFUL, AND SAFE MARKETPLACE .....	10
III. CONCLUSION .....	12

**Page**

Certificate of Compliance .....13

Certificate of Service .....14

**TABLE OF AUTHORITIES**

	<b><u>Page</u></b>
<b><u>Statutes</u></b>	
21 U.S.C. §§ 387, <i>et seq.</i> .....	3
21 U.S.C. § 387j.....	3
21 U.S.C. § 387j(c)(2).....	4
 <b><u>Rules</u></b>	
Federal Rule of Appellate Procedure Rule 26.1(b).....	i
Federal Rule of Appellate Procedure Rule 26.1(c).....	i
Federal Rule of Appellate Procedure Rule 27(d)9e)(A).....	13
Federal Rule of Appellate Procedure Rule 32(a)(5).....	13
Federal Rule of Appellate Procedure Rule 32(a)(6).....	13
Federal Rule of Appellate Procedure Rule 32(g).....	13
U.S. Court of Appeals for the Federal Circuit Rule 27(a)(3).....	i
U.S. Court of Appeals for the Federal Circuit Rule 47.4.....	i
 <b><u>ITC Orders</u></b>	
<i>Certain Tobacco Heating Articles and Components Thereof</i>	
Inv. No. 337-TA-1199, EDIS Doc. ID 754503	
Comm’n Op. at 56-64 (Oct. 19, 2021).....	3
<i>Certain Elec. Nicotine Delivery Sys. &amp; Components Thereof</i>	
Inv. No. 337-TA-1139, EDIS Doc. ID 709572	
Comm’n Op. at 16-18 (May 5, 2020).....	3
<i>Certain Cartridges for Elec. Nicotine Delivery Sys. &amp; Components Thereof</i>	
Inv. No. 337-TA-1141, EDIS Doc. ID 707185	
Comm’n Notice at 2 (Apr. 7, 2020).....	3
<i>Certain Vaporizer Cartridges &amp; Components Thereof</i>	
Inv. No. 337-TA-1211, EDIS Doc. ID 764256	
Comm’n Op. at 8-19 (Mar. 1, 2022).....	3

## I. INTEREST OF AMICUS CURIAE

The Energy Marketers of America (“EMA”) is a federation of 48 State and regional trade associations representing wholesalers and retailers of gasoline and other motor fuel products. The overwhelming majority of the motor fuel outlets they operate contain retail convenience stores or snack shops that sell tobacco and electronic nicotine delivery system (“ENDS”) products. The sales of tobacco and ENDS products, like the ones at issue here, represent a significant percentage of EMA retailers’ profits at the more than 60,000 gas stations operated by retailers represented by EMA.<sup>1</sup>

Although Appellants’ interest in excluding certain infringing ENDS products is pecuniary in nature, it serves the broader interests of everyone benefitting from stricter enforcement of laws regulating illicit and illegal ENDS and other nicotine-based products. The Appellants sought to have the International Trade Commission (“ITC”) exclude infringing Chinese-made disposable vapes from the U.S. market through an import ban under Section 337. This is not, however, a dry patent dispute between a tobacco company and Chinese manufacturers that is of interest only to

---

<sup>1</sup> No counsel for any party wrote any part of this brief. No party other than amicus curiae’s members contributed any money that was intended to fund the preparation or submission of this brief. EMA’s members are listed at: <https://www.energymarketersofamerica.org/memberassociations/>.

patent holders and infringers; there are real-world stakeholders who have an interest in the outcome of this case that is of equal, if not greater, significance.

EMA's 60,000 law-abiding retailer members want those same illicit products excluded from the marketplace. The Chinese-manufactured illegal disposable vape products that Reynolds is trying to exclude via patent enforcement are the exact same products that undercut EMA retailers every day on price, steal their customers, and expose their communities to unreviewed, potentially toxic nicotine products marketed to kids. EMA's interest in this case does not flow from the intricacies of patent law; rather, it cares about the remedy—the exclusion order--- which serves far broader interests.

EMA submits this brief as *amicus curiae*<sup>2</sup> to urge this Court to recognize that strict and stringent enforcement of the federal laws and regulations prohibiting the sale of illegal, unauthorized tobacco and electronic nicotine delivery system ("ENDS") products serves three distinct and compelling interests: (1) the interest of retailers who abide by the law and invest in compliance; (2) the safety and welfare of American children who are attracted, often by the flavoring and packaging of

---

<sup>2</sup>Counsel certifies that neither party's counsel authored this brief in whole or in part, and no person or entity other than amici and their counsel contributed money intended to fund the preparation or submission of this brief.

ENDS products, to experiment with them; and (3) the broad public interest in a fair, law-abiding marketplace governed by the rule of law.

Thus, Appellants and EMA's interests converge, even though their motivations differ. While the Appellants want the disposable vape products flooding the U.S. market from China excluded primarily because they infringe their patents,<sup>3</sup> EMA wants them banned because they evade Food and Drug Administration ("FDA") authorization, undercut compliant retailers, and endanger children. The remedy — an ITC exclusion order — serves both interests simultaneously.

## II. ARGUMENT

### A. **STRICT ENFORCEMENT OF LAWS AND REGULATIONS PROHIBITING THE SALE OF ILLEGAL TOBACCO AND VAPING PRODUCTS IS ESSENTIAL TO PROTECT LAW-ABIDING RETAILERS WHO COMPLY WITH EVERY REQUIREMENT THE LAW IMPOSES.**

The Family Smoking Prevention and Tobacco Control Act ("Tobacco Control Act"), 21 U.S.C. §§ 387, et seq., establishes a comprehensive regulatory framework

---

<sup>3</sup> The United States International Trade Commission routinely excludes infringing ENDS and ENDS related products. *See, e.g., Certain Tobacco Heating Articles and Components Thereof*, Inv. No. 337-TA-1199, EDIS Doc. ID 754503, Comm'n Op. at 56-64 (Oct. 19, 2021); *Certain Elec. Nicotine Delivery Sys. & Components Thereof*, Inv. No. 337-TA-1139, EDIS Doc. ID 709572, Comm'n Op. at 16-18 (May 5, 2020); *Certain Cartridges for Elec. Nicotine Delivery Sys. & Components Thereof*, Inv. No. 337-TA-1141, EDIS Doc. ID 707185, Comm'n Notice at 2 (Apr. 7, 2020); *Certain Vaporizer Cartridges & Components Thereof*, Inv. No. 337-TA-1211, EDIS Doc. ID 764256, Comm'n Op. at 8-19 (Mar. 1, 2022). Nothing about the disposable vaping products at issue here supports a change in course.

governing the manufacture, distribution, and sale of tobacco products, including electronic nicotine delivery systems. Under this framework, any tobacco product introduced into domestic commerce after February 15, 2007 must receive authorization from the Food and Drug Administration (“FDA”) through the Premarket Tobacco Product Application (“PTPA”) process before it may be lawfully sold. 21 U.S.C. § 387j. The PTPA process results in the issuance of either a Marketing Order (permitting sale of the product) or an Order of Denial (effectively prohibiting such sales). The FDA may grant a Marketing Order only upon a finding that the product is “appropriate for the protection of the public health.” 21 U.S.C. § 387j(c)(2). Applicants must generate and submit substantial scientific data regarding product ingredients, toxicology, abuse potential, and projected patterns of use.

None of the Appellees in this appeal have received a Marketing Order for the infringing products. Either they have filed no PTPA with the FDA, their PTPAs have been denied, or one or more of them have filed a PTPA which is currently pending. At worst, their infringing products are being illegally sold in U.S. markets, having not undergone the rigorous examination of their chemical composition, flavoring, and harmful impacts and dangers to public health. At best, they have not proven their consistency with these health-related and other standards to the FDA. They are precisely the types of products law-abiding retailers seek to exclude from the marketplace.

EMA members—who own and operate approximately 60,000 retail motor fuel stations and convenience stores across the United States—take these obligations seriously. They screen and select product lines to ensure compliance with applicable authorization requirements, like Marketing Orders. They train employees to verify the age of every tobacco purchaser, in compliance with federal and state age-verification requirements. They pay all applicable federal and state excise taxes on tobacco products. They maintain records, display required warnings, and comply with restrictions on advertising. These compliance activities cost real money, require ongoing investment, and impose ongoing operational burdens.

Unauthorized and illicit disposable vaping products—overwhelmingly manufactured in China and imported without regulatory authorization—undercut EMA members' competitive position in every dimension. Because their manufacturers bypass the PTPA process, they avoid the substantial costs of scientific research, regulatory filings, and post-market surveillance. And because their distributors frequently evade federal and state excise taxes, they eliminate another major cost component. The result is a structural price advantage for unlawful operators: illicit products are sold at a lower price point than their compliant alternatives, not because they are better or more efficiently produced, but because their producers and distributors refuse to follow the law.

This disparity is compounded by an additional regulatory asymmetry. The FDA's PTPA review process has thus far authorized only a limited range of tobacco products—principally those with tobacco and menthol flavors. Law-abiding manufacturers and retailers are prohibited from selling products in the flavored varieties—such as Gummy Bear, Cotton Candy, or Candy Hearts—that have proven commercially popular. Illicit producers market exactly those flavors without restriction. Compliant retailers thus face the worst of both worlds: they bear the cost of a regulatory framework that simultaneously imposes compliance obligations on them and forecloses product categories that unlawful competitors exploit freely.

For these reasons, EMA members have a concrete and direct economic stake in vigorous enforcement of the Tobacco Control Act and its implementing regulations. Every enforcement action that removes unauthorized vaping products from the retail market—whether through FDA seizure, CBP interception, DOJ prosecution, or court-ordered injunction—restores a measure of competitive fairness to the thousands of honest retailers who have invested in compliance. In 2024, HHS and CBP conducted the largest-ever seizure of illegal e-cigarettes, confiscating 4.7 million units with an estimated value of \$86.5 million, nearly all originating in China. An earlier FDA-CBP operation in Chicago yielded seizures of unauthorized vaping products valued at nearly \$34 million. These results demonstrate that enforcement is both feasible and impactful. The legal framework that this Court

applies in this case will either reinforce or undermine the deterrent effect of such enforcement.

The Court should adopt the interpretation of applicable law that maximizes the deterrent force of federal and state tobacco enforcement. A ruling that creates ambiguity, narrows available remedies, or otherwise limits the reach of enforcement against illicit products will disproportionately harm the law-abiding retailers who have the most to lose from a marketplace in which legal compliance is optional. EMA respectfully urges this Court to resolve any legal uncertainty in favor of the robust enforcement that its members depend upon. And it has a clear opportunity to do so by reversing the Commission's refusal to accept the ALJ's conclusions in this case, conclusions that will lead directly to the exclusion of illicit products.

**B. ILLICIT DISPOSABLE VAPING PRODUCTS ARE DELIBERATELY DESIGNED AND MARKETED TO APPEAL TO CHILDREN; STRICT ENFORCEMENT OF THE LAWS BANNING THESE PRODUCTS IS ESSENTIAL TO PROTECT AMERICAN YOUTH.**

The threat posed by illicit disposable vaping products is not limited to the economic harm they inflict on compliant retailers. These products are specifically engineered—in their flavors, their packaging, their marketing, and their distribution channels—to attract children and adolescents as new nicotine consumers. The harm to American youth is not a collateral consequence of the illicit trade; it is its purpose.

**1. The Products Are Designed to Appeal to Minors.**

Illicit disposable vaping products are sold in flavors with names that are transparently aimed at children: Gummy Bear, Cotton Candy, and Candy Hearts, among many others. These flavor names are not incidental marketing choices. They are calculated appeals to the taste preferences of young consumers who are most likely to become long-term, addicted nicotine users. The flavors are matched by packaging that features bright, vivid colors, cartoon figures, and imagery drawn from childhood and adolescent culture—packaging that bears no resemblance to the restrained, adult-oriented presentation required of products that have undergone FDA review.

The marketing of these products reinforces the packaging. Illicit vaping products are actively promoted on social media platforms disproportionately used by teenagers, with content that depicts vaping as a youthful, social, and consequence-free activity. Promotional content has included references to vaping while trick-or-treating—a Halloween activity associated with elementary-school-aged children. This marketing is not aimed at adult smokers seeking a less harmful alternative to cigarettes *It is aimed at recruiting a new generation of nicotine-dependent customers who have never smoked.*

Enforcement actions that remove these products from the market, and legal rules that make their exclusion easier rather than harder, directly advance the welfare

of the children in those communities. The Appellees refusal to submit their products for FDA review and, consequently, the presence of unknown constituents weigh in favor limiting their use.

**2. Illicit Products Pose Demonstrated Health Risks.**

Because illicit disposable vaping products are not submitted to FDA review, their ingredients and formulations are entirely unregulated. Independent testing has found that certain unauthorized products contain higher concentrations of toxic chemicals—including heavy metals and harmful carbonyl compounds—than products that have received FDA Marketing Granted Orders following scientific review. This is not surprising: without any regulatory accountability for product formulation, manufacturers of illicit products have no incentive to minimize harmful constituents and strong incentives to minimize production costs.

The consequence is that the children to whom these products are marketed are being exposed to nicotine delivery devices of unknown and potentially severe toxicity, with no regulatory body having evaluated their safety or appropriateness. This stands in stark contrast to the products sold by EMA members, whose suppliers have generated the scientific data required by the PTPA process and whose products are subject to ongoing FDA post-market surveillance. The health distinction between authorized and unauthorized products is not hypothetical; it is documented and material.

**C. RIGOROUS ENFORCEMENT OF THE LAWS BANNING ILLEGAL TOBACCO AND VAPING PRODUCTS SERVES THE BROAD PUBLIC INTEREST IN A FAIR, LAWFUL, AND SAFE MARKETPLACE.**

The two interests identified above—the economic interest of compliant retailers and the safety interest of children—are distinct from, but reinforce, the broader public interest in the rule of law as applied to the retail marketplace. Congress enacted the Tobacco Control Act after decades of documented harm from unregulated tobacco marketing, including marketing specifically targeted at youth. The PTPA framework represents Congress's considered judgment that products capable of causing addiction and serious health consequences must be reviewed before they enter the stream of commerce, and may be sold only if their benefits to the public health outweigh their risks. That judgment is entitled to respect, and enforcement of the legal framework it establishes is entitled to the full support of the federal courts and administrative bodies.

A legal regime in which illicit tobacco products proliferate without effective consequence communicates, powerfully and perversely, that compliance with federal regulatory requirements is optional. Manufacturers who invest in the PTPA process—generating years of scientific data and incurring substantial compliance costs—compete against producers who invest nothing because they operate outside the law entirely.

This Court has the opportunity, in this case, to affirm the contrary principle: that the rule of law applies to everyone, and that those who disregard it will be held to account. State and federal enforcement actions in recent years have demonstrated the breadth of the illicit market. Operation Vape Out in Louisiana resulted in ten arrests and more than one million dollars in product seizures. Operation Smoke Signals in Florida led to 27 arrests across 20 stores for selling unauthorized vaping products to minors. Operation Smoke and Mirrors in North Carolina shut down 13 smoke shops linked to narcotics trafficking networks. Local law enforcement in Orange County, California, seized hundreds of pounds of contraband tobacco and narcotics from shops operating under the guise of legitimate retail. These enforcement actions succeeded because federal and state law provided the legal tools to act.

EMA urges this Court to ensure that those tools remain sharp. The legal standards this Court establishes in resolving this appeal—regarding the infringing products—will be applied by courts and administrative agencies across the country to determine the scope and availability of remedies against the illicit tobacco trade. A ruling that strengthens those remedies advances the public interest. A ruling that weakens them invites continued non-compliance and continued harm to the children, families, and honest businesses that federal tobacco law was enacted to protect.

The thousands of convenience store operators who comprise EMA's membership are not merely commercial entities with an economic stake in this litigation. They are community institutions—family-owned businesses that employ local workers, support local tax bases, and serve their neighbors every day. They want to operate in a marketplace governed by fair rules, enforced consistently, against everyone. That is not too much to ask. It is the foundation of the rule of law, and EMA respectfully urges this Court to uphold it.

### **III. CONCLUSION**

For the foregoing reasons, Amicus Curiae Energy Marketers of America respectfully urges this Court to grant the Appellants' Motion for Summary Reversal and to enter a ruling that reinforces vigorous enforcement of the federal laws protecting intellectual property which, if applied here, will have the practical, direct effect of limiting the sale of illicit tobacco and vaping products.

Respectfully submitted,

/s/ Alphonse M. Alfano  
Alphonse M. Alfano  
Jeffrey L. Leiter  
Bassman, Mitchell, Alfano & Leiter,  
Chartered  
1707 L Street, N.W., Suite 560  
Washington, DC 20036  
aalfano@bmalaw.net

Date: March 23, 2026

## CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rule of Appellate Procedure 32(g), the undersigned counsel for amicus curiae certifies that this brief:

(1) complies with the type-volume limitation of Federal Rule of Appellate Procedure 27(d)(2)(A) because it contains 2,555 words, excluding the portions exempted by rule

(2) complies with the typeface and style requirements of Federal Rules of Appellate Procedure 32(a)(5) and 32(a)(6) because this document has been prepared using Microsoft Office Word and is set in the Times New Roman font in a size equivalent to 14 points or larger.

Date: March 23, 2026

/s/ Alphonse M. Alfano

**CERTIFICATE OF SERVICE**

I hereby certify that on March 23, 2026, I caused the foregoing BRIEF OF ENERGY MARKETERS OF AMERICA AS AMICUS CURIAE IN SUPPORT OF APPELLANTS' MOTION FOR SUMMARY REVERSAL to be electronically filed via CM/ECF with the U.S. Court of Appeals for the Federal Circuit, which electronically served the brief on all counsel of record.

March 23, 2026

/s/ Alphonse M. Alfano